IMPLEMENTING A NEWBORN HEARING SCREENING PROGRAMME:

A FEASIBILITY STUDY

A thesis presented in partial fulfillment of the requirements for the degree of Master of Arts at Massey University

Karen Anderson-Hawke
Neonatal Nurse Practitioner™
2004

ABSTRACT

Aim. To determine the feasibility of implementing a universal newborn hearing screening programme at National Women's Hospital (NWH), Auckland, New Zealand.

Method. This feasibility study evaluates the potential for success of a Universal Newborn Hearing Screening (UNHS) Programme in a tertiary hospital setting. A review of the present provision of care for infants with congenital hearing loss and a clear description of the current environment and resources at National Women's Hospital was undertaken. By utilising the four key determinants of a feasibility study as described by Whitten, Bently & Dittman (2001) I was able to provide a clear description of the current position and explore the alternative solutions, ensuring an accurate and comprehensive study approach was undertaken.

Results. A detailed analysis of the environmental setting and population at NWH identified the support required for implementing a UNHS programme. Findings also identified the acceptance by both staff and consumers in providing improved congenital hearing loss detection and intervention early in the newborn period. The evidence supported recommendations for two possible hearing screening protocols that are

both practical and feasible in the National Women's Hospital setting for the detection of congenital hearing loss in the newborn population.

Conclusion. Overall findings indicated that the implementation of UNHS at National Women's Hospital is feasible. The current method of detecting hearing loss in the newborn population is inadequate with unacceptable delays for diagnosis and appropriate intervention to improve outcomes for those identified with a congenital hearing loss. The protocols supported by this study are based on the research findings and are unique to the NWH environment and target population. They will ensure the infants with congenital hearing loss are detected and referred early (soon after birth) so formal audiological diagnosis and strategies for intervention can occur with treatment implemented by six months of age. This will improve the child's communication and learning skills, improving their level of education and long term learning ability. Further and regular audit of the programme, screeners and outcomes will be required to ensure its efficiency as a screening service for congenital hearing loss.

ACKNOWLEDGEMENTS

I would firstly like to thank my husband for his time and support over the years because without his help this would not have been possible.

I would also like to thank Jill Clendon for her guidance and the unrelenting faith she had in me.

Finally, I would like to thank the friendly and helpful staff at the National Audiology Centre and Auckland University. I shall continue with them in the quest for UNHS for the families and their children of New Zealand.

TABLE OF CONTENTS

ABSTRACT.....ii

ACKNOWLEDGEMENTS.....iv

TABLES OF CONTENTS.....v

LIST OF TABLES.....x

LIST OF FIGURES.....xi

CHAPTER ONE: INTRODUCTION.....3

Sensorineural Hearing Loss.....3

Statement of the Purpose.....8

Justification.....8

Outline of the study.....9

CHAPTER TWO: LITERATURE REVIEW.....11

Overview of the Problem.....11

How the Ear works.....16

Current Screening Methods.....18

When to Screen.....22

Hearing Screening Tools 26

Hearing Screening Protocols.....31

False-Positive Screening....32
False-Negatives and Auditory Neuropathy....34
Duration of the Screening Test....35
Where to Screen....36
Staff to Screen....37
Cost of Screening....38
Outcome Measures....40
Long-term Benefits....42
Maternal/parental Anxiety....44
Follow-up....45
Ethnic Issues....47
Conclusion....48

CHAPTER THREE: METHOD....50

Introduction....50
Methodology....52
Examples of Feasibility Studies....54
Advantages of Feasibility Studies....55
Disadvantages of Feasibility studies....56
Theoretical Framework....57
Design....57

The Research Process 59
Research Proposal.....60
Ethics Approval.....60
Data Collection.....61
Operational Feasibility.....61
Technical Feasibility.....65
Schedule Feasibility.....69
Economic Feasibility.....70
Population Demographics.....72
Business Plan Proposal Review.....72
Conclusion.....73

CHAPTER FOUR: RESULTS.....74
Introduction.....74
Operational Feasibility.....74
Technical Feasibility.....82
Schedule Feasibility.....91
Economic Feasibility.....97
Population Demographics.....102
Conclusion.....104

CHAPTER FIVE: BUSINESS PLAN REVIEW.....105

Introduction.....105

Newborn Service Admission Review.....106

CHAPTER SIX: DISCUSSION.....109

Introduction.....109

Operational Feasibility.....110

Technical Feasibility.....117

Schedule Feasibility.....130

Economic Feasibility.....134

Conclusion.....136

CHAPTER SEVEN: CONCLUSION.....140

Recommendations.....142

Protocol 1.....146

Protocol 2.....148

GLOSSARY OF TERMS.....154

REFERENCES.....155

APPENDICES:

Appendix 1: The register of 'at-risk' criteria for newborns at risk for hearing loss.....175

Appendix 2: Newborn Hearing Screening at National Women's Hospital Business Plan 176

Appendix 3: 1999 National Application for ethical review of innovative procedures.....183

Appendix 4: Letter of approval from the ethics committee.....193

Appendix 5: Consent for Newborn Hearing Screening form.....194

Appendix 6. Correspondence with the New Zealand Nursing Council..195

LIST OF TABLES

Table 4.1: Ambient noise levels in non-clinical rooms.....83

Table 4.2: Noise levels detected in Level III, NICU.....84

Table 4.3: Noise levels detected in Level II, NICU.....85

Table 4.4: Noise levels detected in PIN, NICU.....86

Table 4.5: Noise levels detected in incubator verses cot.....86

Table 4.6: Noise levels detected with acoustic shell.....87

Table 4.7: Length of Stay, mothers at NWH 2000 and 2003.....93

Table 4.8: Length of Stay of mothers in January 2004.....93

Table 4.9: summary of the set up costs for UNHS.....98

Table 4.10: Summary of the ongoing costs for a UNHS programme screening 7500 babies.....100

Table 4.11: Summary of the intangible costs.....101

Table 4.12: summary of the number of Deliveries at NWH and the total number of babies cared for NWH.....103

Table 5.1: Summary of the NICU admissions NWH.....107

Table 5.2: Summary of the NICU admissions eligible for Hearing screening 108

LIST OF FIGURES

Figure 3.1: Summary of the four feasibility tests.....58

Figure 3.2: Description of the Research Process.....59

Figure 7.1: Stage One.....145

Figure 7.2: Screening Protocol One.....147

Figure 7.3: Screening Protocol Two.....149

IMPLEMENTING A NEWBORN HEARING SCREENING PROGRAMME:

A FEASIBILITY STUDY

"Among the five senses, people depend on...hearing to provide the primary cues for conducting the basic activities of daily life. At the most basic level...hearing permit(s) people to navigate and to stay orientated within their environment...hearing is a defining element of quality of life" **(Snow, 1993, p. 380).**

CHAPTER ONE-INTRODUCTION

Sensorineural Hearing Loss

Sensorineural hearing loss (SNHL) affects 3/1000 children per year (White, 1996). In New Zealand there are approximately 60,000 births per year. The 1998 National Audiology Centre database estimates that 2 in every 1000 births have bilateral SNHL and 1 in every 1000 births has unilateral SNHL. That is, 1 in every 330 births will be hearing impaired. These figures equate to the international figures where prevalence of moderate to profound newborn hearing loss has been estimated between 1.5 and 6/1000 live births (Watkin, Baldwin, & McEnery, 1991). The current methods in New Zealand to screen for SNHL only identify approximately half of the children with significant hearing impairment. The majority of these fall in to the 'at risk' group, where hearing assessment is offered to any infant meeting the 'at risk' register criteria (see Appendix 1). Limiting hearing screening of infants with risk factors for deafness only identifies approximately 50% of children with SNHL (Mauk, White, Mortensen, & Behrens, 1991).

Currently in New Zealand most infants with risk factors identified for SNHL are referred to audiology centers for screening and management of hearing loss if detected, though alarmingly the average age of identification is around 23 months of age (Pellow, Blais, & McNeil, 1998). Early detection and intervention for SNHL can impact on long-term outcomes. Hearing is essential for the development of

language and communication skills, development of sensory and perceptual skills, as well as social-emotional growth and academic outcomes (Carney & Moeller, 1998). A financial benefit has also been cited. Mauk and White (1995) note that if early identification and intervention occurs there can be a significant reduction in the cost of special services over the educational career of a hearing impaired child. Hearing loss in infants that remains undiagnosed until early in childhood leads to permanent development delays (Knott, 2001). There is little disagreement that early identification of hearing loss is vital for language, speech and social development during the child's critical period for language acquisition.

Recent evidence supports the concept that the age at which early intervention (e.g. the provision of hearing aids, cochlear implants and therapeutic programmes) is initiated is related to speech and language outcomes. Levitt, McGarr and Geffner (1987) found that children with severe and profound hearing loss who received special education services before 3 years of age had better expressive communication outcomes or intelligible speech than those who began receiving remediation at older ages. More recently studies have reported that infants with hearing loss who were identified and provided with amplification and intervention before the age of 6 months were at a much advanced age level on language tasks compared with infants who were identified after 12 months of age (Apuzzo & Yoshinga-Itano, 1995; Yoshinga-Itano, Sedey, Coulter & Mehl, 1998). Newborn hearing screening programmes have been evolving to provide a more effective achievement of earlier detection of SNHL.

The programmes for early identification of infants with hearing loss in the United States of America (USA) far out-weigh those underway in New Zealand (NZ). SNHL detection in the USA was first supported as early as 1969 with the establishment of the Joint Committee on Infant Hearing (JCIH). Throughout its 33-year history the JCIH has explored the complexities of hearing impairment and its effects on children's development. They have published position statements and recommended preferred practice in the early identification of, and the appropriate intervention with, newborns and infants who are at risk for having a hearing loss. Then in 1994, the JCIH updated its position statement and endorsed the goal of universal detection of hearing loss in newborns and infants as early as possible, while still maintaining the importance of risk factors. In 2000, the JCIH issued an expanded statement that endorsed UNHS, recommending dropping programmes that screened only at risk infants. They called for implementation of early hearing detection and intervention programmes across Northern America.

There is increasing evidence supporting the introduction of universal newborn hearing screening (UNHS) programmes from both the USA and the United Kingdom (UK). Universal newborn hearing screening programmes are now established internationally forming the evidence base that supports a universal approach to detecting SNHL in the well and high-risk populations. The National Institutes of Hearing (NIH) (1993) consensus statement recommends in-hospital hearing screening for all infants admitted to neonatal intensive care units (NICU) and screening of all other infants within the first 3 months of life. One method of

detecting all infants with hearing loss is to use universal screening protocols, a strategy that has been applied in many centers in the USA (Maxon, White, Behrens, & Vohr, 1995). Following this the implementation of such UNHS programmes have escalated throughout the world, providing the resources and strategies that we can now review, learning from their experiences and more specifically, the tools they have used and the protocols formulated.

The European Consensus Development Conference on Neonatal Hearing Screening in Milan in 1998 established that neonatal hearing testing in maternity hospitals was more effective and less expensive than behavioural screening conventionally carried out at 7 to 9 months of age (Grandori & Lutman, 1999). However, what has also emerged over recent years, following the NIH statements and establishment of many UNHS programmes, is the need to provide a more holistic approach to hearing screening. Issues have been identified concerning parental anxiety, screening protocols (including the level of test sensitivity and specificity), follow-up attendance, data-analysis and treatment strategies (Bess & Paradise, 1994; Paradise, 1999). There has also been a concern about the cost, utility and sustainable funding of such a programme resulting in the slow implementation of a universal approach to newborn hearing screening into the New Zealand healthcare system. Therefore it is important to develop cost effective screening strategies that can be universally and easily applied within the context of the New Zealand culture. These issues in a New Zealand context have been explored in more detail to determine an optimal protocol, which would permit infants

with normal hearing to be accurately segregated from those with true-positive results who need extensive follow-up.

A review of the National Womens Hospital (NWH) Newborn Service admissions was undertaken from 1997-1999 to identify the numbers of possible screenings and estimated costs. A proposal and business plan for the implementation of UNHS to undertake an innovative treatment study were developed in collaboration with the National Audiology Centre and University of Auckland Medical School (Audiology Department) by a group called the UNHS development group(see Appendix 2). The proposal identified that the NICU population be the starting point for the screening programme. This was because the NICU constitutes a high proportion of the current audiology referrals from NWH, meeting the 'at risk' referral criteria. Therefore, a staged approach to implementing the hearing screening programme was proposed with the NICU population as Stage One. Identified in the proposal was the need to implement a feasibility study as part of the staged approach to implementing UNHS. This thesis is the feasibility study that was identified as required in the overall implementation plan.

Statement of the Purpose

The purpose of this study was to determine the feasibility of implementing a universal newborn hearing screening programme for all newborn deliveries and admissions at National Womens Hospital, Auckland, New Zealand.

Justification

Universal newborn hearing screening is a well documented and accepted protocol of care for early identification of children with hearing impairment in hospital newborn units and nurseries (Yoshinga-Itano, Coulter & Thompson, 2000; Vohr, Carty, Moore & Letourneau, 1998; Wessex UNHS Trial Group, 1998). The need for a newborn hearing screening programme for deafness in New Zealand, which is more effective than the current 'at-risk' register, is clearly required. As previously mentioned there is now strong evidence from studies in the USA where universal hearing screening has been implemented that early detection and intervention (before 6 months of age) markedly improves receptive and expressive language development, and cognitive skills. This in turn results in better lifelong educational and employment outcomes. Hearing loss in infants remaining undiagnosed until early childhood leads to permanent development delays (Knott, 2001). To significantly reduce the current age of detection and minimise the impact a permanent hearing loss has on a child it is necessary to implement a comprehensive screening programme that will reliably and accurately identify the

presence of a hearing loss in all infants. It is proposed to establish this screening programme at National Womens Hospital with the aim to screen all babies early in the newborn period. It is also anticipated that this programme will provide the information that will lead to guidelines for the development of a national universal hearing screening programme. Universal newborn hearing screening is the ultimate goal and all neonates should be allowed to benefit from early diagnosis and intervention.

Outline of Study

As a Nurse Practitioner ™ specialising in neonatal intensive and special care of the newborn it is part of my role to have an extensive understanding of the impact of care on the long term outcomes of this unique population. It is clear there is a need for earlier detection of hearing loss in the newborn. This thesis explores the best way to establish earlier detection that is feasible and sustainable. This chapter of the study has provided a background introduction to the thesis establishing the researcher position in this research study.

The second chapter is an extensive literature review on the topic of UNHS, giving a more detailed background to the topic of hearing loss in the newborn, the effects when left undetected and the experiences of established hearing screening programmes internationally. The literature supports hospital based hearing

screening programmes early in the newborn period with appropriate guidelines and protocols implemented to ensure high rates of capture prior to discharge.

Chapter three outlines the methodology used to undertake this feasibility study and has identified the areas unique to the screening environment of National Womens Hospital in the New Zealand context.

Chapter four introduces the data collected to establish the uniqueness of the National Womens Hospital environment and target population. There is little doubt that screening for hearing loss early in the newborn period identifies congenital hearing loss earlier than the current methods of hearing loss detection in practice in Auckland.

Chapter five further discusses the findings of this study identifying key points for consideration in the protocol development.

Chapter six then completes the study with a final indication of the feasibility of implementing a UNHS programme at NWH, Auckland, New Zealand. The thesis concludes with details of the recommendations for protocol development and identifies aspects of UNHS for future research and follow-up.

CHAPTER TWO: LITERATURE REVIEW

Overview of the problem

Hearing loss is the most common congenital anomaly in the newborn occurring in approximately 3 per 1000 newborn infants (White, 1996). Approximately 20% of these children have profound hearing loss or permanent congenital hearing loss (PCHL) with the rest having varying degrees of hearing impairment either bilaterally or unilaterally. The principle of screening for metabolic and genetic conditions in the newborn is well established. General newborn screening programmes in New Zealand (NZ), like the Congenital Metabolic Screening Programme is an example of accepted everyday practice. However, many of the conditions currently screened for early in the newborn period are much less common than congenital hearing loss. For example cystic fibrosis (CF) is one of the most common life-threatening autosomal recessive disorders among caucasians (Lewis 1995). CF occurs in 0.50 per 1000 live births, phenylketonuria less common at 0.10 per 1000 live births (Mehl & Thompson, 1998); the incidence rate of permanent bilateral hearing loss in NZ is estimated to be 2 per 1000 live births (NZ Deafness Database, 1998). The National Audiology Centre in Auckland houses the New Zealand deafness notification data and estimates that:

- 2 in every 1000 births, will have a bilateral sensorineural hearing loss (SNHL), (120 babies)

- 1 in every 1000 births will have a unilateral SNHL loss (60 babies)
- 1 in every 1000 births will have a hearing loss greater than 55dB HL (moderate to severe hearing loss) (60 babies)
- 1 in every 330 births all hearing loss (180 babies)

(NZ Deafness Database, 1998).

This is considerably higher than other medical conditions that are routinely screened in the newborn period in New Zealand. Despite newborn hearing screening having been advocated in the United States since the pioneer work of Marion Downs in 1964 (Downs & Sterritt, 1964), there is yet to be government mandate or funding support for a universal newborn hearing screening programme (UNHS) in New Zealand.

The need for a newborn screening programme for deafness in New Zealand which is more effective than the current 'at-risk' register, is clearly established on international experience (Yoshinga-Itano, 1999; Garganta & Seashore, 2000). The current 'at-risk' neonatal hearing screening programmes in NZ are inadequate, with only an estimated 50% of infants with significant hearing loss having known risk factors (Joint Committee on Infant Hearing, 1994; Mauk, White, Mortensen & Behrens, 1991). This means that under the current neonatal screening system in NZ at least 50% of neonates with a significant hearing loss go undetected. This is likely an underestimation. The rigor of this referral system was questioned by a review of 849 infants with risk factors discharged alive from NICU, National Womens Hospital (Rush, Battin & Wilson, 2002). They identified nearly one third of the eligible infants

did not attend or were not referred for audiological follow-up, increasing those infants going undetected up to 65%. Not only are some infants inappropriately referred or followed up they are taking an unreasonably long time to be diagnosed and provided with suitable intervention.

To lessen the impact of hearing loss in the various areas of development, hearing loss must be identified as early in life as possible and the child must be provided with habilitation in a timely manner (Carney & Moller, 1998). In NZ from 1991 to 1997 the average age of identification of, at least, a moderate hearing loss was 20.84 months (NZ Deafness Data Base, 1998). A study by Pellow, Blais & McNeil (1998) has shown the age of detection over the last 10 years of hearing loss in the NZ Maori and Pacific Island populations was higher at 25 months. This is well beyond the critical age of intervention. Despite the increased awareness of the importance of early detection of SNHL we are no closer to reaching our national goal of identifying all congenital hearing losses by the age of 6 months (National Audiology Centre, 2002).

Universal hearing screening of the newborn is only one part of the equation in early identification and intervention of hearing loss. The spectrum of care for hearing loss in children includes early identification, evaluation and early intervention and ongoing follow-up. There is now emerging evidence that many of the children who were previously thought to have late onset hearing losses, were really children with congenital mild or moderate progressive hearing loss (PCHL)

(White, 1997). This is becoming evident from some of the well established and long running UNHS programmes like the Colorado, Rhode Island, and Wessex programmes (Yoshinga-Itano, Coulter & Thompson, 2000; Vohr, Carty, Moore & Letourneau, 1998; Wessex UNHS Trial Group, 1998), where they have identified hundreds of children with PCHL. The possibility of delayed-onset hearing loss is a concern, so ongoing surveillance is important in identifying these children early. To ensure these children are not disadvantaged, strategies for increasing parental awareness and education must be established as part of the ongoing monitoring process.

Early identification of hearing impairment in infancy allows for more successful intervention and rehabilitation. Those who favour universal hearing screening, cite the benefit of language and cognitive development, with early detection and intervention (Mauk & White, 1995, Yoshinga-Itano, 1999; Carney & Moeller, 1998). International trends indicate that age of identification of hearing loss and consequent intervention needs to occur at or before six months of age. All infants with hearing loss should be identified before the age of 3 months and receive intervention before 6 months of age because the consequences of delay in identification of early onset hearing loss are significant, for example hearing loss of varying degrees in children affects the normal development of language and literacy (Carney & Moeller, 1998). This has been the basis of New Zealand's goal to implement a universal newborn hearing screening programme.

Children with hearing loss frequently experience speech-language deficits; difficulties in listening in competitive background noise and on average, lower academic achievement and poorer social-emotional development than their peers with normal hearing (Davis, Elfenbein, Schum, & Bentler, 1986). There is also a relationship between congenital severe-to-profound hearing loss and vocational outcomes. The supporting evidence that permanent, congenital and early onset hearing loss is that it can negatively affect all areas of child development, in particular spoken language. Resulting squelae are related to the degree, configuration, type, symmetry and persistence of the auditory disability. Moreover, the age at which hearing loss is identified and intervention initiated also appear to impact on outcomes. Skinner reports (as cited in Northern & Downs, 2002) how hearing loss impacts on a child's language and speech development with decreased consistency of auditory cues, confusion with frequency, duration, intensity, and linguistic boundaries. Therefore, limiting the opportunities to hear information from various sources, this decreases the experiences resulting in negative consequences for language rule information, word knowledge, and vocabulary development (Northern & Downs, 2002).

How the ear works

Normal air conduction sound waves enter the ear and ear canal, causing the tympanic membrane (eardrum) to vibrate. The vibrations of the membrane are transmitted to the inner ear by the three ossicle bones in the middle ear (the malleus, incus, and stapes). As the footplate of the stapes vibrates, the vibration moves the fluids within the inner ear. The vibration of the inner ear fluid creates changes in the sensory cells (outer and inner hair cells) of the chochlea. The hair cells bend on the incoming vibration which in turn stimulates neural impulses that travel along the auditory nerve to the brain, creating a sensation we recognize as hearing.

Hearing loss is classified as conductive, sensorineural or mixed, depending on the type of auditory impairment. Conductive deafness occurs when sound waves are not adequately conducted through the external and middle portions of the ear. Sensorineural deafness occurs when sound waves are not translated into nerve signals that the brain recognises as sound (Purdy, 2000). Hearing loss can be congenital, progressive or acquired. The sensation of hearing results from the neural identification of sound energy, and is dependent on both loudness and pitch (also referred to as intensity and frequency respectively). Sound is defined as a vibration, or wave, in a medium such as air or water. The wavelength of sound is related to its frequency which is measured in cycles per second or Hertz (Hz). The normal range of human hearing is between 20 and 20,000 Hz, that is, our ears can

detect vibrations between 20 and 20 thousand cycles per second (Gray, 2000), a very wide range. The amplitude of any sound wave defines its intensity and is expressed in decibels (dB). Decibels are the logarithmic measurement of sound amplitude in comparison with the faintest sound audible (0 dB) also known as the 'threshold of hearing'. A change of one dB is the minimum detectable difference an individual can hear under ideal conditions and a change of five dB (or five times the intensity) can be clearly heard. Newborn hearing loss can be categorised into levels of severity from mild through to profound by determining the decibels heard across a range of frequencies.

Newborn hearing tests like the auditory brainstem response and outoacoustic emissions evaluate the decibel level at which a response to sound occurs at predetermined frequencies usually across 700 to 5000 Hz. Normal hearing is considered if the individual can detect sound falling within 0 and 15 to 20 dB (American National Standards Institute (ANSI), 1989; Bess & Humes, 1995). The ANSI definition for hearing loss (HL) is defined in the following categories:

- Mild hearing loss between 15-30 dB HL
- Moderate hearing loss 31-60 dB HL
- Severe hearing loss 61-90 dB HL
- Profound 90 dB HL or greater

(Boothroyd as cited in Carney & Moeller, 1998).

Newborn hearing loss can also be temporary or permanent, and bilateral or unilateral and can be congenital (Northern & Downs, 1991). Most permanent

hearing loss in children is secondary to cochlear dysfunction. Most newborn hearing screening efforts are directed towards early identification of sensory (cochlear) hearing impairment. In the human preterm or term infant there is little known of the interactions between the status of the cochlear maturation and commonly encountered clinical factors, such as noise exposure or potentially ototoxic medications. Early identification of hearing loss and enrollment in intervention is the first line of defense in reducing the consequences of hearing loss (Carney & Moeller, 1998).

Current Screening methods

New Zealand has had a national hearing-screening programme in place for approximately 30 years. The two main strategies for detecting hearing loss in children have been and are currently an 'at risk' register (see Appendix 1) and a pamphlet questionnaire 'Can Your Child Hear?' published by the New Zealand Ministry of Health. Following this children attending some kindergarten schools are screened for hearing loss from 3 years of age, otherwise, all children attending primary schools are screened from 5 years of age. Infants meeting the 'at risk' criteria are referred on to audiological centres for formal assessment of hearing loss once they have been discharged form the hospital so are reliant on the follow up services.

The 'at risk' register is a list of risk factors that identify those infants who are at greatest risk of having hearing impairment. These include: congenital infections, family history, low birth weight, congenital and physical anomalies, meningitis, hyperbilirubinaemia and asphyxia (see Appendix 1). Although the criteria for referral appear comprehensive some investigators have reported additional risk factors for hearing loss in the neonatal population. Kountakis , Psifidis, Chang and Steinberg, (1997) identified length of stay (LOS) in the Neonatal Intensive Care Unit (NICU), retrolental fibroplasia and respiratory distress syndrome (RDS) as more prevalent in their hearing loss group than their control group. However, these conditions were not found in isolation and can all be experienced by the premature and low-birth weight populations identified in the 'at risk' register. International studies have shown that approximately 50% of hearing impaired infants identified fall into the 'at risk' group (Watkin, Baldwin, & Laoide, 1990; Mauk et al., 1991). New Zealand's 1995 figures identified that of the 82 children with hearing impairment, 58% had risk factors associated with hearing loss (National Audiology Centre, 1996). All infants that meet the current 'at risk' criteria are then referred on to the audiology centers for hearing assessments and follow-up.

In some aspects the 'at risk' register appears to have out grown the increased technology and quality of care provided in NICU's today. According to Brookhouser (1996) high incidences of hearing loss attributed to rubella, mumps or measles are no longer seen in the developing countries due mostly to the safe and effective administration of vaccines. A recent review of audiological outcome at

National Womens Hospital from 1995 to 1998 (Rush, Battin & Wilson, 2002) found the risk factor having the highest association with hearing loss was perinatal asphyxia, followed by ventilation for more than 5 days. While meningitis, hyperbilirubinaemia and ototoxic drugs showed no association, this however maybe attributed to the low numbers reviewed, more intensive neonatal care and awareness of risk factors, or just be population specific. However in one early hearing loss identification programme hyperbilirubinaemia was identified as the most common risk factor in those infants later identified with auditory neuropathy (AN) (Rance et al., 1999). Other reports of AN in young infants also identify hyperbilirubinaemia as a factor (Stein, Jabaley, Pasternak, Banejee, Lindermann and Kraus, 1996). As we learn more about the causes of newborn hearing loss either congenital or acquired early in the newborn period there is more uncertainty about the associations of 'at risk' criteria and the concern of under referral.

One other risk factor which has been associated with a particularly high risk of deafness and which is frequently asymptomatic in the neonatal period is the congenital infection, cytomegalovirus (CMV), (Hicks, Fowler, Richardson, Dahle, Adams & Pass, 1993). Fowler, Dahle, Boppana and Pass (1999) reviewed their UNHS programme to see if they could identify the infants with SNHL caused by CMV and found that less than half of all SNHL was caused by congenital CMV infection. While those with clinically apparent CMV disease at birth had significantly more SNHL than those without, a certain number of infants with CMV would not be identified and therefore also missed under the 'at risk' referral criteria. These

children would otherwise be reliant on other forms of referral and be at increased risk of being undetected until later when habilitation is more difficult and less successful.

The 'Can Your Child Hear' pamphlet (Ministry of Health, (MOH), 1997) was designed to alert health professionals, caregivers and parents in New Zealand to the normal milestones of speech, language and hearing development, so hearing assessments can be arranged if delays are identified. The pamphlet is distributed to health centers, schools, district nurses, audiology clinics, Maori community health workers and general practitioners. There is however, evidence to suggest that they are not widely used. In a 6-year study by Pellow et al. (1998) they identified that 19 caregivers of the 480 children identified for hearing loss had seen the pamphlet but only one could say they were alerted to the possibility of hearing loss in their child by reading it. Alarmingly, if hearing loss is not yet detected the children are not then screened until at school age ranging from 3-5 years of age. This further cements the issue of not having appropriate screening services or tools available to detect hearing loss early.

There have been other attempts recently to detect early onset senorineural hearing loss in a young population these include:

- the behavioural screening of 9 month olds by well-care workers
- behavioural screening of high-risk 9 month olds by audiologists
- behavioural screening of neonates at two Auckland NICU's.

These initiatives have all been unsustainable due to the high incidence of false-positives and false-negative rates. The 'Can Your Child Hear?' pamphlet has also proven ineffective in screening for hearing loss therefore the 'at risk' register has been maintained as the national criteria for referral for hearing assessment in New Zealand. While the 'at risk' register can alert health professionals to those infants (approximately 50%) at increased risk for hearing loss, delays in follow-up, confirmation of hearing loss and appropriate habilitation occur.

When to Screen

Timing of newborn hearing screening is critical and best achieved before hospital discharge or transfer from a tertiary Neonatal Intensive Care Unit (NICU). This can be dependent on the infant's gestation, age and clinical well being at the time of transfer or discharge home. Hearing screening was initially recommended from 34 weeks gestational age onwards (Jacobson, Jacobson & Spahr, 1990) however some infants are being transferred to smaller units when clinically stable as early as 32 weeks gestation. More recent studies have also identified the need for capture of the more premature infant, as some were transferring to smaller units less equipped to screen or provide follow-up care and so screening commenced at 32 weeks gestation (Van Straaten, Tibosch, Dorrepaal, Dekker & Kok, 2001).

Some animal studies have demonstrated that neurosensory development follows a sequential pattern and it is assumed the same sequence occurs in

humans. Therefore in the preterm infant sensory development begins with touch then movement, chemosensory, auditory and finally visual development. Preterm birth doesn't alter the sequence and sound will produce physiological effects by 23 to 25 weeks gestation within their auditory system. Conclusions about the developmental status of the auditory system are based largely on the subject's response to sensory stimuli and measured by their behavioural responses, which can be influenced by immaturity. However, the earliest evidence of auditory function by evoked response techniques is at about 26 weeks gestation. There is essentially no literature describing behavioural studies of hearing development in human term or preterm infants, with most investigations of hearing development limited to infants ranging from 2-3 months of age and older. This lack of understanding or knowledge is largely due to the problems inherent in testing newborns, especially in the limitations of their behavioural state regulation (long sleeping times) and motor control. However the otoacoustic emission (OAE) screeners seem to be less sensitive to nervous system immaturity than other techniques and are applicable in premature infants as early as 32 weeks gestation (Doyle, Burggraaff, Fujikawa, Kim & MacArthur, 1997).

In the older infant, hearing is defined by the listener's ability to detect very low intensity pure tones (sounds of a single frequency) at specific frequency intervals. Perception of pure tone relies on maturation of both the structures of hearing and central auditory processing. During the first 6 months of life absolute thresholds improve dramatically such that the 6-month-old test is very like adults for

pure tones in the acute hearing range (Philbin & Klaas, 2000). Controversially some other UNHS Programmes are screening regardless of the gestation to ensure higher capture rates. This has yet to be supported while others recommend not screening as early unless extenuating circumstances are present.

Timing is also dependent on the newborn being accessible and in a quiet settled state. Research has also identified the ear canal retains vernix and debris up until 12 hours and to as much as 72 hours following birth (Cavanaugh, 1987). Vernix caseosa (vernix) is a fatty residue of amniotic fluid found on a baby's skin immediately after delivery and may remain and occlude the external ear canal for a day or two. Therefore, hearing screening newborns with the OAE technique is recommended at greater than 24 to 36 hours of age (Sininger, Cone-Wesson & Ma, 1993). More recently, a significant positive relationship has been found between test performance and the age of the infant on the OAE screen, with infants older than 8 hours of age more likely to pass (Gabbard, Northern & Yoshinga-Itano, 1999). When the probe of the OAE is inserted into the ear canal of a newborn within this time frame, the vernix may interfere with the OAE measurement by occluding the ear canal lumen or blocking the tubes of the OAE and affecting the transmission. Despite this more and more studies are screening earlier so to capture the infants prior to discharge.

In Mehl and Thompson's (1998) review of 26 Colorado hospitals undertaking hospital-based screening programmes between 1992 and 1996, they identified

screening occurred between 3 hours of age to greater than 48 hours of age to capture infants prior to discharge. There have been other UNHS programmes where screening occurs early in the newborn period; Saint Barnabas Medical Center's UNHS Programme (Barsky-Firkser & Sun, 1997) screened infants at approximately 4 hours of age and were able to still demonstrate a 97% pass rate. They attributed their improvement from earlier years to the equipment sophistication and comprehensive hands-on training for audiologists performing the tests. Stewart, Mehl, Hall, Thompson, Carroll, and Hamlett (2000) reviewed over 11,000 infants screened over five centre's where greater than 70% were tested in the first 24 hours of life. Capturing infants prior to hospital discharge seems to be the main motive behind screening early, less than the recommended 24 hours of age.

The percentage of infants screened before discharge may be influenced also by the experience of the team and improves over time as demonstrated by Spivak et al (2000) with screening 94.6% to 98.65% from year one to three, averaging 97% screened before hospital discharge across the 3yrs. However the missed infants included not only those discharged to home before they were tested but also those who were too sick to test before being transferred to another hospital and those whose testing was incomplete. It did not include those whose parents refused to have their child screened. Other studies support the 97% capture rate as achievable even with including those not screened due to parental refusal (Barsky-Firkser & Sun, 1997).

Hearing Screening Tools

The choice of appropriate equipment is central to deciding how a newborn hearing screening programme will run and how the false-positives and false - negatives will be managed. There are many facets to coordinating and implementing a successful newborn hearing screening programme, most importantly protocols, guidelines and schedules. The protocols outline the hearing screening tools and combinations that are necessary to provide efficient, reliable and valid methods for the evaluation of infants in a cost effective manner (Vohr, Letourneau, & McDermott, 2001).

Otoacoustic emissions (OAE) and auditory brainstem response (ABR) are the most frequently used types of screening tools for hearing screening in the newborn population and have been used in screening programmes since 1990. Technological advances and improved understanding of the physiology of the auditory system have driven the strategies used to diagnose and treat congenital hearing loss. Until the 1970's our capacity to study audition was limited to behavioural testing. However, neither the otoacoustic emissions or the auditory brainstem response are tests of hearing, which is a behavior response, rather they are tests of physiological status of the auditory system.

Otoacoustic emission (OAE) testing is a commonly used hearing screening tool; it functions by emitting a sound for a brief time in response to clicks or a tone

stimulus. The OAE is a sensitive measure of outer hair-cell function. The phenomenon of the emission clicks was first reported by Kemp (1978). The OAE reflects the integrity of the outer hair cells in the inner ear; the emissions are only present in healthy ears. The emission clicks create a vibration which occurs in the cochlear stimulating the neural impulses that travel to the brain, some of the vibrations within the cochlear also cause the footplate of the stapes to vibrate in the opposite direction. This in turn causes vibration of the other ossicles which is then relayed to the tympanic membrane, this acts as a speaker and relays the sound wave vibrations out into the external auditory canal, where they can be picked up by the sensitive microphone located in the otoacoustic emission device. These OAE sounds can be measured within the external auditory canal so the test involves placement of a small probe containing an earphone and microphone in the neonates external auditory canal (Chang, Moffat, Baguley, 2000). It is this sound wave vibration that has come back from the cochlear that is called an otoacoustic emission or cochlear echo. Their presence indicates hearing better than 20 to 30 dB (Widen et al., 2000).

There are various types of otoacoustic emissions, spontaneous, transient evoked and distortion product otoacoustic emissions. Transient evoked otoacoustic emissions (TEOAE) give a brief broadband stimulus and are used by most of the hearing screening studies. Testing is however affected by background noise, and the test environment can markedly influence the outcome of the TEOAE tests. Headley, Campbell and Gravel (2000) found a difference in the functioning

incubator (turned on), as opposed to the nonfunctioning incubator (turned off) when screening in the Newborn Nursery. They then compared the incubator screening as opposed to the open cot and found a reduction in the percentage of failed screens. Otoacoustic emission testing should ideally be performed in a quiet sound proofed room. Clinical studies show that the average sound levels in the NICU range anywhere form 70-80 dB (A) (Gottfried, Hodgman & Brown, 1984) with the recommended maximum safe noise level of 45 dB (A) (American Academy of Pediatrics (AAP) Committee on Environmental Health, 1997). While ambient noise levels have been shown to affect the pass rate of the OAE's the most attractive features of the OAE remains the ease and speed at performing the screen. The ability of many nonaudiologists to undertake the OAE screening and the low cost of disposables for the OAE are also valuable considerations in choosing a screening protocol.

Auditory brainstem response (ABR) has long been recognised as the most sensitive method of assessing the auditory acuity of newborns, while it does not provide a direct measure of hearing it does give an indirect estimation of hearing sensitivity. ABR equipment and disposable electrodes were also thought to be too expensive and the procedure too time consuming for initial screening of large numbers. However, ABR is considered the 'gold standard' method of detecting hearing loss (Swigonski, Shallop, Bull & Lemons, 1987) and the method of choice for neonatal hearing screening in the NICU setting (Van Straaten, Groote, Oudesluys-Murphy, 1996). The ABR's high tolerance of ambient noise can allow for

more flexibility in the screening location and timing of screening, thus improving the ability to screen before discharge as experienced more recently by Iley and Addis (2000). ABR screening technology has advanced dramatically since the introduction of UNHS programmes.

The new generation of ABR screeners has the greatest potential among current technologies for achieving low false-positive rates in mass screening projects (Van Straaten et al., 1996; Mason & Herrmann, 1998). The Natus ALGO Automated ABR (AABR) screener, a laptop-driven automated device for measuring brainstem auditory evoked responses is an example of the new technology. It works by delivering a 35-dB click (the click consists of frequencies across 700 to 5000 Hz) into special pre-gelled, disposable earphones that are shielded to reduce ambient noise interference. The waveform generated from the brainstem is recorded in raw form through three button electrodes placed on the scalp of the infant and compared with a template derived from normal hearing infants between 34 weeks gestation and 6 months of age. The waveform must comply with the template at nine separate, predefined points for the screener to register a match. The ALGO screener software program logs matches to the repeated clicks and automatically grants a pass when it receives sufficient matches to achieve a minimum statistical confidence of 99.8% that the signals received result from the click delivered. Factors other than hearing loss can influence the test result including; infant state, electrode location and impedance, testing site and infant risk status. Despite this the

ABR has proved reliable in the vast majority of babies under circumstances in which most babies are found in the perinatal period (Sininger et al., 2000).

A multi-site investigation using the AABR screening tools (Stewart et al, 2000) reviewing the clinical settings and tracking infants who did not pass demonstrated that the refer rate for universal hearing screening was acceptably low when performed by a variety of personnel in typical nursery settings within the first 24 hours of age. More recently Lemons, Fanaroff, Stewart, Bentkover, Murray and Diefendorf (2002) when comparing the costs and performance of two UNHS programmes one utilising AABR and the other using TEOAE's found the AABR the preferred method. The AABR programme was performed by neonatal nurses whereas the TEOAE programme by Master's level audiologists. The average age of initial screening in the TEOAE group was 29.5 hours covering only 34% in the first 24hours of age. In the AABR group 84% of infants were screened within the first 24hours at an average age of 9.5 hours. The most supporting aspect of the AABR screening programme was the referral rates with a reduction to 4% at the end of the study from 8% compared with a constant 15% referral rate in the TEAOE group. A low rate of screening failures with the AABR minimises costs associated with subsequent follow-up assessments and lessens any potential impact of false-positive screening on the parent-newborn relationship.

Hearing Screening Protocols

Hearing screening protocols identify the combination of screening tools and strategies for use in a UNHS programme. In the USA the NIH Consensus Statement (1993) recommended evoked otoacoustic emission measures for initial screening, with all failures being re-screened with audiotory brainstem response and those that fail re-screening, to be referred promptly for comprehensive audiological evaluation. This is known as a 2-stage screening procedure using the OAE as a cost effective means of eliminating all infants with normal hearing sensitivity and the ABR for the second stage to confirm the accuracy of the OAE result and determine the need for diagnostic evaluation. The recent evaluation of cost and performance characteristics of one National Health Service programme utilizing AABR and the other TEOAE by Lemons et al. (2002), demonstrated the AABR only screening strategy was associated with lower costs, achieved the lowest referral rates at hospital discharge and had the quickest learning curve to achieve those rates. Higher fail rates have been reported when the TEOAE-only protocol was used in a well baby nursery (WBN), supporting the argument that TEOAE produces higher fail rates than a combination of TEOAE and ABR (Gravel et al., 2000).

Numerous pass criteria have been adapted across the many already introduced hearing screening programmes that dictate the pass/fail rates. Dirckx, Daemers, Somers, Offeciers, and Govaerts (1995) surveyed 25 Newborn hearing

screening programmes and found 21 had different testing criteria, highlighting the importance of a uniform pass criteria adopted by all hospitals, a development many programmes now recommend (as cited in Spivak et al, 2000). The Joint Committee on Infant Hearing, (1994, 2000) recommendations identified the technique or combination of techniques used for a hearing screening protocol must be capable of detecting hearing loss of 30 dB HL and greater in the frequency region important for speech recognition and language. The techniques used must also be capable of detecting hearing loss of this degree in infants aged 3 months and younger.

The goal of any infant hearing screening programme in the development of a screening protocol is to achieve a high level of both sensitivity and specificity. To achieve a high sensitivity as many newborns as possible with a hearing loss need to be identified, and to exclude as many newborns as possible without having a hearing loss would give a high specificity. Referral rates will vary depending on the screening tools, method of screening used and experience of the screeners in the programme and are considerations when a protocol for screening is established.

False-Positive Screening

Some infants screened in UNHS programmes have been referred on for formal audiological testing despite not having a hearing loss. These false-positive rates have varied since the introduction of UNHS programmes, some have been

thought to be too high reporting between 2.5% and 8% of the infants screened. These rates must be contrasted to the anticipated rate of identification of permanent hearing loss of 2-3 per 1000 or 0.2% to 0.3%. False-positive screens in the hospital may reflect a number of factors including experience of the screener, debris in the ear canal, a transient loss, or fluid in the middle ear. The American Academy of Pediatrics Task Force (AAPTF) on Newborn and Infant Hearing revised its recommendations for newborn hearing screening in 1999. Their guidelines identified the referral rate (failures and incomplete screens) for formal audiologic testing after screening should not exceed 4%. The concern driving the change was that the high false-positive screening contributed to the high referral rates, which could have adverse negative effects like emotional trauma, disease labeling and increased expense. This has further driven some UNHS programmes to minimise their neonatal false-positive hearing screening rates.

Mason and Herrmann (1998) were able to demonstrate a huge reduction in their false-positive rates after the introduction of a two stage screening procedure from 3.5% to 0.2 %. Other UNHS programmes (Clemens, Davis, & Bailey, 2000) have also attributed their decrease in false-positives from 5% to 1.9% to re-screening prior to discharge. Clemens and Davis (2001) in later work reported that as many as 80% of infants who failed the initial hearing screen subsequently passed when they were retested the following day, before discharge from the hospital. This inspired them to further their studies and established a re-screening protocol before discharge for those infant failing the initial screen and found they

were able to reduce their false-positive rate further to 0.8% and a corresponding positive predictive value of 24%. They conclude their simple intervention of re-screening all infants who failed their initial UNHS before hospital discharge be instituted for all similar UNHS. Vohr et al. (2001) study reviewed five hospital programmes identifying acceptable referral rates at discharge with the two AABR only screening protocols and one of the two-step protocols (less than the 4%) at discharge, however the TEOAE and one of the two-step programmes achieved much higher referral rates between 4.67% and 6.49%. Lower referral rates result in decreased post-discharge follow-up screening, administrative, and scheduling costs, as well as lower parental anxiety associated with unnecessary referral.

False-negatives and Auditory Neuropathy

There is also the identified false-negative risk, when the screening test indicates the infant can hear and yet they have a hearing loss. False negative outcomes can give reassurance that hearing is normal and thus delay identification of hearing loss. This was thought to be an extremely rare occurrence, however more recent studies have identified that infants later diagnosed with auditory neuropathy (AN) may have been missed in the newborn period due to lack of appropriate testing or a false-negative screen by otoacoustic emission screening. Transient OAE's in infants with AN have been reported as similar to those with normal hearing infants and children (Rance et al., 1999). The pathological changes in neural conduction properties associated with demyelination are likely to have

profound effects on ABR's, which are reliant on the relatively precise synchronous response of a population of auditory nerve fibres to a transient acoustic stimulus. Rance et al (1999) recommend that tests of cochlear function (CM particularly) become part of the standard infant test routine and be undertaken for all children with absent or abnormal ABR's, so that cases of auditory neuropathy can be identified and appropriate intervention strategies considered.

Duration of the screening test

One important consideration in any screening programme should be the time taken to perform a screening test. This is both to minimise the nursery interference and make good use of the screener's time, thus keeping the costs to a minimum. The OAE screening tool has been traditionally a much faster screening tool as demonstrated by Ng and Yun (1992) where the OAE's were in fact 10 times faster to perform than an ABR. Barsky-Firkser and Sun (1997) later demonstrated the mean test time of the ABR decreased from 15mins, 20 second in 1993 to 9 mins, 1 second in 1995 a more equable time. The range however was from 4 to 25 minutes and calculated from the start of preparation of the infant's skin for electrode placement to the end of the test (after the electrodes were removed), not allowing time for valuable information sharing and consent from the parents. This wide range of testing time was reflective of the infant's activity and comfort level, so time was utilized for settling the infant. There has since been great technical advancement and the ABR is now much more efficient and equable to the OAE's. This was

demonstrated more convincingly in several more recent studies for example Dort, Taboliski and Brown (2000) showed the AABR took approximately 19 minutes to perform and the OAE 11 minutes and Stewart et al. (2000) demonstrated an average testing time with the AABR of 7.1minutes. They also demonstrated that the time to screen improves progressively with experience gained and plateaus after only 6 weeks of experience.

Where to Screen

Most existing institutions will have little if any space available for designated hearing screening purposes that will be appropriately soundproofed. Some UNHS programmes have had an existing room modified to improve soundproofing and choose to remove babies from the NICU, ward or mothers room to screen them. Iley and Addis (2000) on the other hand advocated bedside screening as they found they were able to better discuss the screen and hearing with the parents while the screen was taking place, reassuring them. The NICU however, often produces sound levels that exceed those encountered in the home environment with some common activities exceeding recommendations reaching levels at times from 100 to 135 dB (AAP Committee on Environmental Health, 1997). Hearing screening will often occur during the day when many other activities are occurring in the nurseries therefore they are being performed in less then ideal noise conditions. Johnson, Maxon, White and Vohr (1993) reported that the ambient environmental noise was reduced between 10-15dB with room modifications and further reduced by 10dB

using a modified isolette with a closed lid. Headley, Campbell and Gravel (2000) examined the effect of test environment on recording transient-evoked otoacoustic emissions (TEOAE) in neonates. They concluded the test environment influenced the recording of the TEOAE's with the most desirable results (including the shortest test times, fewest high noise samples and fewest fail outcomes) in the groups who were screened in a non functional isolette situated either in the newborn nursery or a room off the nursery. There is a move to incorporate better soundproofing when designing new NICU's and nurseries in hospitals, and advancing technology allows for better screening tools that are affected less by ambient noise levels.

Staff to screen

There have been a variety of staffing regimes implemented to undertake the screening in universal hearing screening programmes worldwide. A number have supported the nurse as the most appropriate of the screeners, others the audiologist. The extensive New York, seven site UNHS Programme (Prieve, 1997) identified that inpatient universal hearing screening although overwhelming at first was easily achieved only if the screeners were competent, dedicated and hard working. Vohr et al. (2001) in their review of screening protocols from five sites identified the screening personnel differed among the sites. Screening personnel at the study sites varied from dedicated technicians to students and volunteers. While this was a cost analysis of the different protocols they noted a significant reduction in referral rate for the two-step protocol with dedicated screening personnel. The

two AABR only protocols showed low referral rates and employed either audiology students or volunteers to perform the screening tests. Another recent two stage UNHS study by Lemons et al, (2002) utilised neonatal nurses for the AABR screen and masters level Audiologists for the TAOAE screen. While the AABR referral rate was initially 8% it reduced to less than 4% at the completion of the study. Of course deciding on the most appropriate personnel and the training required is both a skill and cost issue.

Cost of Screening

The recent expansion of newborn hearing screening and intervention programmes has led to many questions about the cost of screening and intervention, the cost effectiveness of the programme and the cost benefits of early detection and intervention. Expense of infant hearing programmes have been explored, however and as technologies change many are no longer applicable, despite this there are many aspects in the cost analysis of Newborn hearing screening. Universal newborn hearing screening detects more cases of congenital hearing loss than the traditional 'at risk' register and behavioural studies, and while there may appear to be an initial greater cost of implementing amplification strategies the longer term benefits and costs are improved. In examining the Colorado State experience (Mehl & Thompson, 1998; 2002) at the beginning of the third year, true savings could be demonstrated, calculating in the avoidable costs of late evaluations and intensive speech-language intervention. Mehl and Thompson

(1998) also examined the cost effectiveness of UNHS with the screening of other congenital disorders and found while the cost per test for hearing was more than the cost of the blood tests for the congenital disorders currently screened, such as cystic fibrosis and hypothyroidism, the incidence of congenital hearing loss was so much higher that the cost per diagnosed case was in fact cheaper than for most other congenital conditions. Vohr et al. (2001) updated the analysis and included protocol comparisons, these have proved very helpful. There are now a variety of options on the type of hearing screening combinations widely used. They have not only reviewed the costs of the TEOAE, AABR, and the two-step programme but also all three testing procedures. The extension of their analysis included a complete review of operating costs and calculating the total cost per identified child, while others documented the costs of administrating individual hearing screening programmes and compared the costs of screening with other newborn screening programmes (Barsky-Firkser & Sun, 1997; Keren, Helfand, Homer, McPhillips, & Lieu, 2002).

Screening costs also incorporate the time allocated for a single screening procedure which can include, taking parental consent, prepping the baby for the screen (probe fitting or electrode placement), performing any subsequent re-screens, and recording results in the data bank, medical record and any other designated place. A three-year analysis of costs in the Saint Barnabas Medical Centre in New Jersey (Barsky-Firkser & Sun, 1997) demonstrated a cost-effective programme with costs less than US$30.00 per baby, screening approximately 5000

babies per annum. Comparable costs have more recently been identified by Lemons et al., (2002) with cost per infant screened by TAOAE and AABR at US$32.23 and US$33.63 respectively when screening 1500 babies. There has been extensive analysis of the set up cost of an UNHS programmes, the cost of an individual screen through to the long term programme implementation costs and treatment cost of each case of hearing loss identified.

Outcome measures

The inpatient outcome measures most frequently referred to from the UNHS programmes implemented worldwide include the successful screening of a high percentage of live births and attaining low refer rates for outpatient screening (Spivak et al, 2000). The New York State Universal hearing-screening programme (Spivak et al, 2000), along with the Rhode Island UNHS programme (Vohr et al., 1998) demonstrated outcome measures that have improved over time, attributed mainly to the experience gained from screening large numbers. The Rhode Island programme also revealed a steady improvement in the percentage of infants completing a two stage screening protocol, the stage one and stage two refer rates, compliance with re-screening and diagnostic testing, and significant improvement in the age of identification and age of treatment with amplification.

This adds to the growing body of literature supporting the feasibility of screening all newborns before hospital discharge. However, a more recent

summary of the evidence on UNHS (Thompson, McPhillips, Davis, Lieu, Homer & Helfand, 2001) where only 19 of 340 articles met the inclusion criteria, found several gaps in information about UNHS effectiveness. They confirmed that the modern screening tests for hearing impairment can improve identification of newborn with permanent hearing loss, but as many as 10% of newborns with normal hearing will require a second screening test. In the Wessex study (Wessex UNHS Trial Group, 1998) the overall positive predictive value or the likelihood that the infant has hearing loss for the second-stage screening test was 6.7%.

A behavioural test is really the appropriate gold standard determination for permanent hearing impairment (Widen, Folsom & Cone-Wesson, 2000) but cannot be performed reliably before 8 to 9 months of age. Therefore we rely on the OAE and ABR procedures early in life, giving an intermediate diagnosis, one study found these screening tests were not sensitive enough to rule out significant hearing loss (Norton et al, 2000). The sensitivity of OAE ranges from 80% for moderate hearing loss to 98% for profound hearing loss. The ABR sensitivity and specificity were 84% and 90% respectively. Therefore there is a risk of false diagnosis with UNHS, for example of 7800 screening tests 254 would be referred for audiological evaluation because of false-positive second-stage screening results and one of these would be falsely diagnosed to have permanent congenital hearing loss (PCHL). This can also reflect in an over estimation of the number of cases of PCHL as it is not until behavioural testing that they are identified as having normal hearing. The false-negative rate is thus thought to be higher than previously expected, probably 20%

to 30% in most programmes (Thompson et al., 2001). This new finding calls into question the assumption that a newborn that passes a screening test has normal hearing. Overall, neonatal testing resulted in a final diagnosis of bilateral moderate-to-profound PCHL among 1 in 230 high-risk and 1 in 2348 low-risk infants.

Long-term benefits

Despite the above issues there are several advantages to early detection of neonatal hearing impairment, most importantly the benefit for the hearing impaired infant in language development. The age of detection is the most important factor in determining the development of speech, language, behaviour and social skills. The human ear is one of the first parts of the body that is fully formed with the auditory sensory mechanism being fully functional at birth (Sininger, Doyle, & Moore, 1999). In fact some earlier evidence suggests an auditory brain stem response (ABR) can be seen in the premature infant (Sininger, Doyle & Moore, 1999). The brain has critical times for acquiring language and if the language centers in the brain are not stimulated at this time the child will not be able to 'catch up' for this lost time in language development. Marion Down's work (1997) in summary demonstrated the effects of late language development in children with hearing loss:

- A normal hearing baby will have an average of 700 words at 36 months of age
- A baby whose hearing loss has been detected at birth will have an average of 400 words at 36 months of age

- A baby whose hearing loss has been detected at 6 months of age will have an average of approximately 280 words at 36 months age.

A baby whose hearing loss is not detected until 2 years of age will have less than 50 words at 36 months of age.

However the harms of early intervention have not been adequately studied and differing ethical and philosophical attitudes about deafness and culture have led to controversy about the content of early interventions. Although earlier identification and intervention may improve the quality of life for the infant and family during the first year of life the United States Preventative Services Task Force (USPSTF) found few studies addressing those benefits. (USPSTF, 2002). Treatment strategies for hearing loss in children include hearing aids or other amplification (i.e. cochlear implants) speech and language therapy, sign language and family education and support. Different experts advocate substantially different approaches based on competing theories of language acquisition and communication.

Hearing is essential for the development of language and communication skills, development of sensory and perceptual skills, as well as for social-emotional growth and good academic outcomes. Carney and Moeller (1998) and Robinshaw (1995) showed that severely and profound hearing impaired infants identified and fitted with appropriate amplification by the time they were six months of age acquired vocal communication and linguistic skills at an age comparable to their normal hearing peers. Infants identified after the age of six months did not achieve

this goal. The work by Yoshinga-Itano et al. (1998) has strengthened the concept that early identification and intervention are critical to successful habilitation of hearing loss. They found better receptive and expressive language scores in children who were identified and received intervention before 6 months of age, than those children who were identified later.

Maternal/parental anxiety

A positive test result from universal newborn hearing screening has been suspected to cause maternal concern, however, the findings so far are inconclusive and suggestive of the increased stress levels being attributed to the mother being uninformed. There has also been concern that false-positive neonatal screens may have negative effects on parental stress, coping abilities and the parent, child relationship (Bess & Paradise, 1994). In the only controlled trial, parents whose infants were screened had anxiety and attitudes similar to parents in the unscreened group (Wessex UNHS Trial Group, 1998). There has been further support by more recent studies, demonstrating equivalent stress levels for the group requiring re-screening as for those mothers whose infants received a pass on the initial screen (Stuart, Moretz & Yang, 2000; Weichbold & Welzl-Mueller, 2001). Controversially, Vohr, Letourneau and McDermott (2001) identified maternal worry about their infant receiving a neonatal hearing screen greatest for those undergoing a repeat screen. They did however indicate that to educate mothers about hearing screening would minimize unnecessary worry. On that assumption, Weichbold,

Welzl-Mueller and Mussbacher (2001) tested the hypothesis that mothers who are informed about their baby's hearing test are more likely to have a positive attitude towards hearing screening. Their findings supported this view. However, no study has yet attempted to assess the effect of parental anxiety or changes in parental behaviour on infant's development or on the parent-infant relationship.

The reported incidence of parents refusing hearing screening for their infant is very low in most programmes. A study by Barringer and Mauk (1997) showed that virtually all parents interviewed would give their permission to have their baby screened if they were asked. Spivak et al., (2000) reported a significant decrease in the percentage of infants not tested with each consecutive year of their programme operation, putting it down to increased awareness and better informed parents. Interestingly informed consent is not sought in the USA for many of the UNHS programmes and some studies report poor follow-up rates. If all parents were well informed of the process of infant hearing screening, and offered the opportunity to discuss the relevant research, it is likely they would be more inclined to support the UNHS programme and consent for screening and attend follow-up clinics.

Follow-up

The weakest link in any screening programme is follow-up care (Hermann & Thornton, 1996); a comment which has since driven many UNHS Programmes to better prepare for. An important goal of any UNHS programme is to provide

adequate monitoring and follow-up services for all newborns tested. One of the hardest achievements identified to date in newborn hearing screening programmes is the tracking and follow-up of infants found positive, following hospital discharge. This is especially evident in the first year of programme implementation and often found identified in the summary of study results as an area that needs further work (Prieve, 1997). Prieve also supports re-screening of those infants in hospital prior to their discharge. This was due mainly to the difficulty of capturing them again following discharge from hospital. Consequently the majority of them were found to pass the re-screen, thus reducing the number for follow-up.

Tracking and follow-up strategies if well planned have been identified to have a positive impact on the overall success of a programme (Lim & Fortaleza, 2000). The number of infants lost to follow-up should not exceed the recommended 5% (American Academy of Pediatrics, 1999) some studies achieve up to 97% capture over time (Barsky, Firkser & Sun, 1997).However few studies achieve this initially and acknowledge that lower refer rates at discharge help in the challenge to identify all children with significant hearing loss. Some of the contributing factors to non-attendance at follow-up appointments include denial of the problem by the parents (Mindel & Feldman, 1978) and limited awareness of the significance of risk factors for hearing loss among the medical professions (Coplan, 1987), leading to inappropriate reassurance by health professionals. Anecdotal evidence has also indicated that dissatisfaction with the care provided in the intensive care nursery

and the distance families lived from the testing center contributed to their non-attendance (Outlaw, Reid & Wocadlo, 1999).

While the problem of not achieving high follow-up attendance is multifactorial there is the ability to minimise firstly, the number to go for follow-up by re-screening before hospital discharge then review tracking and education strategies with the goal of achieving 97% or better screening rates. The percentage of infants who return as outpatients for re-screening appears to be an indicator of the programmes maturity with higher screening rates achieved over time. Improved dissemination of information and focus on making the follow-up protocols more family friendly was also thought to influence the rapid improved attendance (Finitzo, Albright, & O'Neal, 1998). Education is thus required on several fronts, the community, the employers, healthcare professionals and the parents and families.

Ethnic Issues

Ethnic data has only been collected in New Zealand since 1992. Of the deaf and hearing impaired children notified in 1994 36% were Maori (NZ Deafness Database, 1998). As only 14% of New Zealand children are Maori, Maori are grossly over represented among the deaf and hearing impaired population. Age of detection also shows differences in Maori and Pacific Island children with a tendency for later identification. The average age of identification from data collected between 1991 and 1997 (Pellow, Blais & McNeil, 1998) for the NZ Maori

and Pacific Island group with moderate-severe to profound hearing loss was 28.2 months compared with 22.4 months for children of other ethnic origin, with even more significant delays of up to 46 months in this group due to the high rate of chronic middle ear problems. New born Hearing screening is a key strategy to reduce inequalities of heath care within this group, addressing one of the governments identified health care initiatives for the future (Delegation, 1998).

Conclusion

Newborn hearing screening has been advocated and performed in the United States since the pioneer work of Downs and Sterritt in 1964. However, universal newborn hearing screening for early detection of significant hearing loss has yet to be accepted as a public policy initiative in New Zealand despite the international recognition and extensive legislation and implementation of UNHS programmes. Approximately 120-180 babies in New Zealand are born each year with substantial hearing problems (New Zealand Deafness Notification Data, 2002). Unfortunately our established techniques for identifying these deaf infants are inadequate with the average age of confirming a hearing impairment at just less than 2 years of age. There is certainly good reason to implement UNHS as it will both improve health and reduce health inequalities.

Hearing loss in children is a major impediment to learning and the development of speech and language. Hearing loss in children can be ameliorated

by early intervention with hearing aids or cochlear implants and international research has shown the profound positive impact of early intervention on language acquisition, particularly if before 6 months of age. Identification of hearing loss in infancy, followed by appropriate intervention by 6 months of age, can result in normal language development, regardless of the degree of hearing loss. There are also sound economic reasons for improving population health as UNHS has been demonstrated to be cost effective. Technological advances now allow us to use objective physiological screening techniques such as OAE and ABR from birth. These followed by diagnostic physiological and behavioural audiological assessments for babies will allow us to identify hearing impaired infants before the age of 3 months and begin appropriate intervention before 6 months of age.

A thorough assessment of the environment and the resources available is required to understand how best to implement early detection through the use of a UNHS programme. The following chapter will outline the methodology used to evaluate the feasibility of implementing a UNHS programme in the context of the newborn target population in the unique environment of National Women's Hospital (NWH). The investigation will review the technical, organisational and financial requirements for the development of appropriate guidelines and protocols designed to best suit the baby's and their families who are born at or admitted to NWH.

CHAPTER THREE: METHOD

Introduction

This feasibility study evaluates the potential for success of a Universal Newborn Hearing-Screening (UNHS) project in the tertiary hospital setting of National Women's Hospital (NWH), Auckland, New Zealand. There is little doubt that screening for hearing loss early in the newborn period identifies congenital hearing loss earlier than the current methods of hearing loss detection in practice in Auckland (Pellow, Blais, & McNeil, 1998). There is also good evidence supporting early identification of hearing loss and better outcomes for the infant in their learning ability and socialization skill development (Apuzzo, & Yoshinga-Itano, 1995; Carney, & Moeller, 1998; Yoshinga-Itano, et al., 1998; Knott, 2001). However for a neonatal hearing screening programme to be effective all children must be screened early in the neonatal period.

The literature supports hospital based hearing screening programmes early in the newborn period with appropriate guidelines and protocols implemented to ensure high rates of capture prior to discharge reference. There have been many successful universal newborn hearing screening (UNHS) programmes implemented overseas, in the United States, the United Kingdom and now Australia. Unfortunately while there have been some locally funded attempts of UNHS in some of the smaller hospitals in New Zealand, no such sustainable newborn

hearing screening programmes have been established or appropriately funded. There has been much international work on protocol development with constant refinement as programmes become established, technology advances, more data is processed and the outcomes are clarified.

There are a variety of hearing screening models and protocols in use internationally, from which we are able to gain valuable information. There are the well-known Rhode Island, New York, Colorado and Wessex programmes (Vohr, Carty, Moore & Le Tourneau, 1998; Spivak et al., 2000; Mehl & Thompson, 2002; Wessex UNHS Trial Group, 1998) with their well-documented implementation plans, identifying what works and what doesn't and the protocols used. These UNHS programmes have used various combinations of the auditory brainstem response (ABR) and evoked otoacoustic emission (EOAE) screening tools in their protocols. They all however leave many of the specifics of the screening progammes like the technology, screening personnel and hospital support systems up to the discretion of the individual facility. The extensive overseas data and expertise now available gives us the opportunity to learn from their experiences to evaluate our own newborn environment and to create a unique New Zealand approach to Universal Newborn Hearing Screening.

The design of a newborn hearing screening program will therefore depend on many factors unique to the hospital, including developing an in-depth understanding of our hearing screening population and the best environment in which the

screening will occur to optimise success. For the purpose of this study it is important to have a detailed understanding of the hospital environment into which the newborn hearing screening programme will be implemented, the population to be screened, the resources identified and the level of service presently being provided. This investigation of the technical, organizational and financial requirements for the development of unique guidelines and protocols designed to best suit the NWH environment and its population arose out of a desire to achieve UNHS in New Zealand.

National Women's Hospital in Auckland is New Zealand's largest Maternity Hospital with over 7500 annual births. To successfully implement a UNHS programme, a detailed feasibility study is required along with protocol and programme development and only then with the appropriate government funding could we be better prepared to support a unique New Zealand based approach to a national universal newborn hearing screening programme.

Methodology

A feasibility study identifies the present situation or specification describing one or more design solutions to a specific problem and determines if the proposed solution is practical and feasible (Whitten, Bentley & Dittman, 2001). By providing a clear description in relation to the present technical state of the current provision an understanding of existing resources allows those in the design team to best identify

which solutions best meet the specification. The emphasis is placed on practical and economic viability of the design in comparison with other possible solutions. The aim of the feasibility study is not to promote a single "ideal" solution, but to identify a number of possible solutions and assess the tradeoffs. This will allow the client to make their own informed decision regarding the future course of the project (Whitten, Bentley & Dittman, 2001).

The present situation must therefore be clearly described in relation to the present technical state of the current provision, in this case the detection of and intervention for congenital hearing loss. A clear description of the infrastructure that needs to be improved, its present capacity and an overview of its location is required (EC Regional Policy, 1997). A feasibility study emphasizes the investigation and comparison of alternative solutions. In addition, an accurate and comprehensive design report will help in developing other documents, such as formal proposals, applications for ethical review, specifications and business plans.

Design reports and feasibility reports are crucial for decision making and product development in almost any technical organization. They document how you think through a solution to a problem, and then how to give a description of the solution, and the reasons why that solution should be implemented. The feasibility study represents the first time in a project development process that the pieces are put together to see if they perform together to create a technically and economically feasible concept (Matson, 2000). In other words a feasibility study gives a

recommendation providing the data and the reasoning behind that recommendation (Unitarian Universalist Association (UUA), 2002). In the health profession it is often used to formalise the process of change, by providing the appropriate evidence and identifying the cost and outcome benefits. The acceptability of the project has to be confirmed with the various stakeholders identified and their advice sought on key risks associated with the project.

Examples of Feasibility studies

There are a number of newborn hearing screening feasibility studies documenting the validity, reliability, and effectiveness of newborn hearing screening internationally (Finitzo, Albright, & ONeal, 1998; Prieve & Stevens, 2000; Spivak et al., 2000). However, most available feasibility studies are based on implemented UNHS programmes, and are looking at more technical specifics within the programme, for example a study by Stone, Smith, Lembke, Clark and McLellam (2000) confirms the feasibility of universal hearing screening using otoacoustic emissions testing. This study concluded that this testing can be accomplished easily in the normal newborn nursery. A study by Albuquerque and Kemp (2001) better relates to the New Zealand context in that their feasibility study of hospital-based universal newborn hearing screening was to first establish capture rates prior to discharge. They retrospectively determined the discharge age and time of discharge of approximately 3000 babies over a one-year period. Most babies were found to

pass through the hospital at a convenient time for pre-discharge hearing screening therefore they predicted an optimal protocol coverage of 92.68%.

Advantages of Feasibility studies

While there is evidence from UNHS programmes internationally to draw upon, it is important to establish the unique needs of our own environment and population group. This feasibility study will assist in the implementation of an organised and well thought through UNHS programme that identifies best practice and minimises errors, creating a more seamless operation. The process can be used to forge a consensus among the key leaders and organisations regarding UNHS and in turn become a catalyst to motivate participation. By approaching a formalized model of investigation there is little room for neglecting anything, creative solutions can be developed to overcome obstacles and all stakeholders are kept well informed of the process so it becomes a collaborative project. Therefore a well prepared and researched study can help reduce the risk. Once a full assessment has been completed, a firm launch pad is constructed for implementation of the project (UUA, 2002). A feasibility study will also be useful when applying for government funding and support and is a valuable document that records the early history and activities of a project enabling the succeeding staff to have a reference point from which to work.

Disadvantages of Feasibility studies

It is necessary to research and document proposals for change especially in the health sector where health dollars need to be allocated appropriately and associated risks identified and minimized. The main disadvantage in taking time to preparing this feasibility study will be in delaying the introduction of a UNHS programme. The feasibility study may also spend too much time retrieving secondary demographic statistics and the resulting recommendations and conclusions maybe too general. In the time taken to conduct a feasibility study, many important factors could have also changed (i.e. discharge planning and length of stay in hospital, and technology advances) therefore the recommendations maybe irrelevant to the current climate. Feasibility studies can be conducted by consultants who have never been directly responsible for a project through development and implementation (Meeder, 1993) and may come from other fields so valuable time and effort could be wasted. Employing experts to conduct a feasibility study can be expensive and that cost better spent on the actual screening of infants. Invariably in the health sector these types of studies are assigned to staff already employed who may lack the expertise and experience to be thorough and timely. This may also question the perceived objectivity of the study which is important for credibility, determined especially by potential financiers (Matson, 2000). There are few other disadvantages in conducting a feasibility study in the context of neonatal hearing screening, however, the severe consequences for the

individuals affected by permanent congenital hearing impairment would be a permanent disadvantage.

Theoretical Framework

The design of this feasibility study is based on works by Whitten, Bentley and Dittman (2001) 'Systems Analysis and Design Methods', while also drawing on my own experiences and expertise in the care of the newborn and family. While most feasibility studies are undertaken by outside consultants due to their strong background both in the financial as well as the technical aspects of the project providing a certain credibility and objectivity, there is also strength in the experience of an individual from the area of the analysis (Matson, 2000). All administrative and operational aspects have been addressed in the preparation for the newborn hearing screening programme at National Women's Hospital, to achieve both an effective and efficient basis to start from.

Design

Feasibility, described by Whitten, Bentley and Dittman (2001) is a measure of how beneficial the development would be to an organisation. They list four feasibility tests: operational, technical, schedule and economic. Following their approach has allowed an in-depth analysis of the environment into which a hospital based newborn hearing screening programme can be implemented, the time frame of

implementation and identification of future needs. Table 3.1 defines the four elements of a feasibility study according to Whitten et al. (2001). These four elements provide the framework onto which the study has been built.

Table 3.1 Summary of the four feasibility tests (Whitten, Bentley & Dittman, 2001)

a) **Operational feasibility** *is a measure of problem urgency or solution acceptability and includes a measure of how end-users and managers feel about the solution.*

b) **Technical Feasibility** *is a measure of how practical solutions are, and whether the technology is already available, and whether it can be acquired.*

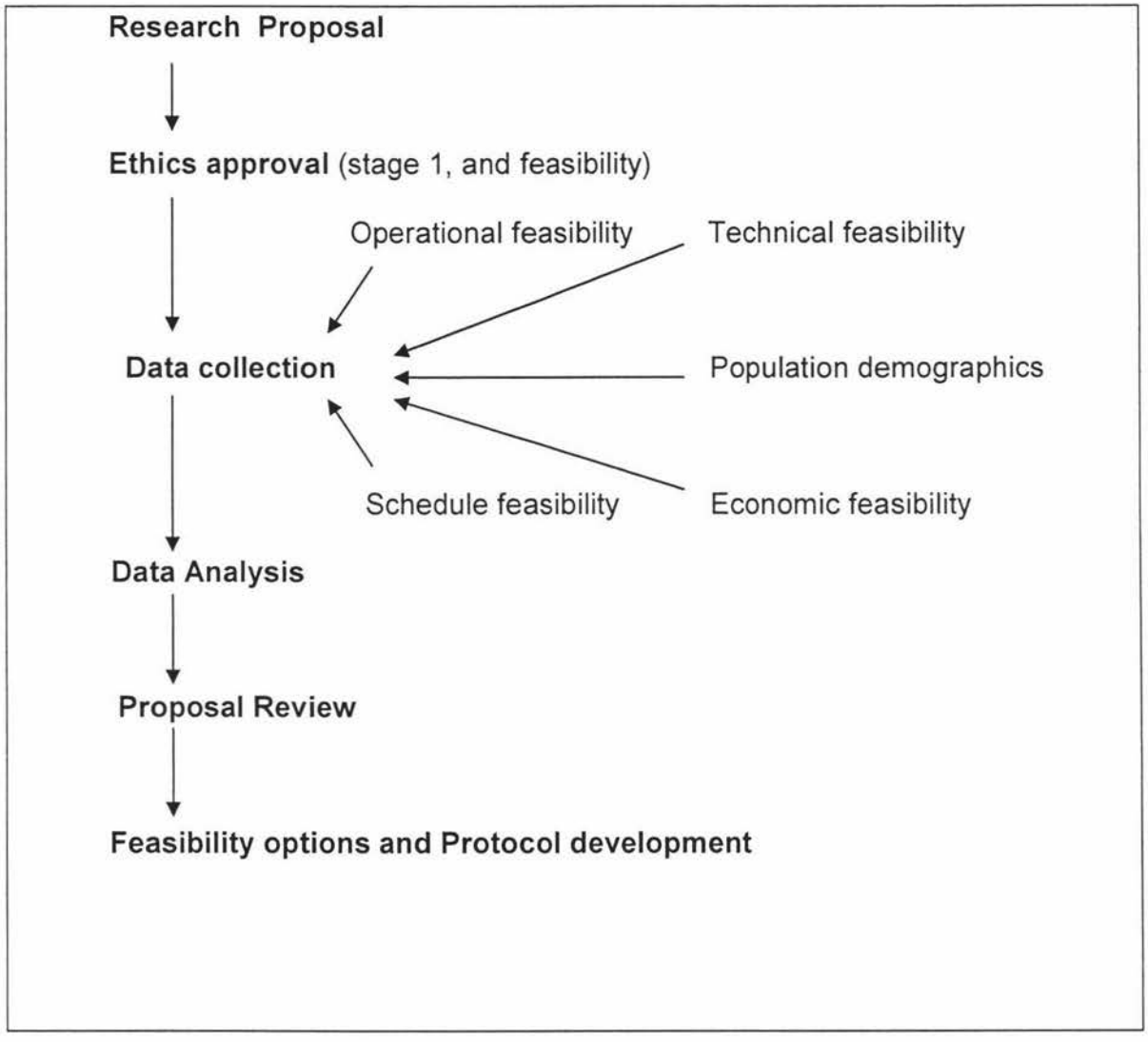
c) **Schedule feasibility** *is a measure of how reasonable the project schedule or deadline is.*

d) **Economic feasibility** *is a measure of whether a solution will pay for itself or how profitable a solution will be. Itemising the benefits and costs, the benefits (tangible or intangible), estimating the value of all benefits. The costs fall into two categories 1) developmental costs; a onetime cost associated with analysis, design and implementation and 2) operating costs, which may be fixed over time or variable depending on the system implemented.*

The Research Process

Table 3.2 displays a flow diagram of the process of this research project.

Table 3.2 Description of Research Process



Research Proposal

The first step in preparation for implementation of a UNHS programme was the development and preparation of a research proposal. This was to establish the first stage of a universal newborn hearing screening programme part of which was to determine the feasibility of implementing it in the unique environment of National Women's Hospital, Auckland, New Zealand. The research proposal was put together by the UNHS development group (described in Chapter One).

Ethics Approval

Ethics approval was sought from The Auckland Regional Ethics Committee (Accredited by the Health Research Council, Health Funding Authority, NZ) for Stage One of the project. An application (see Appendix 3) was submitted by the UNHS development group and approval was given for newborn hearing screening of all babies in the neonatal intensive care unit (NICU) and the undertaking of this feasibility study. Ethics approval was given in July 2000 (see Appendix 4).

Data collection

The following section outlines exactly how each of the four elements of this feasibility study have been addressed:

Operational feasibility (see Figure 3.1)

Implementing a newborn hearing screening programme at National Women's Hospital (NWH) is of utmost urgency to ensure hearing loss is detected early in the newborn to optimize treatment opportunities. Implementation is also important as it will form the basis of a national universal hearing screening programme for New Zealand. The need for universal newborn hearing screening (UNHS) has been identified in international literature and programmes are now well established worldwide. New Zealand has not yet mandated UNHS therefore well researched and established hospital based initiatives will pave the way, gaining unique local data and recognition to link the appropriate support networks and funding.

In this study operational feasibility was established by:

1. establishing appropriate communication links
2. determining the interpretation of UNHS in the NWH environment
3. establishing informed consent processes
4. investigating a recent UNHS programme
5. consumer input

Each of these will now be outlined in detail:

1. Establishing appropriate communication links:

To establish appropriate links between the National Audiology Centre (NAC) and National Women's Hospital periodic meetings with the coordinators were instigated to keep everyone well informed. These links were designed to identify and develop strategies to ease the implementation of the UNHS programme. With regular reviewing and assimilating of preliminary information I was able to provide vital support to maintain motivation for programme development. Representatives of the key departments were identified and formed the newborn hearing screening programme development group. Regular meetings occurred between November 1999 and June 2000 initially weekly then fortnightly until December 2001. This group had representation from NWH and links were established with the Ministry of Health, Nursing Council of New Zealand, national audiology groups and other relevant departments within NWH. A consultative process was established to recommend appropriate sound proofing to be incorporated into the new NICU being designed as part of the health service delivery plan (HSDP) for the end of 2004.

2. Determining the interpretation of UNHS in the NWH environment:

To determine the interpretation of UNHS within the NWH community required discussion with hospital administrators and staff. Presentations were given on sensorineural hearing loss, the impact of late versus early identification and intervention and the long term benefits to groups of medical and nursing staff

allowing opportunity for discussion and debate. Programme development updates were also tabled at meetings with the NICU quality of service group and with hospital and NICU management, these occurred monthly between June 2000 and December 2001.

3. Establishing informed consent process:

The process of informed consent for introducing an innovative procedure was reviewed to determine the most appropriate methods of information sharing and consent at NWH. The policies on informed consent and methods of information dissemination to parents were identified and a plan for informed consent developed. This involved meetings and advice from the Quality of Services Manager at NWH, meetings with parent group representatives and with the nursing and medical staff of NWH. The work undertaken by the New Zealand Ministry of Health's (2000) National Neonatal Review on informed consent was also reviewed and key points identified. A review of already existing information in the form of pamphlets and packages and the methods of their availability, distribution and sharing was also undertaken.

4. Investigating a recent UNHS programme:

Prior experience of a screening tool or programme development may also influence the protocol development and the type of equipment purchased and so identification of these resources was explored. A field visit occurred to review the NICU UNHS programme recently introduced at Flinders Medical Centre, Adelaide, South

Australia in 2003. Discussions were held with the paediatrician running the programme, and nursing and clerical staff who managed the process of screening and referral. The purpose of the visit was to identify the aspects of documentation, information for parents and other implementation material and referral processes.

5. Consumer input:

Public input was considered at the initiation of the study process. This was in the form of meetings often informal, which occurred several times a year since 2000 with 'Parentcare' (NICU parent group). The discussions with parents identified their philosophy, feelings on the equipment to be used, the OAE and the ABR screening tools were discussed. A rapport was developed and a valuable link for future consultation established, for example critique of information packages, consent forms and letters. The importance of a 'family friendly' approach, clarification of the processes of being informed and involvement in the development of the programme were essential so everyone had equal access to screening, follow-up and intervention.

Cultural Issues were also addressed to ensure this programme was developed as a bicultural initiative as hearing is a priority area for health gains for Maori. Currently Maori children are significantly disadvantaged when it comes to detection of sensorineural hearing loss (NZ Deafness Notification Data, 1998). There are several New Zealand Ministry of Health and Maori strategies that have identified the need to close the social and economic gaps between Maori and Non-

Maori. Therefore guidance was sought from Maori Health Services to ensure that all components of the programme are culturally appropriate and have a positive proactive focus that has appeal with Maori families. Interpreter services were also identified as an important aspect of information dissemination and an analysis of available interpretation services was undertaken.

Technical Feasibility (see Figure 3.1)

Technical feasibility was determined in this study b examining:

1. Hearing screening tools and protocol
2. resources available
3. hearing screening environment
4. population dynamics

1. Hearing Screening Tools and Protocol

Information on the available Hearing Screening tools appropriate for the newborn is readily available, the ABR and OAE hearing screening equipment is well researched within the hospital and the community setting on the newborn infant. The National Audiology Centre and the UNHS development group gave advice on the equipment purchases, which was also influenced by the funding and the availability of the machines. More importantly was the protocol development,

identification of the personnel most appropriate to do the screening, the environment and the follow-up processes to be implemented.

2. Resources Available

In determining the suitability of implementing a newborn hearing screening programme it is firstly important to establish the already existing resources, including the personnel, the environment and the equipment. A review was undertaken of the NICU and postnatal ward (PNW) environments, and the existing staffing in these areas in relation to job descriptions and workloads. Discussions were undertaken with staff in the NICU, both nursing and medical, to identify current ethos and practices. An important aspect of introducing a new project or change in practice is to identify the most appropriate dissemination of hearing screening information to all stakeholders (parents and family, lead maternity caregivers, general practitioners, nursing and medical personnel). To establish the suitable staffing personnel to undertake the screening, a review of the possible role was undertaken looking at parental contact experiences, availability and cost.

3. Hearing Screening Environment

Environmental assessment of Newborn services included a detailed assessment of the following:

a) The NICU ward layout: identification of available space or office for the storage of screening equipment, information resources, computers and disposables. This involved a review of the current storage rooms and other rooms that may be

suitable within the Newborn Services. Aspects of the room requiring consideration included the distance from the clinical rooms, space available for equipment and disposables storage, power and internet supply, current usage, availability and security.

b) Identification of suitable rooms for hearing screening: This involved a review of the Newborn service rooms that might be suitable for undertaking a newborn hearing screening test and assessing the sound level with the sound level meter in dB(A). Once a room or rooms were identified modifications required to soundproof the rooms were considered and quotations acquired.

c) NICU clinical room noise levels in the Level II, Level III and Parent Infant Nursery (PIN), a well-baby nursery, were obtained. A sound level meter was used with the results given in decibels sound weighting A or dB(A) and slow meter response as recommended by Gray and Philbin (2000). The A-weighted sound-pressure levels are electronically shaped to approximate the response of the human ear to relatively soft sounds. The purpose was to determine the background noise levels of each room and accompanying operational noise levels, to see if the levels exceed the recommended ambient noise levels for screening. The ambient noise includes the buildings heating and air conditioning systems and the operational noise of all the machinery in close proximity mainly the incubators and monitoring equipment noise. There was no staff talking or interaction at the time of the data

collection. Each room in each service (NICU; Level II and III, PIN and the PNW at NWH) were assessed.

d) Infant accessibility and the impact on daily family and NICU routines: Discussions with the medical consultants and nursing staff as to the impact on the daily routine within the NICU were undertaken. This included the impact of screening at the bedside or removing the infant to a soundproofed room for screening and the effect it would have on the daily multidisciplinary ward round, discharge planning, information sharing and education of both families and staff.

4. Target / accessible Population

A review of the target population was completed. A review of NWH births and admissions was undertaken detailing the numbers born and admitted to the hospital from 2000 until 2003, and their length of stay (LOS). The LOS was further defined to estimate the possible number of babies eligible for in-hospital screening at less than 24 hours of age.

Schedule feasibility (see Figure 3.1)

In the original research proposal a three staged approach to screening a population of approximately 8000 babies per annum was designed to give the opportunity for the screening team to gain experience and learn the best way to manage such a large population. This study reassesses the three staging screening protocol in view of its responsiveness to the changing target population dynamics and more recent supporting international evidence on UNHS protocol and equipment developments since its submission in 1999.

To determine the revised project schedule a review of the target population was undertaken to also include babies identified from 2000-2003. The main factors affecting the schedule deadline include the staging of the protocol in relation to:

- the length of hospital stay (therefore the accessibility of the babies)
- the time undertaken to train the screeners
- selecting, purchasing and setting up screening equipment
- establishing database software appropriate for outcome monitoring
- allowing for timely dissemination of information for both staff and consumers
- ensuring all documentation required is identified
- identifying appropriate follow up services are ready
- ensuring appropriate sustainable funding is allocated for screening and follow-up and the commencement date.

This study reviewed the current follow-up services identifying the above points as key factors in the consideration of the protocol development, and sought recommendations from the NAC on appropriate database software packages for hearing screening. This database would allow for comprehensive monitoring and tracking of screened infants and identifying the outcomes of sensorineural hearing loss (SNHL) in the newborn. However, the single isolating factor that will influence the commencement and sustainability of this UNHS programme is funding.

Economic feasibility (see Figure 3.1)

Economic feasibility is evaluated by the techniques of 'cost-benefit analysis'; this determines whether the project will be cost-effective, that is, if lifetime benefits will exceed lifetime costs. The cost analysis reviewed the identified setup costs and ongoing running costs in the first year along with the associated costs at each stage. The set up costs included:

- equipment
- software design
- initial supplies
- educational and marketing materials
- initial preparation and staff salary and training costs.

The ongoing costs include:

- staffing salary

- ongoing training
- additional equipment purchases and consumables

The intangible costs included:

- storage of equipment and consumables
- office facilities and furniture
- phone, fax, computer and copier and consumables
- training facilities
- travel and vehicle expenses
- administrator and accounting support
- Nurse Practitioner™ coordinator
- Audiologist

The long-term benefits of early intervention of SNHL have been identified in international literature in relation to long term earning capacity and ongoing treatment. This has not been detailed in the costs analysis of this feasibility study. However these will be a necessary part of ongoing data analysis and assessment to give a unique understanding of the long term benefits of UNHS in New Zealand.

A cost analysis of a three-staged approach to implementing and maintaining the UNHS programme was formulated in 1999 by the UNHS programme development group based on the then available data and literature as part of the Business Plan, (see Appendix 2). As part of this thesis this three staged approach to UNHS was reviewed because the population dynamics had changed, and stage

three required extensive community involvement. The international literature and improved technology also supported hospital based screening to optimize newborn capture, therefore reducing community funding and limiting the extensive logistics.

Population demographics

A review of how NWH is placed in the national and local context was undertaken to identify any factors that may influence the population dynamics in the near future. This includes the national referral strategies of admissions and transfers to NWH and the health service delivery plan (HSDP) and associated proposed changes. A review of the NWH deliveries and live births between June 2000 and June 2003 was also undertaken to determine the current population dynamics and identify changes to the previous data

Business Plan Proposal Review

This analysis also includes identifying all potential participants in a newborn hearing screening programme and reviewing of the initial three staged proposal detailed in the 1999 Business Plan (see Appendix 2). Due to lack of appropriate and secure funding this project was postponed until suitable funding had been established. The dynamics of the target population, the environment in which UNHS will occur, the literature on UNHS programmes and technologies have changed significantly since its development giving rise to this feasibility study.

Conclusion

In this chapter the methodology to undertake this study was explored detailing the approach required to identify the amount of service necessary for a quality and effective UNHS programme at NWH. This was a feasibility study and incorporated the operational, technical, scheduling and economic aspects of a proposed programme to deliver the most effective and efficient service. The following chapter details the results of this investigation.

CHAPTER FOUR: RESULTS

Introduction

This investigation approach in the following chapter details the results of the research under the four feasibility measures identified in the Methods chapter (Whitten, Bentley & Dittman, 2001) followed by the population demographics.

Operational feasibility *(a measure of problem urgency or solution acceptability and includes a measure of how end-users and managers feel about the solution).*

1. Establishing appropriate communication links:

The UNHS programme development group was established and representatives from the National Audiology Center (NAC) and National Women's Hospital (NWH) were members. An audiologist co-ordinator represented NAC and a Nurse Co-ordinator (Neonatal Nurse Practitioner™) represented NWH and met on a regular basis (fortnightly) from June 2000 to December 2001. Close communication was also maintained by email and phone to allow for seamless dissemination of information and progress.

The following screening guidelines were formulated by the UNHS development group and used as a guide for protocol development in this thesis:

- A minimum of 95% of newborns must be screened successfully for it to be considered effective.

- The methodology should detect, at a minimum, all infants with significant bilateral hearing impairment, i.e. those with hearing loss greater or equal to 35 dB HL in the better ear.
- The methodology used in screening should have a false-positive rate, i.e. the proportion of infants without hearing loss who are labeled incorrectly by the screening process as having significant hearing loss of less than or equal to 3%. The referral rate for formal audiological testing after screening should not exceed 4%.
- The methodology used in screening should ideally have no false-negative rate, i.e. the proportion of infants with significant hearing loss missed by the screening programme is zero.
- Until a specific screening method/s is proved to be superior, acceptable methodologies for physiological screening include otoacoustic emissions (OAE) and auditory brainstem response (ABR) either alone or in combination.
- Screening should be conducted before hospital discharge whenever possible.
- A central monitoring system should be established and maintained at the NAC, so tracking for all future hearing screening programs can be co-ordinated and national and critical performance data generated. Data generated should be collected in a timely manner for example, so results can be extrapolated and responded to, including the number of infants born; the proportion of all infants screened; the referral rate; the follow-up rate; the false-positive rate; and the false-negative rate.

- A central tracking programme should be established and maintained that monitors all referrals and misses, ensuring that children with significant hearing loss are not missed.
- Mechanisms for communicating results of follow-up activities with the parents/ family, paediatrician, general practitioner, audiologists and other associated health professionals should be developed.
- Critical performance data should be reported to the Ministry of Health.
- Recommendations on NICU sound dampening strategies were formulated by the UNHS programme development group for the Clinical Director of Newborn Services in time to support the Health Service Delivery Plan (HSDP) and new NICU design and construction, planned for June 2004.

2. Determining the interpretation of UNHS in NWH environment:

A discussion with the neonatologists and nursing staff in NICU at NWH was undertaken to determine the impact of newborn hearing screening (NHS) on current daily routines and practices. The responses strongly identified the support of a programme that was family friendly and supported a collaborative and informed approach. There would be little perceived effect or disruption to the daily multidisciplinary ward rounds if the screening was at the bedside or if the infant and mother were absent for a hearing screen during that time. However, the staff voiced concern over increased ambient noise levels during ward rounds which might impact on the screening at that time.

3. Establish an informed consent process:

There was over whelming support from both families and staff for an informed consent process that was transparent and informative. Staff and families also thought it was important to take advantage of systems that worked well to ensure everyone remained well informed. Families also requested that all staff be well informed so that they could assist in the dissemination of information that was both timely and informative. A review of the Ministry of Health (MOH) guidelines for informed consent in the NICU (MOH, 2000) supported an informed consent process that involved both informative methods of information sharing (parent teaching and information pamphlets) and a written consent form. There is no generic consent document that is appropriate for parents to acknowledge they consent to procedures that could include the newborn hearing screening procedure at NWH. Therefore discussions with the Quality of Services manager on the development of an appropriate written consent form were undertaken and the NWH informed consent template was employed. The consent form (see Appendix 5) developed for newborn hearing screening was reviewed by consumer groups and formulated for use at the anticipated commencement of stage one of the UNHS programme in 2000.

The first point of contact for women wishing to use the National Women's Hospital (NWH) birthing facilities is at the time of booking. Essential booking information is usually gathered at this time and information on the services the hospital provides is given to the family. The parents may then choose to attend

antenatal classes where further information is disseminated and discussions and presentations occur. Newborn service nursing staff contribute to these classes providing education on various aspects of newborn care, growth and development. There are also a number of lead maternity carers (LMCs) who are private practitioners utilising the NWH services independently. The processes of information dissemination by the LMC may vary depending on their antenatal involvement at NWH. The LMC can also be the general practitioner and would be an important contact to keep well informed of a proposed hearing screening programme.

The Women's and Child's Information Service is situated in the entrance hall of NWH and provides a wealth of information to mothers and families who visit. There is internet computer access and a large resource of information including audio-visual aids and pamphlets to access at leisure or with assistance from an independent parental support. The Newborn Service also has a selection of tailored information packages for new parents and families, so topic information pamphlets can be taken away and read at leisure. The nursing staff are very knowledgeable and provide a valuable resource for parents and families assisting in the sharing of information. All these resources are easily accessible for including as strategies for information dissemination on UNHS at NWH.

Newborn Services has an established nursing position specifically to address parental support and ensure there is adequate dissemination of information

throughout their infant/s stay at NWH. The role of the Family Liaison Nurse (FLN) is to assist liaison between families and health professionals and improve communication. The role combines education and planning of care, especially in relation to discharge and follow-up care. The FLN promotes multidisciplinary collaboration and facilitation of communication so parents and families remain informed. The FLN's have a series of information packs that are given to the families at the most appropriate time, for example, the admission pack is given as close to the time of admission as possible. This is a selection of information pamphlets that can be taken home/to their room for reading over, giving the parent's and families opportunity to bring back questions on their next and following visits. Again this is a suitable opportunity to disseminate information on informed consent for the UNHS programme.

National Women's Hospital has an extensive interpreter service available to all patients and parents of patients. There are an increasing number of different ethnic and cultural groups accessing the NWH birthing facilities, and a comprehensive interpreting service had been established by the Auckland District Health Board of which NWH is a part. An important part of informed consent is the dissemination of information in an appropriate format, so the people receiving the information clearly understand it and are able to have there questions answered.

4. Investigating a recent UNHS programme.

A field visit was undertaken to Flinders Medical Centre in Adelaide, South Australia to investigate the strategies and issues experienced when first implementing a UNHS programme. This visit occurred in 2003 and involved discussions with the paediatrician running the programme, and nursing and clerical staff who managed the process of screening and referral. The programme was supported by the Variety Club a hospital based fund raising organization and was titled the 'Variety Newborn Hearing Screening Program'. Information packages were available for parents; written consent was sought prior to screening. Information sheets were available for parents on:

- Routine screening
- Follow-up hearing testing for infants who need ABR
- Information for parent of infants at risk
- Full hearing assessment; for infants found on the two stage screening to be deaf and in need of diagnostic assessment.

The protocol for this program uses otoacoustic emission (OAE) screening devices and the screener is a nominated NICU nurse (registered nurse or midwife). Guidelines for staff undertaking the OAE screening test detailing the prescreen preparation and the test procedure were provided for training and ongoing reference. The test was conducted at approximately 24 hours of age with a retesting arm at 48 hours if the infant didn't pass the initial screening test. Infants who fail the two-stage OAE screen are referred to the in hospital audiologist for auditory brainstem evoked response (ABR) currently performed once a week in the NICU.

Those that do not pass the ABR are referred for definitive assessment, attending the Hospital Audiology Centre. An assessment / result sheet is completed once the OAE screen has been performed and placed in the baby's blue book (equivalent to the Well Child Book in NZ), this is the patients record of the result and details the next appointment for a retest if required. The test results are also recorded in the patient case notes, using a prepared stamp, results are then sent to the NICU ward clerk for processing. The purpose of the visit was to identify the aspects of documentation, information for parent's, protocol and screening details and other implementation material and referral processes that work well.

5. Consumer Input

Informal discussions with 'Parent-care' suggested they would not merely assume that early detection is beneficial, but instead were eager to have their child's hearing status confirmed as early as possible. The actual screening tests were acceptable to Parent-care representatives as being non-invasive and causing no physical harm. Parent-care were keen to disseminate the information, they publish a bimonthly newsletter, present topical information on their own web site and have weekly coffee mornings with parents at National Womens and North Shore Hospitals. They invited representation of the UNHS development group to their regular coffee meetings with parents and requested articles to be published on newborn hearing screening in their newsletters.

Technical Feasibility *(a measure of how practical solutions are, and whether the technology is already available, and whether it can be acquired).*

1. Hearing Screening Tools and Protocol

The literature supports ABR and OAE in a screening protocol. Other electronic equipment is also required for data collection and analysis that can provide accurate quality assurance monitoring, tracking and follow-up statistics. The UNHS programme development group identified the ABR and OAE as both useful and appropriate tools, with the aim of a protocol that provided a re-screening approach. There is one automated auditory brainstem response (AABR) currently available donated by the Auckland Rotary Club. Further funding is being sought to support a sustained Newborn hearing screening programme.

2. Resources Available: Hearing Screening Environment

a) NICU ward layout: A review of the current layout and utilisation of the NICU environment was undertaken to assess the most appropriate place for hearing screening. Options included screening the infants in a sound dampened room close to the NICU or at the bedside, provided ambient noise could be minimized in the clinical rooms. All of the Newborn Services, intensive care and special care rooms and associated service rooms were tested for noise levels at various times of the day and night (see Tables 4.1, 4.2 and 4.3).

b) Alternative screening sites: A walk through of NICU and review of all possible alternative rooms for screening was undertaken, appropriate staff were interviewed and the option of utilizing rooms for hearing screening was discussed. Five possible non-clinical rooms were selected (see Table 4.4) The clinic room requires further sound dampening due to periodic traffic noises from outside (a busy bus stop is situated just outside the window at the front entrance of the NWH) and a quote was sought for sound dampening curtains.

Table 4.1 Summary of the ambient noise levels in the five non-clinical rooms selected as alternative screening site.

	Average dB(A)
NICU Interview Room	45dB(A)
Room 15: clinical Isolation/storage	46dB(A)
Room 14: gas machine/storage	48dB()
Out Patient Clinic	42dB(A)
PIN Interview Room	45dB(A)

NB. The average noise levels given for these five rooms identified the Out Patient Clinic Room as the quietest with 42dB(A), with a range of 45-48dB(A) for the other four rooms.

c) NICU ward noise levels: Noise levels dB(A) were undertaken in the three designated clinical areas, Level III, Level II and PIN. Each room in each clinical area was tested during the day and again at night. The assessment during the day included the multidisciplinary ward round in one of the clinical rooms in Level III and

Level II. There are four clinical rooms in both the Level III and Level II clinical areas. Staff activities were noted, for example talking and movement by nursing staff when preparing for a procedure. Noise levels were taken initially without alarms then with alarms sounding, the range and average noise levels in dB(A) were recorded (see table 4.1, 4.2, 4.3).

Table 4.2: Summary of noise levels detected in Level III NICU, NWH

	Noise Range dB(A) day	Noise Range dB(A) night	Noise Average dB(A) day	Noise Average dB(A) night
Clinical Rooms no alarms	53-63dB(A)	48-60dB(A)	57dB(A)	53dB(A)
Clinical Rooms with alarms	65-68dB(A)	65-67dB(A)	67dB(A)	66dB(A)

NB. The noise levels in the Level III clinical rooms showed little variation between them and the noise range is representative of all four rooms. The noise range at night shows a 7% reduction compared with the noise level during the day with out alarm noise. The clinical rooms showed no difference in the noise level either during the day or at night when alarms sounded.

Table 4.3 Summary of noise levels detected in Level II NICU, NWH

	Noise Range dB(A) day	Noise Range dB(A) night	Noise Average dB(A) day	Noise Average dB(A)night
Clinical Rooms no alarms	50-54dB(A)	44-56dB(A)	52 dB(A)	51dB(A)
Clinical Rooms with alarms	61-66dB(A)	61-63dB(A)	64dB(A)	62dB(A)
Talking (no alarms)	56-60dB(A)	44-56dB(A)	58dB(A)	51dB(A)
Multidisciplinary Round	67-70dB(A)	N/A	69dB(A)	N/A

NB. While the clinical rooms in Level II had periods of <45 dB(A) at night, they averaged the same noise levels as during the day. The clinical rooms showed little difference in noise levels during the day or night when the alarms sounded. General talking during the day generated more noise than at night. The multidisciplinary ward round was the noisiest time of the day, approximately 25% more noise is generated during the ward round than when the clinical room is without alarms sounding.

Table 4.4 Summary of noise levels detected in PIN, NICU NWH

	Noise Range dB(A)	Noise Average dB(A)
Clinical Room	46-54dB(A)	49dB(A)

NB. The noise levels in the Parent Infant Nursery were generally less than the Level II and III clinical rooms, these infants were preparing for discharge home so generally there were less incubators and monitors that could be contributing to the background noise. These infants were feeding and growing in cots.

Table 4.5. Summary of noise levels detected in the incubator versus the cot.

	Noise Range dB(A)	Noise Average dB(A)
Incubator (no CPAP)	44-46dB(A)	45dB(A)
Incubator (CPAP)	52-54dB(A)	53dB(A)
Cot	46-56dB(A)	51dB(A)

NB. The noise levels detected were measured in a Level II clinical room during the day with no alarms sounding at the time of assessment. The sound levels inside the incubator without CPAP were more than 10 dB (A) less than the noise levels detected in the open cot in the same room exposed to the same ambient noise.

An acoustic shell was designed to cover the open cot, it was made of perspex and fitted easily and snuggly over the cot like a hood and allowed for monitor (cardiothoracic, apnoea and/or saturation) leads to be positioned at the head of the cot through a gap that also allowed for air movement. The babies remained monitored during and after the testing. There was no indication that they were compromised in any way, they remained settled or asleep during the procedure with little or no fluctuations in saturations and number of aponea's were recorded. A series of noise levels were taken with the measure reading close to the

infants head and level with the ears. The readings were compared with a double walled incubator and an open cot (no shell) in the Level II and Level III clinical rooms.

Table 4.6: Summary of noise levels detected with the Acoustic shell over the cot verses Incubator and cot with no shell.

	Noise Range dB(A)	Noise Average dB(A)
Incubator (no CPAP)	44-46dB(A)	45dB(A)
Cot no shell (no CPAP)	46-56dB(A)	51dB(A)
Cot with shell (no CPAP)	40-45dB(A)	43dB(A)

NB. The noise levels in the cot with an acoustic shell were comparable to the double walled incubator and notably less than without the shell under similar conditions.

d) Personnel Review

A review of the NICU personnel was undertaken to identify those that would be most suitable and easily integrated into the programme for screening training. The literature supports a variety of skilled and non-skilled or volunteer staff for screening of the high risk and well baby populations.

Nursing Staff:

The Neonatal Nurse Specialist Advanced Practice (NSAP) formally known as a Neonatal Nurse Practitioner (NNP); was an innovative role implemented in the early 1990's following a need for Registrar and House Officer replacement due to staffing

shortages, lack of experience and an ideal role for extended nursing practice. The Nurse Practitioner ™ (NP) role has since been identified by the New Zealand Nursing Council (NZNC) as the role of the future for supporting staff development and extending nursing responsibility (NZNC, 2001). This extended nursing role at NWH currently has two registered Nurse Practitioners™ and supports six NSAP preparing for registration. The role offers the permanency of an expert workforce benefiting both parents and infants, as they manage new admissions through a spectrum of care from birth to discharge home. Their role involves providing care throughout NWH in the NICU, delivery unit and postnatal wards. The role also has a strong teaching focus where the NSAP/NP's are involved in the training and orientation programmes for both nursing and medical staff across neonatal and midwifery services. Since the endorsement of Nurse Practitioners™ in New Zealand and the credentialing of 2 NPs currently working in Newborn Services for the Auckland District Health Care Board (ADHB), the ADHB has yet the has yet to appoint NP roles.

The current NSAP/NP rotational roster ensures on duty shifts for these staff cover at-least 93% of the week 24hours a day. The NSAP/NP cover 13 hour shifts working day or night duty, rotating between Level III (intensive care) and Level II (special care). They are accessible by locator, working 'on call' when rostered, in Level II they cover the postnatal wards and delivery suite so are aware of all aspects of newborn care throughout the hospital. Their responsibilities include attending high risk deliveries to assess and manage the compromised or premature

infant, including all follow-up management, and working with families to ensure they are informed and involved in the care of their infant/s. They are skilled at developing a rapport with parents and families and experienced in imparting information in a culturally sensitive and empathetic manner, assisting the informed consent process. The NSAP/NP works collaboratively with the on duty neonatologist undertaking all aspects of referral and discharge planning and examination.

The Family Liaison Nurse (FLN): A more recent innovation in the NICU following a hospital review in 1997, which identified the need for improved family support and co-ordination of care through the Newborn Service. The FLN covers a Monday to Friday service with some flexibility of day-time hours to accommodate parents visiting times. They are accessible by locator and cover either the Level III, II or PIN areas. The FLN's provide a seamless approach to care by coordinating with the family, keeping them and other health professionals informed and assisting them with discharge planning. They provide timely information on all the services provided anticipating and supporting parents and families needs.

The Clinical Charge Nurse: This is a 24 hour, 7 day a week cover for the combined Newborn Service Level III and II. These skilled nurses provide clinical support to nursing and medical staff, coordinating both staff and resources to provide skilled care to infants and their families. They are accessible by locator and have on-call support from a designated resource nurse, who is deployed in areas of most need.

The Clinical Nurse Educator: There are two nurse educator roles for the Newborn Service. They are accessible by locator working a variety of shifts to accommodate staffing educational needs. The nurse educators support both formal and informal education and clinical support, are a major staffing resource and undertake a more supportive role with parent education.

The Bedside Nurse: The registered Nurse or midwife works shift work, taking responsibility for a specific caseload in a designated room, so are unable to leave the room unattended. The bedside nurse works closely with parents to provide expert clinical care during the transition to home. The bedside nurse is skilled in handling premature or unwell newborns and instrumental in relaying valuable information between parents and other health professionals involved in their care.

Medical Staff:

Audiologist: an experienced audiologist skilled in the use and interpretation of AABR, trained in the use of the computer programme used to monitor hearing screening results is available to support the programme. This audiologist will co-ordinate and monitor the pass and referral statistics for each screener and liaise with the National Women's co-ordinator. The audiologist will be responsible for ensuring that all neonates receive hearing screening and appropriate follow-up.

Paediatricians/Neonatologists: Three consultants are on clinical service at any one-time, one covers Level III, another Level II and PIN, and the third consultant oversees the babies under paediatric care on the postnatal wards. The Level II and III consultants are on service for a calendar month working Monday to Friday, other consultants are rostered on-call to cover the evenings, nights and weekends. There are eight consultants in all working both part and full–time positions.

Registrars: The three month rotational paediatric positions, cover a shift roster, taking responsibility for Level III or II as do the NSAP/NP's.

House Officers: one is employed for the postnatal wards (PNW) Monday to Friday. This person is locatable, working closely with the families and PNW nursing and midwifery staff, assessing and managing minor medical issues in the newborn and preparing infants for discharge.

Schedule feasibility *(a measure of how reasonable the project schedule or deadline is).*

The project schedule for this feasibility study firstly required identification of the target population and associated dynamics to develop a suitable approach to universal newborn hearing screening. The objective was to gain optimum access while babies were still in hospital. A review of the target population was undertaken

to include babies identified from 2000-2003. A review was undertaken of the NWH admissions in 2000; the data was obtained from the records (as detailed from the Admitting Services for the Registration of Births, Deaths and Marriages) which were reconciled at one month for the NWH admitting spreadsheet database. The average length of stay (LOS) of both the 2000 admissions and the 2003 were compared (see table 4.7). Data was also obtained form the clinical information system (Healthware) for NWH. The discharge times were compared and are based on the 'placenta to discharge' hours identifying a percentage of the women discharged within 24hours for the 2000 group. This was revised in the 2003 group to identify those babies discharged prior to 4 hours of age, a time frame that may not be feasible to screen. To compare the latest LOS trends the most recent data (January 2004) was obtained from the Healthware database. This analysis was undertaken to identify how many and where women and their babies were discharged to at less than 4 hours, less than 12 hours and less than 24 hours after delivery, especially to identify if they were a hospital transfer or home discharge (see table 4.8).

Table 4.7. Summary of LOS of mothers at NWH 2000 and 2003.

	Discharged within 4hours	Discharged within 12 hours	Discharged within 24hours	Average LOS
2000	N/A[1]	N/A[1]	26.6%	2days and 19 hours
2003	2.2%[2]	6.3%[2]	23%[2]	3days and 9.5 hours[3]

[1] This data was not recorded at the time as part of the data set for data entry.
[2]This is an estimate based on the available data for 2003 on 5564 deliveries.
[3]LOS data: the time to final discharge, includes readmission episodes associated with delivery.

Table: 4.8 Summary of LOS in Jan 2004.

	Discharged within 4hours	Discharged Within 12 hours	Discharged within 24 hours	Average LOS Days/hours
Jan 2004	2.7%	9%	22.8%	3 days and 9 hours

NB. This data (from the Healthware system at NWH) was available on only 407 of the 700 deliveries that occurred in January 2004 and therefore is estimation only. Of the 2.7% discharged within 4hours of delivery nearly 60% transferred to the private birthcare facility (Birthcare) with only 32% going directly home and the remaining transferring to other hospitals. Of the number discharged at less than 4 hours after delivery only 0.7% (52.5 per year or 4.3 per month) are discharged directly home. The LOS hours relate to placenta-to-discharge time and are rounded down to nearest whole hour. The data was collected per calendar year.

The results identified an increase in the average LOS of women admitted to NWH in 2003 and identified the number of women discharged within the first 4 hours following delivery to be only 2.2%. This equates to approximately 165 women discharging home per year at less than 4 hours after delivery. The remaining women staying longer than 4 hours are transferred to a postnatal ward within NWH then discharged from there. They are discharged to either home, another birth-care facility (i.e. Botony Downs) closer to home or to a private birth-care facility (i.e. Birthcare). Approximately 30% of the women delivering at NWH women are transferred to the private birth-care facility, Birthcare with 6% of these transferring within the first 4 hours of birth. The 2003 LOS estimates are based on completed data only; 5564 of the 7749 known deliveries are currently detailed in the clinical information data system (Healthware) and so this is only an estimation of the actual events around time of discharge.

Secondly the other factors affecting the schedule deadline including the staging of the protocol were identified and strategies developed in the following areas as outlined in the methodology (page 69):

- An estimation of the time required for selecting and training appropriate screeners for both the NICU and at-risk population and the well baby population was undertaken. The New Zealand Nursing Council was consulted and supported the training of experienced neonatal nurses in a UNHS progamme (July 2000) see attached correspondence (Appendix 6). The UNHS development group identified an initial 2 day screening training programme for the selected screeners with one

day updates every year there after (an estimated costing is provided in the economic review). The training of staff for the data software package to assist in monitoring and audit of information would however be additional and most appropriate for only the audiologists and co-ordinators of the programme.

- Advice was sought for the selection of the equipment from the NAC and UNHS development group. The purchase of a second AABR, and associated consumables was identified as necessary.
- The NAC also advised on the selection of the OZ software package for establishing a database for tracking and outcome monitoring. A selection of software packages were reviewed by the UNHS programmme development group. Consultation also occurred with staff experienced in newborn screening at the National Testing Centre for congenital disease – for example Guthrie screening to identify the best strategies for documentation of the screen. The staff at the National Testing Centre identified the NHI number as a necessary tracking identification and a data base that could be monitored and managed nationally. To support the universal approach to newborn hearing screening all newborns will be screened and the inclusion of a national register of hearing impaired and deaf children is necessary and supported by the NAC.
- Information dissemination required completion of information pamphlets, numbers required for printing and identification of modes for distribution. Appropriate correspondence was designed for caregivers (parents/family or guardian) identifying a Pass or Refer screen and recommended follow-up. Appropriate tracking and follow up of all infants completing hearing screening required

documentation strategies that would enhance the seamlessness of UNHS: The written consent form would be completed prior to screening and filed in the patients clinical records (see Appendix 5). The results of the screen would be documented in the clinical records (page CR102), the 'Visit Record Front Sheet'. A stamp would be positioned under the 'Alerts' heading where the vaccine stamp is also positioned. A Pass/Refer result would be signed by the screener immediately following the screen.

- The Well Child Health Book (Tamariki Ora) contains two sections on hearing 1) page 76 Indicators at birth for deafness and 2) page 90 headed ' Before the 3 month check' both were identified as suitable places to add information on UNHS. Again a stamp will be provided outlining the results (pass/refer) to be completed by the screening staff and this can be positioned at the bottom of either page. Following the introduction (after six months) of stamping the Well Child Book an audit to identify the usefulness of the information and consideration for a formal request to MOH for inclusion of the UNHS pass/refer criteria in the Well Child Book will be undertaken. Staff training will involve education on the tracking and documentation strategies to ensure UNHS becomes part of the discharge planning limiting the number of infants missing screening.
- Follow-up of paediatric audiology services that are of good quality, timely, accessible and appropriately funded are important to the success of this UNHS programme. Review of the follow-up and intervention services for babies who are referred for further audiological assessment in New Zealand found there is already well established facilities for audiological rehabilitation, including the fitting of

hearing aids. The project when fully operational will detect approximately eight babies per year with moderate to severe permanent hearing loss, and a further 20 babies will be detected with permanent mild to moderate hearing loss.

- To ensure appropriate sustainable funding is allocated for screening and follow-up and the commencement date.

Economic feasibility *(a measure of whether a solution will pay for itself or how profitable a solution will be).*

A breakdown of the set up costs, the ongoing costs and the intangible costs are given in stages. This is summarised in the following tables (4.9, 4.10, and 4.11):

A costing of the initial set up costs for the UNHS programme commencing with stage one; all NICU admissions and/or the at-risk population (see table 4.9). This table demonstrates the initial preparation costs (including staff salary and marketing material), equipment, software, initial supplies (consumables for training), education and training costs:

Table 4.9: Summary of the set up costs for UNHS:

Preparation:	**Unit Cost**	**Costs**
Preparation: 3months		
Audiologist: (0.4FTE)	$30.00/hr	$5760.00
Coordinator NP™:(0.2FTE)	$30.00/hr	$2880.00
Marketing material		$ 2,500.00
Sound Proofing Curtains		$635.00
Acoustic shell		$350.00
Equipment:		
Computer	$3000.00	$3000,00
HP Laser Printer 1100	$670.00	$670.00
Portable AABR	$38,000.00	$38,000.00[3]
TEOAE/AABR	$22,800/$38,000	$22,800/$38,000
Consumables: (x 40) TEOAE /AABR	$3.00/$15.00[1]	$120.00/$630.00
Staff training		
Educational material	$500.00	$500.00
Training x1 day[2]		
Audiologist/coordinator	$360.00	$624.00
Screeners x2	$192.00 x4	$768.00
Total costs 1.	TEOAE	**$40,607.00**
2.	AABR	**$56,317.00**

[1] Based on a quote of US$9.75 per baby for AABR and $2.00 for TEOAE and exchanged at 0.65¢ to account for fluctuations in exchange rate and assuming 5% of consumables are discarded for various reasons. Consumables allocated for staff training for 4 staff x10 trails each.

[2] Based on one days training of x4 screening staff, coordinated by NP and supported by 4 hrs from Audiologist.

[3] This item has already been donated by the Auckland Rotary Club so will not be included in the total of the set up costs.

The set up costs identified preparation time of 3 months for the audiologist in-charge and the NWH coordinator. The equipment included one AABR machine that was donated and either an OAE or second AABR machine, and a printer; the consumables are for x40 test screens for training purposes. The costs quoted for the computer and printer was based on the prices through the Auckland Healthcare procurement office. The educational material included training packages for the screeners, and the hospital wide marketing promotional material including videos (x4) for training staff and parents/families and the marketing material for promotional use for parents and families providing them with information sheets and pamphlets.

The ongoing costs identified the annual staffing salaries, ongoing training costs and the consumables required to screen 7500 babies (see table 4.10).

Table 4.10: Summary of the ongoing costs for a UNHS programme screening 7500 babies per annum.

	Unit Cost	Costs
Staffing salaries:		
Audiologist: (0.2FTE)	$30.00/hr	$12,480.00
Coordinator: (0.2 FTE)[1]	$30.00/hr	$12,480.00
Screening staff:(2.1FTE)[2]	$24.00/hr	$104,832.00
Ongoing training:		
8hours per year[3]	$24.00	$1152.00
training material	$700.00	$700.00
Equipment:		
Consumables AABR/TEOAE	$15.00/$3.00	$118,125.00/$23,625.00
Marketing material		$ 2,500.00
Total costs AABR/TEOAE		**$252,269.00/$157,769.00**

[1] Based on the coordinator undertakeing 0.1 FTE screening to maintain skills and 0.1FTE providing screening supervision and coordination of the UNHS at NWH, ensuring Quality indicators are met and staff are supported.
[2] Based on screening approximately 7500 newborns per annum, screening during normal waking hours i.e,. between 0800-2000hrs and covering 7days per week (84 hours/week).
[3] Based on each existing screener receiving 8 hours per year of updates/audit (x4staff) and new staff training (x2 staff per year).

NB. The ongoing costs were based on screening approximately 7500 babies per annum. The staffing salaries included a audiologist and coordinator at NWH with screening staff covering approximately 20 screens per day, 7days per week, providing flexibility of hours worked. The ongoing training provides 8hours per year for updates and audit purposes for each existing screener and 8hours for new screeners (x2) allocated per year for natural attrition. The equipment costs are based on the additional purchase of a second portable AABR or TEOAE machine.

The intangible costs are detailed but not allocated a cost as they are absorbed in the infrastructure of NAC and NWH (see table 4.11).

Table 4.11: Summary of the intangible costs

Intangible cost	Site:
storage of equipment and consumables	NICU, NWH
office facilities and furniture	NICU,NWH and NAC
phone, fax, copier and consumables	NICU, NWH and NAC
training facilities	NICU, NWH and NAC
travel and vehicle expenses	NICU, NWH
administrator and accounting support	NICU, NWH and NAC

Population demographics

National Women's Hospital (NWH) is the largest Maternity Hospital in New Zealand with approximately 7,600 births per annum (see table 4.12) which is greater than 10% of New Zealand's total deliveries and supports the largest Neonatal Intensive Care Unit (NICU) in Australasia with over 1300 annual admissions. NWH is a regional Neonatal Centre providing services for the care of premature and sick babies in central, north and west Auckland and for the northland region. NWH is also a national referral centre for New Zealand's other tertiary/quaternary hospital health services, particularly when other neonatal units are at capacity. However this is proposed to change as services are redistributed and decentralised in Auckland.

The Health Service Delivery Plan (HSDP) is a planned merger and movement of services anticipated for June 2004 to a new Hospital in Grafton, Auckland where the Paediatric and General Auckland Hospital services are currently situated. There will be a staged cot reduction of NWH as redistribution of Level II services occurs prior to the merger. New Level II units are being established at North Shore and Waitakere Hospitals which means reduction in cot allocation from the previous 59 cots to a projected 48 cot unit, currently NWH has been reduced to 54 cots as the new units' transition to their new Level II services. There is however no future reduction forecasted in the number of deliveries at NWH, with a record 706 deliveries identified in January 2004. The prelim results as detailed in

the Business Plan represent the service up until 2000, the last few years prior to these changes so an analysis of more recent data has been provided.

The target population is all live births at NWH and babies admitted to NWH in the newborn period. A review of National Women's Hospital deliveries and live babies was undertaken from June 2000 to June 2003, this includes single and multiple births.

Table 4.12: Summary of number of live deliveries at NWH and the total number of babies cared for at NWH.

Year June to June	No. Deliveries	Total no. live of babies
June 2000 to June 2001	7645	7767
June 2001 to June 2002	7528	7659
June 2002 to June 2003	7804	7927

NB. The number of deliveries at NWH has remained constant over the last three years with a range form 7528 to 7804 giving an average of 7659 deliveries per annum; this represents the possible number of babies available for universal newborn hearing screening, and includes multiple births, but not those transferring into the hospital postnatally. The available data (i.e. Jan to Dec for 2000) identified 218 multiples deliveries (207 twins and 11 triplets), 33 babies were also born before arrival, and 305 transferred in for postnatal care. Therefore an average of 7787 live babies per annum are identified as available for newborn hearing screening in the current climate.

Conclusion

The results outlined in this chapter have covered the four aspects of a feasibility study detailed in the previous methods chapter and presented the current population dynamics of NWH in the context of UNHS. The following chapter reviews the 1999 Business Plan's findings in view of changing population dynamics and reviews the relevant new data.

CHAPTER FIVE: BUSINESS PLAN REVIEW

Introduction

This chapter reviews the initial proposal as outlined in the 1999, Business Plan, (see Appendix 2) to implement a Universal newborn hearing screening (UNHS) programme at National Women's Hospital (NWH) in relation to the changing dynamics of the environment and target population. A staged approach to the UNHS programme was developed for the Business Plan in 1999 and for ethical review (2000) as the programme estimated screening over 8000 babies per year when fully operational. It was to be implemented in three stages. The first stage is centered in the NICU where approximately 1300 babies will be screened. In the second stage all possible babies that stayed in the hospital for 24 hours and greater were to be screened (greater than 3890 babies per annum). The programme will then move into the community for full implementation. This would allow for screeners to gain experience and competence and give the National Audiology Centre (NAC) time to adapt to the initial increase in numbers of full audiological assessments required following referral and provide good data and feedback for ongoing project refinement and development. Good existing overseas programmes find that 2-4% of babies tested, using the re-screening protocol will need further assessment. This assessment of the target population has changed and requires an updated and more detailed analysis of the current situation. The stage one target population (NICU) has been reviewed to identify changes following the Auckland

Healthcare redistribution of cots across Auckland. The remaining infants at NWH (delivered or transferred postnatally) are reviewed to determine the best approach to screening as many as possible before hospital discharge.

Newborn Service Admission Review

The target population includes all newborns born at NWH or transferred into NWH in the newborn period. Maternal length of stay (LOS) and therefore age of the babies at discharge from NWH has been reviewed (see Table 5.1). A number of babies are admitted to NICU, NWH after birth. The NICU admissions from January 1st 1996 to December 31st 2003, an eight-year period were identified (see Table 5.1).

Postnatal admissions from January 1st 1999 to December 31st 2001 were also reviewed.

Postnatal management of newborns under paediatric care was identified to capture their length of stay (LOS).

Table 5.1: Summary of the NICU admissions NWH

Year	No. of NICU admissions
2003	1241
2002	1361
2001	1338
2000	1431
1999	1352
1998	1300
1997	1420
1996	1690

NB. NICU Admission data identified the number of neonatal admissions to Newborn Services at National Women's Hospital from 1996 to 2003. The average number of admissions is approximately 1424 per annum. However if we take the latest figures from 2002-2003 then there is an average of 1300 admissions/transfers per year.

The Newborn Service underwent a structural review in 1997. As a result an amalgamation of the Special and Intensive Care Units (Level II and Level III services respectively) occurred in January 1999. Admission and LOS details best representing the current Newborn climate are post this amalgamation. The admission data is supported by the NWH Annual Clinical Reports covering admissions from 1996 through to 2001, the 2002 and 2003 data is obtained from the admissions data base in the NICU where details collated by the Newborn Services NICU Ward Clerks and has not been verified by the computerised data.

To estimate the number of infants eligible for newborn hearing screening a closer review of the 1999, 2000 and 2001 Newborn Service admission records was undertaken. This data has been verified and is available from the respective NWH annual clinical reports. Those infants not available for hearing screening were those who died and those who were transferred to other hospitals for further investigations and /or surgery (e.g. Greenlane Hospital or Starship Children's Hospital) and remained too unwell to screen for hearing loss(see table 5.2). This data is unlikely to change enough to impact on the screening numbers.

Table 5.2: Summary of the NICU admission's eligible for hearing screening.

	Admissions	Died	Transferred	NHS
2001	1338	25	53	1260
2000	1431	40	67	1324
1999	1352	48	57	1247

NB. An average of 7% per year of NICU admissions will not be screened for hearing loss in their first admission to NICU, NWH because they either died or were transferred to another hospital for ongoing intensive care and/or surgery. From this data the average number of NICU infants available for newborn hearing screening is 1277 per annum.

The feasibility of implementing a UNHS programme at NWH is discussed in the next chapter in relation to the research findings of the current population dynamics and unique NWH environment (Chapter 4) and following the review of the 1999 Business Plan (Chapter 5).

CHAPTER SIX: DISCUSSION

Introduction

To lessen the impact of hearing loss in the various areas of development, hearing loss must be identified as early in life as possible (Carney & Moller, 1998), therefore effectively screening a newborn population. The purpose of this study was to determine the feasibility of implementing a universal newborn hearing screening programme (UNHS) at NWH. The issue of feasibility will be discussed in terms of the practical implications and appropriateness of the protocols for newborn hearing screening given the constraints of time, finance and the clinical application within the unique population and environment of NWH. Discussion of the research findings are detailed in this chapter. For clarification the research findings will be discussed in the same approach as they were investigated commencing with operational, then technical followed by the scheduling and economic findings and finishing with the population demographics. They will then be discussed collaboratively to identify the best feasibility options for implementing a UNHS programme at NWH.

Operational feasibility *(a measure of problem urgency or solution acceptability and includes a measure of how end-users and managers feel about the solution).*

1. Establishing appropriate communication links:

Strong commitment from both the National Audiology Centre (NAC) and National Women's Hospital (NWH) management enabled the development of a dedicated UNHS development group. This group had representation from both sites (an Audiologist and Nurse Practitioner™ respectively) and support from the Auckland University Medical School. Established links with regular meetings enabled the UNHS Development Group to be clear about the goal of UNHS in New Zealand. They issued guidelines detailed in the results chapter on which to base the programme, these clear minimum expectations of the programme assist in determining the feasibility of the programme. These continued to be disseminated across the sites so the staff at NWH remained well informed throughout the study. By also preempting the Neonatal Intensive Care (NICU) and NWH proposed move to the Grafton site in 2004 recommendations on sound proofing could be made to enhance the screening opportunities at the new site.

2. Determine interpretation of UNHS in NWH environment:

A discussion with the neonatologist's and nursing staff in NICU at NWH was undertaken to determine the impact of Newborn Hearing Screening on current daily routines/practices, assuring minimal disruption as possible. As UNHS may be performed at varying times of the day and especially during the morning so to capture those babies identified on the morning ward rounds for transfer or discharge, it was felt the process be as transparent as possible, become part of the daily routine and performed at the bedside if possible. This would assist in the education and dissemination of information to both families and staff. There would also be a need for flexibility of the screeners so that screening could occur in the evening or night when the NICU was quiet and babies were also sleeping and quiet, providing less risk of interference of ambient noise levels and disturbed or unsettled babies. Sininger et al. (2000) identified the factors other than hearing loss that affect the test result included infant state, testing site and the infant risk status.

3. Establish an inform consent process:

The feasibility study results, particularly the LOS in hospital of newborn infants identifies that parents have the opportunity to have their child screened for hearing loss at the time of their birth and/or if their newborn requires hospitalization early in the newborn period. Communication of the correct information to parents and families should be at a time when they can understand it and when they are likely to benefit from it. The essential ingredients are the sharing of information and reaching an agreement about the intervention or treatment to be undertaken (MOH,

2000). New Zealand has previously experienced inadequate sharing of information associated with screening programmes and is cautious of how the informed consent process is undertaken with recommendations supporting a well structured informed process following the Gisborne cervical cancer inquiry (Duffy, Barrett, & Duggan, 2001).The current NWH service practices also support streamlining the dissemination of information leading to informed consent through many points of contact with parents and families. Utilising the already established links, information on newborn hearing screening can be provided that is accessible to the parents and families who need it to make an informed choice. A specific consent form for newborn hearing screening was also developed as a strategy in the informed consent process. Written information reinforces for parents and family members the meaning of the findings. Pamphlets or other materials written for parents allow them to seek information at their own pace, as well as provide information to share with other family members (Johnson, 1997).

The identified links for information dissemination include information packages and /or pamphlets to be given at the following points of contact with parents and families:

- Time of booking in the form of information (sheet or pamphlet)
- Antenatal classes in the form of a video, presentation, pamphlets or information sheets.
- Lead maternity caregivers (LMC) in the form of an information flyer describing the UNHS programme also providing information on hearing loss in the newborn and contact details of the NAC.

- General practitioners and medical centre's in the Auckland Healthcare region in the form of an information flyer describing the UNHS programme, their expectations as health carers, information on hearing loss in the newborn and contact details of the NAC.
- The Women's and Child's Information Service at NWH in the form of information material, associated articles, website address, video's and pamphlets.
- Newborn Service information packages in the form of information sheets and pamphlets given out on admission then specific information sheets or pamphlets for those identified with a hearing loss in the newborn period to be disseminated by the Family Liaison Nurses.
- Support from the NICU staff, nursing and medical to assist in the dissemination of the information. This can be in the form of resource material, Grand Round presentations and accessing daily nursing meetings to keep staff informed prior to and during the introduction of UNHS.

Health information is very complex and can be hard to understand even when it is presented in a language you are familiar with. When presented in a language the parents are not familiar with it is even more difficult. In one study by Watkins and Nanor (1997) about mother's feelings towards UNHS, mothers who were not fluent in English were excluded because of a lack of interpreter services; therefore, one can not assume parental anxiety did not exist for the ethnic minority groups. The availability of an interpreter service is essential for many parents to be

fully informed and participate in the care of their baby. Patients and parent's right to an interpreter is contained in right 5 (1) of the Code of Health and Disability Services Consumer's Rights (1994): every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter. National Women's Hospital has a well supported interpreter service that is accessible 24 hours per day and this will be accessed as required for families that have limited understanding of English. Information sheets and pamphlets on UNHS can also be provided in different languages.

Programmes should be parent focused, reflective in all aspects of the process from its development to the provision of intervention services. Parents should be assured there is appropriate follow-up, that is both diagnostic and provides appropriate intervention and treatment with enough resources available to be coordinated in a timely fashion. The collaboration of this information sharing will also minimise the cost and workload of this project. The importance of educating parents regarding UNHS during the prenatal period to improve follow-up rates has been supported by Wittmann-Price and Pope (2002). Awareness of parental anxiety and increased stress due to mothers being uninformed on aspects of UNHS has identified the importance of the informed consent process. Recent studies support the well informed parental approach as positive and less stressful (Wessex UNHS Trail Group, 1998; Weichbold, Welzl-Mueller, & Mussbacher, 2001). Between 20%

and 30% of hearing impaired infants will acquire their hearing loss during early childhood therefore may have normal hearing at birth (NIH, 1993). UNHS is therefore not a replacement for ongoing surveillance of hearing status throughout infancy and early childhood and appropriate information on further detecting hearing loss should be included in the parental and family education strategies at the time of screening the newborn.

4. Investigate recent UNHS programme:

The analysis from the recent visit to the Flinders Medical Centre (FMC) to review their newborn hearing screening programme was beneficial from both the perspective of gaining experience and identifying the things that worked well and the issues experienced with the implementation of their programme. The programme was equivalent to the Stage One (NICU and 'at-risk' population) of this research project screening approximately 900 babies per year. The FMC newborn hearing screening team identified the importance of funding not only to implement but to sustain the programme. The selected information packages for UNHS were in the form of information sheets, easily reproducible and considered an intangible cost, covering different topics depending on the parental need. Written consent was sought prior to the screen and assisted in the informed consent process giving parents the opportunity to ask questions around the screening programme or on newborn hearing loss. A selection of NICU nurses including those in the Homecare follow-up programme were trained as screeners of the OAE screening tool. They were provided with information packages on ear anatomy, how to undertake a

hearing screen and how to implement a protocol. Screening occurred in the interview room in the NICU due to higher ambient noise levels in the open plan clinical room of the NICU. The screening was undertaken at approximately 24 hours of age using OAE's and had the potential to miss some of the infants prior to discharge limiting the number screened. Those not screened prior to discharge or who required re-screening were given an appointment to return to the unit for screening increasing the risk of non-attendance and further decreasing the overall capture rate.

It is too early to determine the effectiveness of the Flinders UNHS programme; however their multidisciplinary approach and utilisation of nursing staff as screeners increased the opportunities for parental education and support. Wittmann-Price and Pope (2002) found that having nurses working closely with audiologists and well educated in UNHS was key to the parental education demonstrated by the 100% follow-up attendance achieved in the intervention group as opposed to 77% in the non-intervention group.

5. Consumer input:

'Parent-care' was identified as a valuable link with families and supported the concept of UNHS. The opportunity to further establish links with families of young children was identified and invitations to attend meetings and contribute to their website and publications on the topic of hearing loss and UNHS would be undertaken. Arguments about parental anxiety stem from lack of information and

parents feeling they have not been well enough informed about the screening (Weichbold & Welzl-Muller, 2001). Giving parents the news of a diagnosis of hearing loss is also a difficult task, and parents can be totally unprepared for the information that is delivered. Much of what parents hear and understand is affected by how the information is delivered and other parent resources should be included in a UNHS programme especially community resources and parent support groups (Johnson, 1997).

Technical Feasibility *(a measure of how practical solutions are, and whether the technology is already available, and whether it can be acquired.)*

1. Hearing Screening Tools and Protocol:

Minimising false-positives in universal hearing screening is essential for both limiting unnecessary parental anxiety and expense and can be achieved by re-screening all infants who failed their initial screen before hospital discharge. The North Carolina programme (Clemens & Davis, 2001) were able to reduce their false-positive rate of UNHS to 0.8% from a demonstrated range of 2-10% where hospitals used a one screening test prior to discharge. This is both an inexpensive and simple intervention and may also enable an earlier screening approach to the preterm infant. The re-screening protocols used internationally vary from just using the OAE's like Flinders Hospital in Adelaide, Australia to using the OAE's and re-screening those who do not pass with the ABR. However the protocol is fashioned it should be drawn up to deal with all aspects of the screen in operation, taking into

account the sensitivity, specificity, false negative rates and false positive rates. The aim would be to achieve a referral rate for formal audiological testing after screening that does not exceed 4% and a less than 3% false-positive rate, (NAC guidelines) that is the proportion of infants without hearing loss who are labeled incorrectly by the screening process as having significant hearing loss. To achieve an acceptable referral rate at NWH with between 7500-8000 admissions per year, means screening as many infants as possible before discharge or have strategies to screen them within the first three months of age. The referrals for formal audiological assessment would be 300-320 per year with a predicted false-positive rate of 225-240 per year.

The estimated 7500-8000 NWH admissions per year equates to screening between 19 and 21 babies per day to efficiently support a 95% capture. It would be more efficient to have flexibility in the time the screening staff were available (i.e. covering most of the waking hours), and to support this, increase the number of screening tools available. If the hospital culture is for short length of stays for mother and infants, it is possible that the referral rate for outpatient testing may be higher and may preclude a multistage inpatient model because so little time exists to test infants more than once (Orlando & Sokol, 1998). All NWH admissions (babies) that were greater than four hours of age at the time of discharge (approximately 97.8% of all admissions) could theoretically be screened as time would allow for them to have a screening test.

Establishing good communication links with midwifery, nursing and medical staff, preempting those that are planning discharge from the postnatal wards, Delivery suite and the NICU could capture those that would otherwise be missed. The majority of discharges occur during normal waking hours 0800-2000 hours therefore the screening could be covered by two staff working across these hours (i.e. working consecutive 6 hour shifts). A closer review of the discharge data identified the babies discharged at less than four hours of age were made up of 2.2% (equates to three times per week), of that 0.7% went directly home, the remainder to other Postnatal care facilities within the Auckland region. The babies transferring to other Postnatal centres effectively remain a captive population and with the flexibility of two screening staff per day, two portable hearing screening tools and access to transport still allows this population to be screening for hearing loss early in the newborn period. Oudesluys-Murphy and Harlaar (1997) identified screening at home may be necessary to achieve a high level of capture in the newborn period. They showed that neonatal hearing screening by nurses using an AABR infant screener in the home was feasible with a mean screening time of 18minutes. The screening role would suit both the NICU nurse and the Newborn homecare nurse. The Homecare service in 2004 is projected to decrease in workload due to the redistribution of Level II services so this maybe an opportunity to increase the flexibility of the homecare position and retain a valuable service. Approximately three babies per week will be discharged earlier than 4 hours of age, these babies could be either scheduled for a outpatient visit to the NICU clinic in the afternoon for screening or if unable to attend could be visited in the community by a

screener utilizing the homecare car. The homecare staff could also be trained as screeners and follow-up the babies not screened or re-screened prior to discharge especially the preterm and 'at risk' populations. Given the anxiety for parents that may be engendered by cases that do not pass the screen, follow-up without delay is essential.

The proposed staging of this NHS programme will assist in detailing the variability in performance associated with the 'learning curve' that most programmes experience over time. Screeners soon develop their skill level to be screening efficiently by 6 weeks in to a programme (Dort, Taboliski and Brown, 2000). To reveal how the programme will perform over time it would be important to report the year-to-year outcome statistics. This will later allow individual hospital statistics yet allow the collaboration in a multi-centred program i.e. New Zealand's, allowing inter-hospital comparisons of performance over time and improved quality of care. The Audiologist co-ordinator has input into the equipment purchase, funding has been made available for one AABR, on its own however it is not enough and other electronic equipment is also required for data collection and analysis that can provide accurate quality assurance monitoring, tracking and follow-up statistics. A second AABR machine is advised and a revised costing of the equipment is provided.

The benefits of a universal hearing screening programme are at a population level, provided the programme has a consistent approach and is of high

quality. Extensive workforce planning is critical and the setting up of effective information systems and their maintenance strategies are imperative for efficiency and accuracy. The directive of the Audiology department is to provide a review of the requirements essential for a newborn hearing screening programme not only in the short term but for growth and development of the programme, essential for its future success. As the use of UNHS rapidly increases, it is important to conduct longitudinal studies of UNHS, following the speech, language and scholastic achievements over time of the identified deaf and hard of hearing children.

Equipment continues to be modified and improved, and it is almost certain that better, faster and easier to use equipment will become available. The evidence supports using Automated ABR screening in the NICU and early discharge babies (Mason & Herrmann, 1998; Lutman, Davis, Fortnum, & Woods, 1997) while Transient OAE's may be better for the large numbers of healthy babies discharged after 12 hours of age in maternity units. The possible combinations are numerous, in the well baby population the most commonly emerging system is currently the TEOAE as an in-patient screen, followed by either a repeat TEOAE or ABR, if inconclusive and prior to discharge. The false-positives (those infants with normal hearing who do not pass the screening test) will be reduced due to the re-screening. However OAE's traditional have more false–positives than AABR's when used early in the newborn period (less than 24hours of age) due to vernix in the ear, background noise in the nursery and fluid in the middle ear (Stone et al., 2000). In the NICU and/or the 'at risk' group the AABR is first line with repeat AABR screening

if inconclusive prior to referral on to the audiology centre for formal assessment and follow-up.

The time to screen an infant with either the ABR or OAE screening tools are now comparable, although the time taken to set up the ABR is longer. There is less restriction on the age of the baby at the time of screening with the ABR as compared with the OAE, and ABR would be a more useful tool for optimizing the capture of infants before discharge from hospital. The automated ABR is a computer system could that would better support the development of a local shared register of hearing impaired children, leading to the establishment of regional and national registers and links to child health record information systems.

Recent research has identified an increase in the cases of auditory neuropathy (AN), a significantly higher incidence than previously reported (Rance et al., 1999). Auditory neuropathy occurs where there are functional disturbances and /or pathological changes in the peripheral nervous system and generally these subjects have presented with an acquired hearing loss. Evidence for AN in the infant population has more recently begun to appear in the literature with one group identifying four children through a special care screening programme with normal OAE's and absent or abnormal ABR's in the neonatal period. This finding has been further supported by Rance et al. (1999) where OAE screening results were similar to those reported for normal hearing and approximately half of their subjects would have gone undiagnosed if screened by OAE's only. They also found a strong

association with hyperbilirubinaemia and AN and suggested with advancing neonatal care, decreased mortality rates and survival of more premature infants the incidence of paediatric AN will increase. This would imply that AN can be one of the possible diagnoses for an infant who is identified in a UNHS programme with an absent or abnormal ABR screening. These infants would be missed in an OAE arm of a combination screen and would become a false-negative statistic. The alerting factor to AN is the infant passes the OAE screen and fails an ABR screen, as the AABR has the advantage of testing both the cochlea and retrocochlear functions. The AN cases also require different intervention strategies than those currently implemented for senorineuronal hearing loss which is the aim of detection in the UNHS programme. Screening all infants with the AABR would eliminate the risk of not detecting AN and therefore they would be referred for formal follow-up. Even though the exact cause of their hearing loss is unknown they would still be followed up by the NAC who would then be alerted to the possible cause of the hearing loss and appropriate strategies for identifying this group would be implemented.

Securing a transparent, seamless, well-coordinated screening and follow-up service requires quality control mechanisms, audit, a coordinator or coordinating team and good quality information and tracking systems. The most reliable tracking method currently used is the link to the infants national health identification number (NHI) as with the metabolic screening programme. The Well Child Health Book is also an option for tracking, this book is taken with the child at discharge and used by well child services like Plunket, the LMC and the general practitioner (GP) with a

section already on infant hearing. The consent and documentation of the screening results 'pass' or 'refer' should also be identified in the patients clinical records along with copies of referral letters. This should be included as part of pre-hospital discharge check list and can be identified by the staff discharging the infant and/or mother as being competed or not and refer to the screening personal. Infants cared for at NWH are currently required to have a pre-hospital discharge examination that is documented on the discharge check list and includes a list of referrals and follow-up required. An eye check for the 'red reflex' is one of the current pre-discharge examinations. If absent it may denote an ocular abnormality of the lens, vitreous, or fundus and it is important to identify early in the newborn period so immediate treatment can optomise the infants outcome (Fanaroff & Martin, 2002). Screening for congenital cataract is completed when the baby is preparing for discharge and requires a Paediatric Registrar or Advanced Practice Neonatal Nurse or Neonatal Nurse Practitioner™ to complete, this maybe an opportune moment to include the newborn hearing screen.

2. Resources Available: Hearing Screening Environment:

a) NICU ward layout: Ideally space should be assigned to the UNHS programme, it should be close to the nursery, quiet and available during the majority of the screening day, for screening and /or storage of equipment and supplies (Orlando & Sokol, 1998). To establish the existing resources; the review of the NICU ward layout identified the limited options available for storing the screening equipment and its resources, computers and disposables. A locked room accessible

by the screeners that can have office like facilities like a desk, phone, internet access and storage cupboards would have to be in a shared facility with a researcher or an existing room identified and tabled at a future management meeting, as possible options for change or sharing of functions. The only rooms available were already assigned to other departments. The disposables could be stored in the designated NICU storage room which is close to the screening environment and more suitable for accessing on a day-to-day basis.

b) Alternative screening sites: To provide optimal screening conditions it was important to explore the option of removing infants from the clinical rooms to a quiet non-clinical room designated for hearing screening. Orlando and Sokol (1998) identified the NICU as too noisy and less able to be modified for sound dampening and reducing ambient noise levels would decrease the time needed for data collection. This study investigated the screening room options by taking isolated readings from the five possible 'non clinical' rooms thought as most suitable. The results of sound testing identified the outpatient clinic room as the most quiet at 42 dB(A). The other four rooms were discounted due to already high utilization time, being a high activity area, being too isolated, or due to their higher ambient noise levels. The room selected was the outpatient clinic room situated near the Parent Infant Nursery (PIN) but some distance (100 meters) from the NICU on the some floor. The ambient noise level in this room was 42 dB(A) increasing to 48dB(A) when the buses passed necessitating the need for sound dampening curtains. The outpatient clinic room is utilised for outpatient follow-up appointments most

mornings of the week restricting the time for hearing screening. A designated room would be more ideal without the time restrictions to capture those infants being discharged following morning ward rounds. Near patient testing in the clinical rooms was therefore better supported than adapting a non clinical room for hearing screening in the newborn. However, the flexibility of having a non-clinical room suitable for hearing screening may be advisable and utilised for example for screening or re-screening babies at or following clinic appointments, their first appointment usually occurs between 4-6 weeks post discharge home, still well within the recommended referral time of 3months of age.

The option of screening at the bedside was supported as most suitable by the medical and nursing staff and the parents interviewed at the time of testing. This would not only increase general awareness but cause less disruption to the day to day running of the NICU. Newborn hearing screening has been successfully carried out in various NICU settings and is forging the way for new Neonatal Intensive Care Unit design that is 'developmentally friendly', minimizing ambient noise levels. National Women's Hospital's NICU is a well established unit built in approximately 1974 and therefore not new enough to be designed with the more recent neonatal developmental issues in-mind, especially sound and light level modifications that best suit the preterm population. The American Academy of Pediatrics, Committee on Environmental Health (1997) recommends a maximum safe noise level of 45dB in the NICU to positively impact on infant sleep state and oxygenation.

c) NICU ward noise levels: NWH is a very large and busy unit with high levels of ambient noise with between 4 and 6 babies per room and on average 3-4 admissions and discharges per day. The sound levels identified for the clinical rooms; Level III, II and PIN (see tables 4.1, 4.2, 4.2) demonstrated the more intensive care in the clinical rooms the greater the ambient noise generated. PIN was the quietest with an average of 49 dB(A) this still exceed the average noise level detected inside a double walled incubator at 45dB(A) and could still compromise the hearing screening test. While the infants in the double walled incubators are screened further from ambient noise levels making a more acceptable environment for newborn hearing screening the cot babies remain exposed to the everyday noises created in the NICU. Newborn incubators have become more sophisticated and are being produced with double walled hoods to minimize noise exposure to the preterm population in their vulnerable developmental period.

Most babies progress through the unit as they become well or are growing moving from Level III to Level II and onto PIN. As babies improve with increasing gestation and /or weight gain they transfer to a cot in preparation for discharge. While some preterm babies may be well enough to screen for hearing loss while still in the incubator most would have progressed to a cot before hearing screening could be performed. The results of the sound testing compared between the incubators and cots (see Table 4.5) identified noise levels were lowest for the incubator (turned off) with the highest identified in the cot group. Ambient noise

levels can affect the screening result (Orlando & Sokol, 1998) and further sound dampening using a modified isolette with a closed lid (Johnson et al., 1993) would further reduce the environmental noise. This drove the development of an acoustic shell or hood which when tested (see Table 4.6) convincingly demonstrate ambient noise levels can be reduced by a further 10dB making it equivalent to the double walled incubators. It was therefore appropriate for the cot population in Level II and Level III were ambient noise levels on average ranged anywhere between 51-69dA(B) to develop strategies to further dampen the ambient noise levels to facilitate bedside hearing screening.

d) Personnel Review: The success of any UNHS programme will depend on the personnel selected and the practical issues specific to each hospital. An Audiologist is required to oversee the programme, assuming responsibility of all the selected screening personnel, training and supervision, education, staff schedules, quality assurance, interpretation and notification of results, monitoring and follow-up coordination (Orlando & Sokol, 1998). This traditional approach may however not suit the NWH environment as the audiologist resides off site at the NAC where their responsibilities include co-ordination of the data, analysis, follow-up and diagnostic investigations and interventions making it more appropriate to have an experienced and designated coordinator of the programme employed on the NWH site. The collaborative nature of the development of this UNHS at NWH also identified the value of onsite personnel familiar with the existing structure, systems, staff and families that frequent the service. The size of the programme also dictates the

responsibilities of coordination and a large programme like this requires a screening coordinator to run the day-to-day operations such as assuring all infants are screened, developing screener's schedules and skills, training and supervision of the screeners on the NWH site. This role appears ideally suited to the Nurse Practitioner™ model with the selection of experienced neonatal nurses as screening staff. Neonatal nurses are familiar with handling small and premature babies, collaboratively working with and educating families and staff and increase the resource network. Nursing staff can be flexible with their hours of work, and with the current NICU ethos of rotating between nursing positions it further creates opportunity for career development and job satisfaction. A positive and caring disposition is a necessary first step to developing effective rapport with families (Johnson, 1997). This is something the neonatal nurses are well experienced in as they care for the premature and sick newborns in the NICU, and already emphasise the partnership model of care where parents are important members of the team.

The National Screening Committee in the United Kingdom (2000) recognised the need for a co-ordinated training programme for screeners, follow up of referral screens and the early management of babies identified with significant hearing loss and established an accreditation body to define training syllabi and accredit short courses submitted for approval. This could be adopted for the New Zealand environment to support the development of a consistent national approach to UNHS.

Schedule feasibility *(a measure of how reasonable the project schedule or deadline is).*

NWH is a large tertiary hospital with over 10% of New Zealand's total deliveries; it is a center of excellence and has support from the National Audiology Centre and NWH management to pursue this project. The target population was reviewed from 2000-2003 to identify those babies discharging early (less than 4 hours of age) therefore identifying those available for newborn hearing screening prior to discharge. It has been identified that babies admitted to NICU's represent approximately half the infants later identified with hearing impairment. With the current at risk register in situ in NZ, there is an expectation that infants in the 'at risk' category are referred for hearing assessment. Even though, the referral and follow-up strategies are less than the expected 50% as identified in New Zealand by Rush, Battin and Wilson (2000), the NICU population is a known captive population. The initial Business Plan proposal in 1999 identified this as the starting point for a screening programme and it remains an ideal place to begin the hearing screening process.

To capture between 7500-8000 babies for UNHS requires a staged approach to cover the already 'at risk' NICU population and develop an efficient universal hearing screening approach through learning and perfecting screening techniques. Stage one should include all Newborn Service Admissions at National

Women's Hospital. This will exclude those infants who died or were transferred out of the region before they became eligible for hearing screening. NWH is a Level III Regional Perinatal Centre accepting transfers of high-risk obstetric as well as neonatal patients from surrounding hospitals, therefore, the degree of disability including hearing loss maybe higher in these infants than other institutions. Infants from out side the region may then be transferred back to the referring hospital when stable or referred on to other intensive care units for more specialised care or surgery i.e. PICU at Starship Hospital or Greenlane Intensive Care Unit. It should be identified that some of these infants will not be screened, however should be identified for referral when more appropriate.

The schedule of this feasibility study measures how reasonable the project deadline is, so to screen the entire NWH target population (between 7500-8000 babies per annum) as an initial project would be unreasonable. The international literature supports a staged approach suggesting starting with the high risk population and NICU admissions to gain experience as screeners and develop appropriate system supports. It was clear that a staged UNHS programme was required this was developed for the business plan for the purchasing board and for ethical review of innovative procedures in 1999 (see Appendix 2). On development and review of the staged screening approach and re-screening protocol a full understanding of the impact that the UNHS programme would have on the existing infrastructure, what new systems were needed and the time needed to adjust to the changes were clarified. This would include the time needed to train staff, the time

needed for screeners to gain experience and adjust to the increase in services. In Stage one it would mean approximately 26-52 babies per annum would be referred for further assessment to the NAC, this in its self was not a significant increase as many of these babies would have been referred on to the NAC as they meet the 'at risk' criteria. The stage two screening would increase the babies for referral from between 78-156, and when the programme is fully implemented the number would rise to 145-290. Currently the NAC carries out 231 diagnostic ABR tests on infants per year.

Intervention Services and follow-up

The NAC feels confident they can manage the initial cases identified earlier, these will be the infants in the 'at risk' group who would have all been referred but now screened before referral so less will appear for formal assessment. The follow up of infants who have been identified with SNHL should be ongoing and is an important component of perinatal audit. The introduction of appropriate technology to record and track referrals is essential to the seamlessness of this programme. Information sharing has been identified as essential in supporting parents awareness and wiliness to attend follow-up appointments. A family centered approach should be implemented with the unbiased advice given to the families in the form of a resource guide that is available in the appropriate language and format.

Hearing loss in children, from mild through profound ranges, significantly affects a child's auditory, language, speech and academic and social-emotional development. A variety of treatments exist for this hearing loss from sensory aids through to intervention programmes, though no one form or combination is applicable to all children. Hearing aids for children are usually provided for the range of hearing loss from mild to severe and cochlear implants for those with severe to profound deafness. Implants are already being performed as early as 6 months of age which gives children an excellent chance of normal development. The cochlear implant foundation in NZ has been established to help ensure that children who need cochlear implants receive them as young as possible and that they receive appropriate and comprehensive habilitation as required. Therefore there is a need for a well defined and supported intervention service to cope with the early treatment of SHL which may include additional resources and co-ordination of these. The literature supports prompt diagnosis followed closely by prompt intervention (Johnson, 1997; Delegation, 1998).

The schedule feasibility of this project has identified important factors influencing the protocol development and timing of a staged implementation plan for UNHS. The updated population data is key in the protocol development. The careful documentation of the screening events are essential for tracking and follow up. Then ensuring the appropriate follow-up and intervention services are available for full audiological assessment determines the effectiveness of the UNHS programme,

because not until formal diagnosis, intervention and treatment have occurred will it be successful.

Economic feasibility *(a measure of whether a solution will pay for itself or how profitable a solution will be).*

Itemising the costs, for setting up a programme and for sustaining full screening of a population of between 7500-8000 babies was detailed in the results chapter. The intangible costs were also identified by service provision. A onetime cost associated with analysis, design, implementation and operating costs which may be fixed over time would be variable depending on the system implemented (AABR only or AABR and TEOAE). The otoacoustic emission screening equipment is cheaper than the auditory brainstrem response equipment and has predominated hearing screening programmes internationally.

Costs may also vary depending on the numbers to screen in any one programme, for example Colaordo while averaging 54,000 deliveries per annum compares well with New Zealand's 60,000 annual births, however the number of babies to screen in the Colorado hospitals range between 40 and 4,000, not so comparable to National Women's 7,500 annual births. The NWH UNHS programme may be more cost effective as the majority of screening occurs on the one site.
A weakness in the costing exercise is that it is possible to underestimate the actual costs of running a programme as a number of costs are absorbed into the already

established infrastructure and there are a number of contributing departments. The In terms of flexibility for improvement, there is scope for targeted UNHS to become more cost effective over time as experience is gained as screening protocols are fine-tuned and follow-up systems established.

The importance of hearing for learning can clearly be demonstrated with measurable outcomes. The work by Carney and Moeller (1998), Robinshaw (1995) and Yoshinga-Itano et al. (1998) as discussed in chapter two clearly demonstrates the benefits of early intervention (before 6months of age) on language and communication skills. The report from the National Health Committee (1998) in New Zealand supports innovative public policy initiatives like UNHS. The opportunity to alleviate the health impact for those with SNHL is to identify and implement treatment early with well defined interventions such as hearing aids and choclear implants. To demonstrate good evidence for effectiveness and long term cost effectiveness of implementing UNHS at NWH will only be achieved over time and is beyond the scope of this study. However it is important to plan the strategies for measuring these outcomes in the future so appropriate data can be collected from the outset, and links with the involved departments established as it will be a collaborative approach.

Conclusion

It is important to endeavor to be universal, since selective screening based on high-risk criteria fails to detect at least half of all infants with congenital hearing loss (Mehl & Thompson, 1998). For a universal newborn hearing screening(UNHS) programme to be effective all infants must be tested early in the neonatal period. Yoshinga-Itano (1999) provides substantial evidence of the effects of 0-6month identification on vocabulary, expressive and receptive language, and consonant and vowel production. Markides (1986) also has identified that at 0-6month identification and intervention children at 8-12 years of age have better speech intelligibility than those identified later than 6months of age. To implement early intervention for sensorineuronal hearing loss newborn screening needs to be carried out in the hospital prior to discharge. The ideal screening programme would identify all individuals who are hearing impaired by aiming to screen as many babies as possible in hospitals, 99% coverage is possible (100% sensitivity) while eliminating those who have normal hearing (100% specificity) (Barsky-Firsker & Sun, 1997; Mason & Herrmann, 1997; Vohr et al., 1998). In reality perfect test performance is never quite achieved, with reports of 95% coverage from several studies when first starting out, however this improves with time and experience of screener's. It is important to learn from those that have the experience of introducing UNHS programmes and develop specific strategies that would best suit the National Women's Hospital environment and establish our own experiences with the ultimate goal of securing unique protocols for further development throughout New Zealand.

The National Audiology Centre (NAC) first identified the urgency of implementing a universal newborn hearing screening programme in New Zealand. This was based on the international literature and the overwhelming concerns of late detection. Also the knowledge that detecting and helping babies with congenital hearing loss earlier would lessen the need for extra help as they progressed through the educational system not only aided their development but be a financial benefit. Children could then be mainstreamed through schools and not require as much costly support or segregated education. There is not only urgency to improve the health and educational status of these children but also to optimise the spending of the health dollar.

In today's healthcare delivery and cost saving climate the support for UNHS programmes will be predicted on the availability of outcome data that support the efficacy, as well as the ultimate cost-benefits of UNHS. Ongoing evaluation of the programme is vital for improving the programme and judging progress. This should be undertaken on an annual basis and should involve not only the analysis of the data collected but consist of questionnaires from a random sample of parents, screeners and other relevant participants.

Ongoing monitoring and auditing of the programme is required for further refining of the screening techniques, protocols and systems. Future research and monitoring should include a cost effectiveness analysis which can be determined

when the programme is up and running, and later can be compared to other established programmes. Cost analyses of early hearing detection and intervention programmes in New Zealand are needed to clarify the ongoing costs for better projection of resources and health dollars.

With regards to genetics in hearing loss, about 1 in 300 infants have congenital mild to profound hearing loss. It is estimated that genetic causes account for at least 50% of such hearing loss and about 90% of genetic hearing loss is non-syndromic with autosomal recessive inheritance representing the most common etiology. Several genes have been identified as causing hearing loss and further genetic determination may be key in determining a better understanding of the etiology and pathologies of genetic hearing loss which could lead to prevention or therapy.

While the NAC has based their estimates of hearing loss on well established American programmes where UNHS has been carried out for many years, they agree with the information they gathered at a later age on the prevalence of hearing loss in New Zealand. Currently in New Zealand for hearing loss greater than 55dB HL (moderate to severe) the average age of detection is 20.8 months and over the period 1991-1997 the average age of detection has ranged from 19-28months (NZ Deafness Notification Data, 1998) well outside the recommended 0-6month range. In the Maori and Pacific Island group detection was further delayed from up to 46 months of age, that's just less than 4 years of age.

The internationally recommended age for confirmation of hearing loss is 3 months, with intervention commenced by 6 months at the latest. This late identification and intervention of the hearing impaired children in New Zealand has devastating effects on language acquisition and their consequent development.

CHAPTER SEVEN: CONCLUSION

Implementation of universal newborn hearing screeningbegins long before the first newborn is tested and a carefully planned programme will have the greatest likelihood of success (Spivak & Jupiter, 1998). The design of a UNHS programme depends on many factors unique to the hospital. This feasibility study has evaluated the potential for success of a UNHS programme in NWH, Auckland and identified several options for protocol development (outlined below), which remain dependent on funding and equipment acquisition. International literature supports the use of objective, physiological screening techniques (Transient OAE (TEOAE) and Automated ABR (AABR)) at birth. These procedures substantially improve the detection rate over other behavioural screening techniques and the use of the 'at risk' registry criteria for referral for hearing loss assessment.

Testing only high-risk newborn infants, results, at best, in early identification of only half of the infants with hearing loss (NIH, 1993). UNHS is now endorsed by many international groups, including the American Academy of Pediatrics Task Force on Newborn and Infant Hearing (1999) and the Joint Committee on Infant Hearing (2000). The two electrophysiologic techniques; the ABR and OAE's are well researched in the use for the identification of sensorineural (SNHL) in newborn infants. While the numbers of potential false-negatives are unknown in the New Zealand context, the numbers of false-positives are also a concern and both require close monitoring to determine our unique perspective. A clearer picture of the

consequences of delayed diagnosis in the low-risk newborns would also strengthen the case for universal screening.

New Zealand (NZ) has the opportunity to capitalise on the international experiences where universal neonatal screening programmes have been successfully implemented and develop research strategies to answer some of the outstanding issues around UNHS and those unique to our population. We have recognised that developing a screening programme in NZ is challenging because of the population distribution and history of poor auditing and follow-up strategies in screening programmes (Duffy, Barrett, & Duggan, 2001). Therefore it requires a different and innovative approach to other countries, that is unique and best suits our environment and culture.

The informed consent process will involve dissemination of information strategies outlined in the discussion chapter and a written consent form to be completed prior to the screen of any infant is recommended in the NZ environment. Parents are partners in care and every endeavor to ensure they are well informed is important for the success of the hearing screening programme. Parental questions will be answered in a timely fashion with supporting information and interpretation readily available. Ongoing audit of this process will occur to ensure parental satisfaction; this will be undertaken utilising various networks for example, Parentcare, and randomly selected consumers at both prescreening, post screening and follow-up stages.

For practical and cost efficient reasons this screening programme should be hospital based with the aim to screen all babies prior to discharge. This type of screening programme is already successfully operating in over 550 hospitals in the United States of America. To significantly reduce the current age of detecting SNHL it is necessary to implement such a universal hearing screening programme. Early detection and treatment implementation (before 6 months) has been demonstrated in the USA to improve outcome (NIH, 1993) with receptive and expressive language development and cognitive skills (Apuzzo & Yoshinaga-Itano, 1995; Yoshinaga et al., 1998). However, earlier identification before 3 months of age is now feasible using objective, physiological screening techniques like the AABR and TOAE at birth.

Recommendations

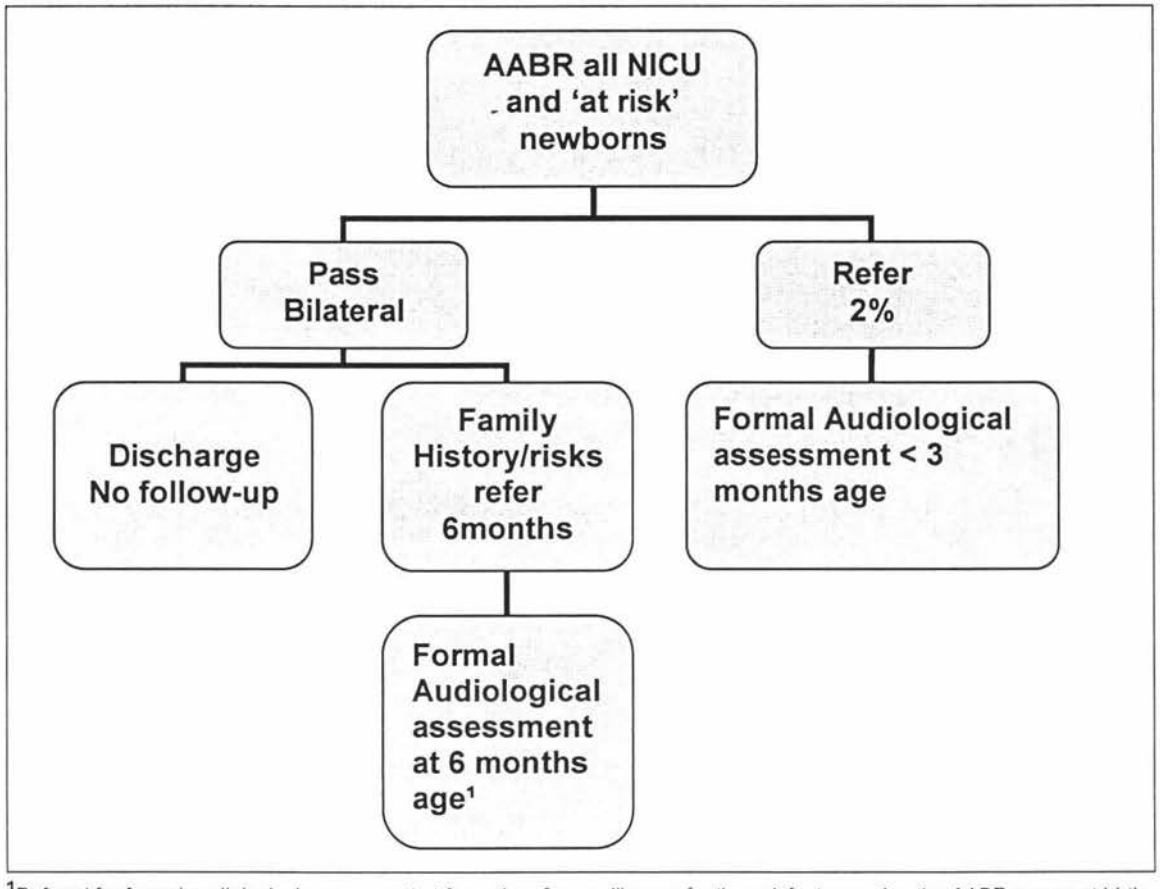
This feasibility study supports two protocol options of infant hearing screening, both will have the same support networks and systems established, however they will have different approaches based on the literature and research findings identified in the discussion chapter. Reiterating the aim of the feasibility study identified in the Methods chapter which was not to promote just a single "ideal" solution, but to identify a number of possible solutions and assess the tradeoffs (Whitten, Bentley & Dittman, 2001). The final recommendations are based on the thorough evaluation of the operational, technical, scheduling and economic factors along with the current population dynamics identified in this study. These

factors have influenced the remodeling of the Staged hearing screening protocol outlined in the initial 1999 Business Plan and identified another appropriate protocol. The final protocol options are more feasible in the current climate and reflect the current international literature.

The initial three stage protocol identified in the 1999 Business Plan commenced the UNHS programme with the 'at-risk' and neonatal intensive care (NICU) populations using the AABR screening tool. This seems the most logical place to start testing; the high risk environment where babies are admitted for relatively long periods, enables the establishment of the test procedures, training of the screeners, setting up the data base and developing and trailing protocols for follow-up. By including those that do not enter the NICU but meet the 'at risk' criteria due for example to a family history of hearing loss will enable experience in screening a smaller number of the well baby population managed on the wards. The advantage of screening early in the newborn and NICU period is the high programme coverage of 'at-risk' newborns that can be achieved. The infants from the well baby population and the NICU that are identified under the 'at risk' register are currently referred on for formal audiological assessment, by screening this group as part of the initial screening stage no infant that would otherwise have been referred will be missed. This may prove to be a more effective way of capturing the 'at-risk' population. As part of the birth record a detailed history of every newborn at NWH is undertaken and any criteria on the 'at risk' register are identified. This 'at risk' criteria for referral will continue, during the screening programme (stage one

and stage two). The 'at risk' criteria will be re-examined by the screeners at the time of obtaining consent, to further identify those at risk so appropriate referral can occur as recommended by the UNHS programme development group. Stage one will be established over the first 6 months of the screening programme then the screening programme will move to the well baby population on the wards and delivery suite where all babies will be screened. The previous protocol identified a further two steps with those staying in hospital for greater than 24 hours (as stage two) and those discharged at less than 24 hours of age (as stage three) to be screened in the home or community. With the improved technology and re-screening protocols false positives can be reduced to acceptable levels of less than 5% (Mason & Hermann, 1998; Maxon et al., 1995; Melh & Thompson, 1998; Vohr et al., 1998) so newborns can also be screened earlier while in the hospital with more confidence. The literature also supports in-hospital capture to increase the numbers screened prior to discharge and limit the number for follow-up in the community and the risk of lost cases.

Figure 7.1: Protocol One and Two : Stage One: All NICU and 'At risk' populations

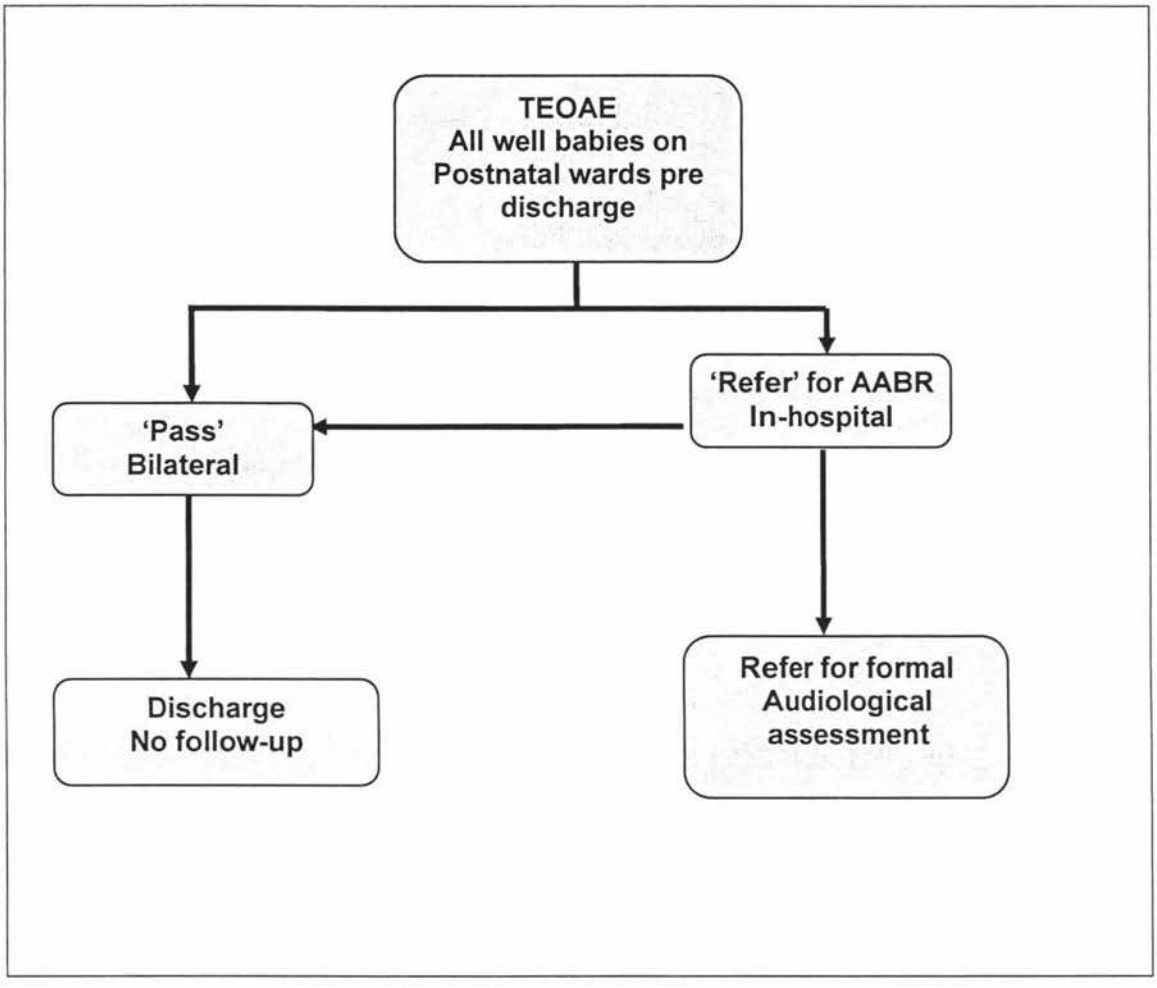


[1]Referral for formal audiological assessment at 6months of age will occur for those infants passing the AABR screen at birth but have significant risk factors that predispose them to progressive hearing loss or Auditory Neuropathy.

Protocol One*: *Following the Revised Business Plan 1999

- AABR will be the screening tool of choice for the 'at risk' and NICU population, Infants >32 weeks will be screened when stable off CPAP, approximately 2% of these infants will require referral.
- A hand held TEOAE will be used for the well babies prior to discharge, the use of the acoustic shell to reduce the risk of failure from ambient noise levels will be used on all babies nursed in cots.
- A re-screen using the AABR of the well baby population that does not pass the initial TEOAE will be undertaken prior to discharge where possible. Approximately 8% of these infants will not pass the first screening and can be retested following the TEOAE screen and prior to discharge using the AABR. Approximately 4% of these re-screened infants will not pass and be referred on for formal audiological assessment.
- Any infant identified with a family history of hearing loss or with significant 'at risk' factors will be referred for follow-up audiological assessment at approximately 6 months of age to rule out Auditory neuropathy and progressive hearing loss.
- All parents will be given information on on-going assessment of hearing loss to increase their awareness of auditory neuropathy and progressive hearing loss.

Figure 7.2: Screening Protocol One: Inpatient TEOAE and re-screening AABR of the well baby population.



Those babies discharged prior to screening or re-screening will be followed up with an AABR only screen in the community (at home or other birthing facility within the Auckland region). This will be performed by nurse screeners utilising the homecare cars to access those in the community. This will equate to approximately

53-56 per year or 4-5 per month. The re-screening protocol is most cost effective when the infants are re-screened prior to hospital discharge.

The cost estimates are based on 1) the set up cost and the 2) the on-going costs which crudely can be equated to the screening cost per infant. Based on the economic estimations outlined in the results chapter the estimated cost per infant screened using this protocol will equate to: $NZ 21.00.

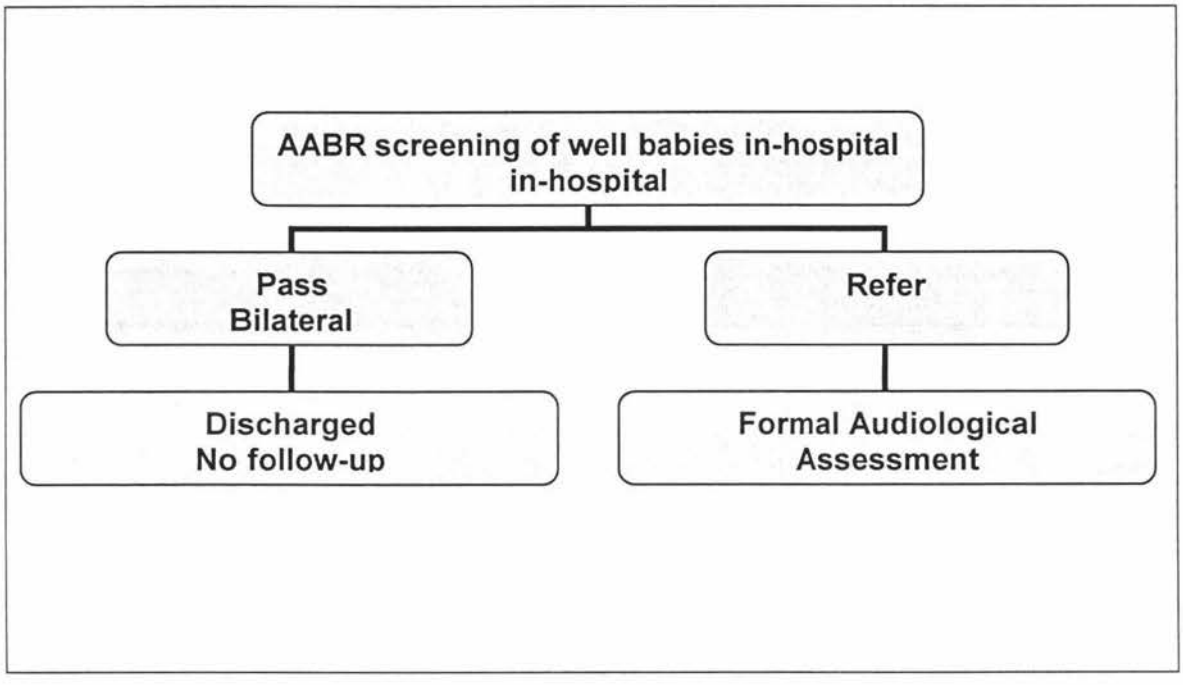
Protocol Two. AABR Protocol

To facilitate the maximum pass rates, the screening of young infants is best suited to the use of the AABR as a first-tier screening procedure. The AABR is more efficient than the TEOAE as demonstrated by Gabbard, Northern and Yoshinanga-Itano (2000) due to significantly increased pass rates (97% pass rate vs 63%) and the younger age group passed at first screening. The one stage AABR screening has also been support for its time and money saving approach as a one screen method (Barsky-Firkser & Sun, 1997).This will also be a one screen programme.

- All infants will be screened with the AABR prior to hospital discharge. Commencing with the NICU and 'at risk' populations as the first stage then including all infants prior to discharge. 4% of these infants will require a formal audiological follow-up assessment and will be scheduled an appointment prior to 3 months of age at the Manukau, Starship audiology departments or the National Audiology Centre.

- The use of the acoustic shell to reduce the risk of failure from ambient noise levels will be used on all babies nursed in cots.

Figure 7.3: Screening Protocol Two; AABR only screening of well baby population



For Protocol One and Two, parents will be given an information sheet clearly explaining why we wish to screen, what the screening involved, what would happen to the results. A consent form would be signed before the screening could take place. Parents would be encouraged to remain with their child for the screen and would be reassured that at no time would their child be moved elsewhere for the purpose of the screening. This creates an opportunity for any further questions or concerns to be answered. Because parents are usually their child's best advocate,

the more knowledgeable they can be, the better they can support their child (Johnson, 1997).

The cost estimates are compared for the two protocols and are based on the on-going costs of each programme detailed in the Results chapter, which can be equated to the screening cost per infant. Dort et al. (2000) demonstrated the cost of an AABR screen per infant was US$25.55 and a TEOAE US$15.70 based on equipment, staffing and disposables. Based on the economic estimations outlined in the results chapter the cost per infant screened using Protocol One equate to NZ$24.00 (approximately US$15.63 per infant screened and Protocol Two to $NZ38.00 (approximately US$24.70) per infant screened. These costs are also comparable to others documented internationally (Lemons et al., 2002; Kezirian, White, Yeuh, & Sullivan, 2001).

Screening would take place between the hours of 0800 and 2000 daily Monday to Friday and 0800 to 1200 (flexi hours) at the weekend by a trained neonatal nurse. The babies would be settled and ideally asleep. The AABR when performed is recorded; the parents are informed of a pass or refer result. The record is noted in the patient records (on the progress notes using the stamp provided identifying pass or refer result, and on a results sheet to be included in the infants record along with the consent form) and in the infants Well Baby Health Book, a letter will be generated for the GP and LMC. Referrals for re-screening prior to discharge are entered in the UNHS work book situated at the NICU reception for the

screeners to update. The ward clerks ensure screening has occurred for each infant prior to discharge or transfer by checking the patient records for the results sheet.

A list of all new deliveries and admissions are obtained every morning, information on newborn hearing screening has already been given to these families, either at antenatal class or on admission to the hospital. The screener on duty will determine an estimation of LOS of all new admissions and deliveries and appropriately prioritise the order of screening for the day, identifying those that will discharge early and those that can be scheduled later for screening.

The audiologist co-ordinator will manage the data-based program, they will be in charge of the early identification of hearing loss in the newborn population by receiving a continual flow of information from the screenings. This information will include the number of babies born at NWH , the percentage of babies successfully screened, the percentage of babies referred, the percentage of babies re-screened and /or diagnosed, the number of babies identified with hearing loss and how well each of the screeners are functioning. Regular and timely summaries of such information are critical to keep track of the quality of the programme and keep everyone well informed of the progress. Monthly meetings will be established following the commencement of the screening to review the functioning of the programme and determine if the goals are being met for example; are the screening rates reaching the expected 95% or are they less than the target; are the screeners performing equally and if not why not. When this information is reviewed on a regular basis, it can be the key to enhancing the programme efficiency and success.

At 6 months into the programme, efficacy should be assessed and modifications in follow-up methodology made in an attempt to improve the rate of return of infants failing newborn screening. Annual statistical reports for the administrators, senior medical and nursing staff will be generated to keep them informed of the progress and when successful identification of congenital hearing loss occurs early because of the UNHS programme.

Before we can claim success or recommend application of our methods more generally, this programme must go beyond testing and achieve early identification and habilitation of the children we find to have defective hearing. Early diagnosis provides the opportunity for babies to be fitted early with hearing aids, and it marks the beginning of the education process for families. Screening is part of that continuum of care which includes diagnosis and treatment. Infants who are screened and diagnosed with hearing loss should have access to appropriate ongoing intervention as needed. Only by researching the goals (lowering false-positives; achieving 95% plus capture rates; increasing access to amplification or cochlear implantation and reducing the cost of screening) can UNHS demonstrate its value in the care of the children who are deaf or hearing impaired.

This feasibility study has identified the number of babies to be screened, detailed the dynamics of the environment, identified supporting strategies and developed two protocols that demonstrate how best to achieve optimum coverage.

The recommendations of this research echo the most important conclusions leading to the final feasibility options, that there should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards. This completed feasibility study serves as a plan to implement a newborn hearing screening programme, a joint venture between National Women's Hospital and National Hearing Centre. Describing how the provision of a joint service would be organised and administered, identifying potential policy or operational problems and the cost. It will be the basis for policy decisions by local governing bodies and be an integral part of the inter-local agreement that puts the joint service into effect.

As more NICU's achieve appropriate acoustic environments, it will be possible to assess the actual frequency and magnitude of the predicted benefits. The potential for future research as well as benefits from the practice changes are important opportunities. If noise abatement and sound control can be achieved in the new unit within the recommended levels, benefits could include a) more consistent and age appropriate neurosensory maturation and b) fewer longer term problems in areas of speech and language.

GLOSSARY OF TERMS

ABR: auditory brainstem response

AABR: automated auditory brainstem response

At Risk: National register of at risk criteria for hearing loss in the newborn. Children and /or their families who are in need of extra services because of the risk of poor health, education or welfare outcomes due to social and economic factors (Ministry of Health, 1998a)

Congenital: present at birth

dB HL: decibel, log-scale measure of hearing level using pure tone average or an estimate of dB HL made using alternative scales (e.g. dB(A)).

Hereditary: caused by the effect (or expression) of a gene. Hereditary is synonymous with genetic

JCIH: Joint Committee on Infant Hearing

MOH: Ministry of Health, Wellington, New Zealand

NICU: neonatal intensive care unit

OAE: otoacoustic emission

SNHL: sensorineural hearing loss

TEOAE: transient evoked otoacoustic emission

UNHS: universal newborn hearing screening

References

Albuquerque, W., & Kemp, D. T. (2001). The feasibility of hospital-based universal newborn hearing screeningin the United Kingdom. *Scandinavian Audiology, supplement* (53) 22-3.

American Academy of Pediatrics, Committee on Environmental Health (1997). Noise: a hazard for the fetus and newborn. *Pediatrics, 100*_(4), 724-27.

American Academy of Pediatrics, Task Force on Newborn and Infant Hearing. (1999). Newborn and infant hearing loss: detection and intervention, 1998-1999.. *Pediatrics, 103* (2), 527-530.

American National Standards Institute (1989). Specifications for audiometers (ANSI S3.6-1989). New York: Acoustical Society of America.

Apuzzo, M., & Yoshinaga-Itano, C. (1995). Early identification of infants with significant hearing loss and the Minnesota child development inventory. Seminars in Hearing, 16 (2), 124-139.

Barringer, D., & Mauk, G. (1997). Survey of [parents perceptions regarding hospital-based newborn hearing screening. Audiology Today, 9, 18-19.

Barsky-Firkser, L., & Sun, S. (1997). Universal newborn hearing screenings year experience. Pediatrics, 99 (6), 1-5.

Bess, F.H., & Humes, L. E. (1995). Audiology the fundamentals. Baltimore: Williams & Wilkins.

Bess, F. H., & Paradise, J. L. (1994). Universal screening for infant hearing: Not simple, not risk-free, not necessarily beneficial, and not presently justified. Pediatrics, 98 (2), 330-334.

Brookhouser, P. E. (1996). Sensorineural hearing loss in children. Pediatric Clinics of North America, 43, 1195-1216.

Carney, A. E., & Moeller, M. P. (1998). Treatment efficacy: Hearing loss in children. Journal of Speech Language and Hearing Research, 41 (1), S61-S84.

Cavanaugh, R.M., (1987). Pneumatic otoscopy in healthy full-term infants. Pediatrics, 79, 520-523.

Chang, P., Moffat, D., & Baguley, D. (2000). Universal neonatal hearing screening-current review. Australian Journal of Otolaryngology, 3 (5), 543-50.

Clemens, C. J., Davis, S. A., Bailey. A. R. (2000). The false-positive in universal newborn hearing screening. Journal of Pediatrics, 106 (1), E7

Clemens, C.J., & Davis, S.A. (2001). Minimizing false-positives in universal newborn hearing screening: a simple solution. Pediatrics, 107 (3), E29.

Code of Health and Disability Services Consumer's Rights (1994). Health and disability commissioner. [On-line] Available: http://www.hdc.org.nz/act_code/the_right_of_code/thecode.html (accessed 08/01/04)

Coplan, J. (1987). Deafness: ever heard of it? Delayed recognition of permanent hearing loss. Pediatrics, 79 (2), 206-13.

Davis, J.M., Elfenbein. J., Schum, R., & Bentler, R.A. (1986). Effects of mild and moderate hearing impairments on language, education, and physiological behavior of children. Journal of Speech and Hearing Disorders, 51, 53-62.

Delegation (Tapsell, P., Clark, J., Goodey, R., Upton, M., McNeill, E., & Cooper, M. (1998, September). Maximising the potential of deaf Infants: The need for neonatal hearing screening and appropriate intervention. A presentation to the Ministers of Health and Education. Ministry of Health, Wellington.

Dirchx, J. J., Daemers, K., Somers, T., Offeciers, F. E., & Govaerts, P., J. (1995). Numerical assessment of TOAE screening results: currently used criteria and their effect on TOAE prevalence figures. Acta Otolaryngol 116 (5), 672-9.

Dort, J.C., Tobolski, C., Brown, D. (2000). Screening strategies for neonatal hearing loss: which test is best? Journal of Otolaryngology, 9 (4), 206-10.

Downs, M. (1994). The case for detection and intervention at birth. Seminars in Hearing, 15 (2), 76-84.

Downs, M. P., & Sterritt, G. M. (1964). Identification audiometry for neonates: a preliminary report. Journal of Audioloy Research, 4, 69-80.

Doyle, K. J., Burggraaff, B., Fujikawa, S., Kim, J., & MacArthur, C. J. (1997). Neonatal hearing screening with otoscopy, auditory brain stem response, and otoacoustic emissions. Otolaryngol Head Neck Surgery, 116, 597-603.

Duffy, A.P., Barrett, D.K., & Duggan, M.A. (2001).Gisborne Cervical Screening Inquiry. Ministry of Health: [On-line] Available: http://www.csi.org.nz (accessed 08/08/2002)

European Commission. Regional Policy, 1997. [On-line] Available: http://www.inforegio.cec.en.int/wbdoc/docgener/guides/cost/cost_en.htm (accessed 010/08/2002).

Fanaroff, A. A., & Martin, R., J. (2002). Neonatal-Perinatal Medicine; diseases of the fetus and infant. (7th ed) Mosby, Inc. St Louis.

Finitzo, T., Albright, K., & O'Neal, J. (1998). The newborn with hearing loss: Detection in the nursery. Paediatrics, 102, 1452-60.

Fowler, K.B., Dahle, A. J., Boppana, S. B., & Pass, R. F. (1999). Newborn hearing screening: will children with hearing loss caused by congenital cytomegalovirus be missed? Journal of Pediatrics, 135, 60-64.

Gabbard, S. A., Northern, J. L., & Yoshinaga-Itano, C. (1999). Hearing screening in newborns under 24hours of age. Seminars in Hearing,20 (4), 291-305.

Garganta, C., & Seashore, M. R. (2000). Universal screening for congenital hearing loss. Pediatric Annuals, 29 (5), 302-308.

Gottfried, A.W., Hodgeman, J. E., & Brown, K., W. (1984). How intensive is newborn intensive care? An environmental analysis. Pediatrics, 74, 292-4.

Grandori, F., & Lutman, M. (1999). The European consensus development conference on neonatal hearing screening. American Journal of Audiology, 8, 19-20.

Gravel, J., Berg, A., Bradley, M., Cacace, A., Campbell, D., Dalzell, L., DeCristofaro, J., Greenberg, E,. Gross, S., Orlando, M., Pinheiro, J., Regan, J., Spivak, L., Stenens, F., & Prieve, B. (2000). NewYork State universal newborn hearing screeningprotocol on inpatient outcome measures. Ear & Hearing, 21 (6), 640-4.

Gray, L. (2000). Properties of Sound. Journal of Perinatology, 20, S6-S11.

Gray, L. & Philbin, K.(2000). The Acoustic environment of Hospital Nurseries: Measuring the sound in hospital nurseries. Journal of Perinatology, 20 S100-S104.

Headley, G.M., Campbell, D. E., & Gravel, J. S. (2000). Effect of neonatal test environment on recording transient-evoked otoacoustic emissions. Pediatrics, 105 (6), 1279-1285.

Hermann, B. S., & Thorton, A. R. (1996). Audiological follow-up after failure of an infant hearing screening . Current Opinion in Otolaryngology & Head and Neck Surgery, 4 367-70.

Hicks, T., Fowler, K., Richardson, M., Dahle, A., Adams, L., & Pass, R. (1993). Congenital cytomegalovirus infection and neonatal auditory screening. Journal of Pediatrics, 123 (5), 779-82.

Iley, K. L., & Addis, R. J. (2000). Impact of technology on service provision for universal newborn hearing screeningwithin a busy district hospital. Journal of Perinatol, 20 (8 pt 2), S122-7.

Jacobson, C.A., Jacobson, J.T., & Spahr, R.C. (1990). Automated and conventional ABR screening techniques in high-risk infants. Journal Of American Academy Audiology, 1 (4), 187-95.

Johnson, C., D. (1997). Understanding and advising parents and families. The Hearing Review, (October)18-20.

Johnson, M., Maxon, A. B., White, K. R., & Vohr, B. R. (1993). Operating a hospital-based universal newborn hearing screening program using transient evoked otoacoustic emissions. Seminars in Hearing, 14, 46-56.

Joint Committee on Infant Hearing (1994). Position statement. ASHA,36 (12), 38-41.

Joint Committee on Infant Hearing (2000). Position statement: Principles and guidelines for early hearing detection and intervention programs. American Journal of Audiology, 9 (1), 9-29.

Kemp, D. T. (1978). Stimulated acoustic emissions from within the auditory system. American Journal of Acoustic Society, 64, 13-1391.

Keren, R., Helfand, M., Homer, C., McPhillips, H., & Lieu, T.A. (2002). Projected cost effectiveness of statewide universal newborn hearing screening. Pediatrics, 110 (5), 855-64.

Kezirian, E.J., White, K.R., Yeuh, B., & Sullivan, S.D. (2001). Cost and cost-effectiveness of universal screening for hearing loss in newborns. Otolaryngology, Head and Neck, 124 (4), 359-67.

Knott, C. (2001). Universal newborn hearing screeningcoming soon: "Hear's why. Neonatal Network, 20 (8), 25-33.

Kountakis, S.E., Psifidis, A., Chang, C.J.,& Stiernberg, C. M.(1997). Risk factors associated with hearing loss in neonates. American Journal of Otolaryngology, 18 (2), 90-93.

Lemons, J., Fanaroff, A., Stewart, E. J., Bentkover, J. D., Murray, G., & Diefendorf, A. (2002). Newborn hearing screening: costs of establishing a program. Journal of Perinatology, 22 (2) 120-4.

Levitt, H., & McGarr, N.S., & Gaffner, D. (1987). Development of language and communication skills in hearing impaired children. American Speech-Language-Hearing Association Monographs, 26.

Lewis, P. A. (1995). Cystic Fibrosis. The epidemiology of cystic fibrosis. London: Chapman & Hall Medical, 1-5.

Lim, G. & Fortaleza, K.(2000). Overcoming challenges in newborn hearing screening. Journal of Perinatol, 20 (8 Pt 2), S138-42

Lutman, M.E., Davis, A.C., Fortnum, H.M., & Woods, S.(1997). Field sensitivity of targeted neonatal hearing screening by transient evoked otoacoustic emissions. Ear and Hearing, 18, 265-267.

Markides, A.(1986). Age at fitting of hearing aids and speech intelligibility. British Journal of Audiology, 20, 165-167.

Mason, J. A., & Herrmann, K. R. (1998). Universal infant hearing screening by automated auditory brainstem response measurement. Pediatrics, 101, 221-28.

Matson, J. (2000). Consultant's feasibility study can predict success of 'next great idea'. [On-line] Available: www.rurdev.usda.gov/rbs/pub/aug00/tip.htm (accessed 08/08/2002)

Mauk, G. W., White, K. R., Mortenson, L. B., & Behrens, T.R. (1991) The effectiveness of screening programs based on high-risk characteristics in early identifiacation of hearing impairment. Ear & Hearing, 12 (3), 312-319.

Mauk, G., & White, K. (1995). Giving children a sound beginning: the promise of universal newborn hearing screening. The Volta Review,97, 5-32.

Maxon, A. B., White, K. R., Behrens, T. R., & Vohr, B. R. (1995). Referral rates and cost efficiency in a universal newborn hearing screeningprogram using transient evoked otoacoustic emissions. Journal of American Academy of Audiology, 6, 271-77.

Meeder, R. A. (1993). Forging the incubator: How to design and implement a feasibility. study for business incubation programs: National Business Incubation Association. Ohio.

Mehl, A., & Thompson, M. A. (1998) Newborn hearing screening: the great omission. Pediatrics, 101, 97-98.

Mehl, A., & Thompson, M. A. (2002). The Colorado newborn hearing screening project, 1992-1999: on the threshold of effective population-based universal newborn hearing screening. Pediatrics, 109 (1), E7.

Mindel, E., & Feldman, V. (1997). The impact of deaf children on their families. In: Mindel, E. & Feldman, V. (eds). They grow in silence: understanding deaf children and adults (2nd ed). Boston: College-Hill.

Ministry of Health, (1997). Can your child hear? (Pamphlet, Code 2404). Ministry of Health: Wellington.

Ministry of Health (1998a). Child health programme review. Ministry of Health, Wellington.

Ministry of Health, (2000). Informed consent and neonatal intensive care: a consultation and discussion document. Ministry of Health, Wellington.

New Zealand Deafness Notification Data (1996). January-December 1995 National Audiology Centre, Auckland, New Zealand.

National Audiology Centre. (2002). New Zealand screening statistics January-December 2001: Auckland District Health Board. Auckland, New Zealand.

National Health Committee (1998). The social, cultural and economic determinants of health in New Zealand: Action to improve health. Ministry of Health, Wellington. [On-line] Available: http://www.nhc.govt.nz/Publications/he_social.html (08/08/2002)

National Institues of Health (1993). Early identification of hearing loss in infants and young children. NIH Consensus Statement, 11, 1-24.

National Screening Committee. (2000). Report of the UK national screening committee, London: Department of Health.

New Zealand Deafness Notification Data (1998). New Zealand deafness notification document: Annual reports from 1991-1997 inclusive. NZ Deafness Notification Data ISSN, 0114-0825. National Audiology Centre, Auckland, New Zealand.

Ng, J., & Yun, H.L. (1992). Otoacoustic emissions (OAE) in paediatric hearing screening- the Singapore experience. Journal of the Singapore Paediatric Society, 34 (1&2), 1-5.

Northern, J., & Downs, M. (1991). Hearing in children, (4th Ed), Baltimore: Lippincot Williams & Wilkins. London.

Northern, J., & Downs, M. (2002). Hearing in children, (5th Ed), Baltimore: Lippincot Williams & Wilkins. London.

Norton, S. J., Gorga, M. P., Widen, J. E., Folsum, R.C., Sininger, Y., Cone-Wesson, B., Vohr, B. R., & Fletcher, K. A. (2000). Identification of neonatal hearing impairment: evaluation of transient evoked otoacoustic emission, distortion

product otoacoustic emission, and auditory brain stem response test performance. Ear Hear, 21, 508-528

Orlando, M. S., & Sokol, H. (1998) Chapter 4: Personnel and supervisory options for universal newborn hearing screening. In Universal newborn hearing screening. Thieme, New York.

Oudesluys-Murphy, A.M., & Harlaar, J. (1997). Neonatal hearing screening with automated auditory brainstem response screener in the infant's home. Acta Paediatrica, 86 (6), 651-5.

Outlaw, J., Reid, S., & Wocadlo, C. (1999). Evaluation of a hearing screening program for at-risk infants. Neonatal, Paediatric and Child Health Nursing, 2 (1), 12-17.

Paradise, J. (1999). Universal hearing screening: should we leap before we look? Pediatrics, 93, 330-34.

Pellow, E. J., Blais, R. L. & McNeil, E. E. (1998). Long term high risk register use in New Zealand: Why it doesn't work. Poster presentation at universal neonatal hearing screening conference, Milan.

Philbin, M. K., & Klaas, P. (2000).The full-term and premature newborn: Evaluating studies of behavioral effects of sound on newborns. Journal of Perinatology, 20, S61-S67.

Prieve, B., A. (1997). Establishing infant hearing programs in hospitals. American Journal of Audiology, 6 (3), 84-86.

Prieve, B., & Stevens, F. (2000). The New York State university newborn hearing screening demonstration project: Introduction and overview. Ear and Hearing, 21, 85-91.

Purdy, I. B. (2000). Newborn auditory follow-up. Neonatal Network, 19 (2):25-33.

Rance, G., Beer, D. E., Cone-Wesson., Shepard, R.K., Dowell, R.C., King, A. M., Rickards, F.W., & Clark, G.M. (1999). Clinical findings for a group of infants and young children with auditory neuropathy. Ear and Hearing, 20 (3), 238-52.

Robertson, C., Aldridge, S., Jarman, F., Saunders, K., Poulakis, Z., & Oberklaid, F. (1995). Late diagnosis of congenital sensorineural hearing impairment: why are detection methods failing? Archives of Diseases in Childhood, 72 (1),11-15.

Robinshaw, H. M. (1995). Early intervention for hearing impairment: differences in the timing of communicative and linguistic development. British Journal Audiology, 29, 315-34.

Rush, W., Battin, M., & Wilson, O. (2002). Audiology outcomes in infants weighing less than 1500 grams at birth. Australian and New Zealand Journal of Audiology, 24 (1), 46-8.

Sininger, Y.S., Cone-Wesson, B., & Ma, E.(1993). Auditory status of the newborn during the first days postpartum. [abstract]. Association of Research Otolaryngology, 16, 5.

Sininger, Y.S., Doyle, K. J., & Moore, J.K. (1999). The case for early identification of hearing loss in children: Auditory system development, experimental auditory deprivation, and development of speech perception and hearing. Pediatric Clinics of North America, 46, (1), 1-13.

Snow, J. (1993). The National Institutes of Health: Deafness and other communication disorders. Otolaryngology Head and Necks, 108 (4), 380-3.

Spivak, L., Dalzell, L., Berg, A., Bradley, M., Cacace, A., Campbell, D., Decrisofaro, J., Gravel, J., Greenberg, E., Gross, S., Orlando, M., Pinheiro, J., Regan, J., Stevens, F., & Prieve, B., (2000). The New York State universal newborn

hearing screeningdemonstration project: Inpatient outcome measures. Ear and Hearing, 21 (2), 92-103.

Spivak, L., & Jupiter, T. (1998). Chapter 2: Preparing the groundwork: Planning the universal newborn hearing screeningprogram. In Universal newborn hearing screening. Thieme, New York.

Stein, L.K., Jabaley, T., Pasternak, J., Banerjee, S., Lindermann, K., & Kraus, N. (1996). Brainstem abnormalities in neonates with normal otoacoustic emissions. Seminars in Hearing, 17 (2), 197-213.

Stewart, D. L., Mehl, A., Hall, J. W., Thompson, V., Carroll, M., & Hamlett, J. (2000). Universal newborn hearing screeningwith automated auditory brainstem response: A multisite investigation. Journal of Perinatology, 20, S128-S1331.

Stone, K., Smith, B., Lembke, J., Clark, L.A., & McLellan, M, B. (2000). Universal newborn hearing screening. Journal of Family Practice, 49 (11), 1012-16.

Stuart, A., Moretz, M., & Yang, E.Y. (2000). An investigation of maternal stress after neonatal hearing screening. American Journal of Audiology, 9 (2),135-41.

Swigonski, N., Shallop, J., Bull, M. J., & Lemons, J.A. (1987). Hearing screening of high risk newborns. Ear and Hearing, 8, 26-30.

Thompson, D. C., McPhillips, H., Davis, R. L., Lieu, T. A., Homer, C. J., & Helfand, M. (2001). Universal newborn hearing screening: summary of evidence. JAMA, 286 (16), 2000-10.

Unitarian Universalist Association (UUA). (2002). Office for Congregational fundraising: A feasibility study for capital campaign. [On-line] Available: http://www.uua.org/cde/fundraising/feasibility.html (accessed 08/08/2002)

US Preventative Services Task Force. (2002). Newborn hearing screening: Recommendations and rationale. American Journal of Nursing, 102 (11), 83-89.

Van Straaten, H. L., Groote, M. E., & Oudesluys-Murphy, A. M. (1996). Evaluation of an automated auditory brainstem response infant hearing screening method in at risk neonates. European Journal of Pediatric, 155, 702-705.

Van Straaten, H. L., Tibosch, C. H., Dorrepaal, C., Dekker, F.W. & Kok, J. H. (2001). Efficacy of automated auditory brainstem response hearing in very preterm newborns. Journal of Pediatrics, 138 (5), 674-678.

Vohr, B. R., Carty, L., Moore, P., & Letourneau, K. (1998). The Rhode Island hearing assessment program: Experience with statewide hearing screening (1993-1996). Journal of Pediatrics, 133, 353-357.

Vohr, B.R., Letourneau, K.S., & Mc Dermott, C. (2001). Maternal worry about neonatal hearing screening. Journal of Perinatology, 21 (1), 15-20.

Vohr, B. R., Oh, W.,Stewart, E. J., Bentkover, J. D., Gabbard, S., Lemons, J., Papile, L., & Pye, R. (2001). Comparison of costs and referral rates of 3 universal newborn hearing screeningprotocols. The Journal of Pediatrics, 139 (2), 238-244.

Watkin, P. M., Baldwin, M., & Laoide, S. (1990).Parental suspicion and identification of hearing impairment. Archives of Diseases in Childhood, 65, 846-50.

Watkin, P. M., Baldwin, M., & McEnery, G. (1991). Neonatal at risk screening and the identification of deafness. Archives Diseases of Childhood, 66 (10), 1130-5.

Watkin, P. M., & Nanor, J., (1997). The implications for educational services of universal neonatal hearing screening. Deafness and Education, 21 (1), 19-33.

Weichbold, V., Welzl-Mueller, K., & Mussbacher, E. (2001). The impact of information on maternal attitudes towards universal hearing screening. British Journal of Audiology, 35 (1), 59-66.

Weichbold, V., & Welzl-Mueller, K. (2001). Maternal concern about positive test results in universal newborn hearing screening. Pediatrics, 108 (5), 1111-6.

Wessex Universal Neonatal Hearing Screening Trial Group. (1998). Controlled trial of universal neonatal hearing screening for early identification of permanent childhood hearing impairment: Wessex Universal Neonatal Hearing Screening Trial Group. Lancet, 352, 1957-1964.

White, K.R. (1996). Universal newborn hearing screeningusing transient evoked otoacoustic emissions: Past, present, and future. Seminars in Hearing, 17, 171-83.

White, K. R. (1997, October) Universal newborn hearing screening: Issues and evidence. Paper presentation at CDC Workshop on Early Hearing Detection and Intervention, Atlanta, Georgia.

Whitten, J. L., Bently, L. D., & Dittman, K. C. (2001). Systems analysis and design methods. The McGraw-Hill Companies. [On-line]. (accessed 10/10/2002) Available: www.mhhe.com/business/mis/witten/student/olc/chs_ch09.mhtml

Widen, J. E., Folsom, R. C., Cone-Wesson, B., Carty, L., Dunnell, J. J., Koebsell, K., Levi, A., Mancl, L., Ohlrich, B., Trouba, S., Gorga, M. P., Sininger, Y. S., Vohr, B. R., & Norton, S. J. (2000). Identification of neonatal hearing impairment: hearing status at 8 to 12 months corrected age using a visual reinforcement audiometry protocol. Ear Hear.;21(5):471-87.

Wittmann-Price, R.A., & Pope, K.A. (2002). Universal newborn hearing screening: One hospital's project improved follow-up rates for infants who didn't pass the initial test. American Journal of Nursing, 102 (11), 71-77.

Yoshinga-Itano, C., Sedey, A.L., Coulter, D. K., & Mehl, A.L. (1998). Language of early and later-identified children with hearing loss. Pediatrics,6, 1161-1171.

Yoshinga-Itano, C. (1999). Benefits of early intervention for children with hearing loss. Otolarynologic Clinics of North America, 32 (6), 1089-1102.

Yoshinga-Itano, C. Coulter, D., & Thompson, V. (2000). The Colorado newborn hearing screening project: effects on speech and language development for children with hearing loss. Journal of Perinatology, 20 (8), S132-S137.

APPENDIX 1

Newborn Services Clinical Guidelines

Note: The electronic version of this guideline is the version currently in use.
Any printed version can not be assumed to be current.
The general disclaimer regarding use of Newborn Services Guidelines and Protocols applies to this Guideline.

Auditory Testing

Reviewed by Simon Rowley

December 2000

Clinical Guidelines Back Newborn Home

Identifying Infants at Risk of Hearing Loss

Generally speaking all those infants admitted to NICU and some in SCBU are all at high risk of future hearing impairment. The Newborn Hearing Screening Committee of United States of America, which includes a panel of Otolaryngologists, Audiologists and Paediatricians suggest that 9 groups of high risk should be followed up with hearing tests. These are as follows:

1. Familial (member of family deaf. In Auckland this comprises the largest group of children with hearing defects).
2. CMV, rubella (or other congenital infections).
3. Immaturity (birthweight <1500g).
4. Malformation (of cranium or face, e.g cleft palate, auricular deformity, **not** pre-auricular tags alone).
5. Hyperbilirubinaemia (>340umol/L).
6. Meningitis.
7. Asphyxia.
8. Therapy with ototoxic drugs (where toxic levels reached, particularly loop diuretics and amnioglycosides in combination).
9. Prolonged mechanical ventilation (> 5 days).

Follow up of the above children will detect 50% of all deaf children in any community and give a greater yield of abnormal hearing testing. Therefore in New Zealand it is general strategy to screen all the above children within the first few months of life. A newborn hearing screening programme is being developed at National Women's Hospital.

Practically speaking this is accomplished as follows:

Referral **BEFORE** or **AT** discharge to:

a. Starship Hospital Audiology

b. Middlemore Hospital if the family are in the South Auckland catchment area (south of Otahuhu, east of Panmure)

or

c. National Audiology Centre

APPENDIX 2

Newborn Hearing Screening at National Women's Hospital - *Business Plan*

December 1999

Prepared by:

- National Women's Hospital: Karen Anderson-Hawke
- National Audiology Centre: Emma Russell and Ellen McNeil
- University of Auckland Medical School: Peter Thorne

Executive Summary

Objective: *To establish an effective Neonatal Hearing Screening programme for all National Women's Hospital newborn Deliveries and Admissions by July 2001.*

The need for a neonatal screening programme for deafness in New Zealand, which is more effective than the current at-risk register, is clearly required. The results of research into the effectiveness of 'at risk' screening programmes are alarming. Only 50% of infants with significant hearing loss have known risk factors, which means that under the current neonatal screening system in New Zealand at least 50% of neonates with a significant hearing loss are going undetected. This is likely to be a conservative estimate, as there appears to be a wide variation as to how the "at risk register" is implemented. From 1991 to 1997 the average age of identification of at least a moderate hearing loss in New Zealand was 20.84 months.

There is now strong evidence from studies in the USA where screening has been implemented that early detection and intervention (before 6 months of age) markedly improves receptive and expressive language development, and cognitive skills. This in turn results in better lifelong educational and employment outcomes. To significantly reduce the age of detection it is necessary to implement a universal hearing screening programme. For practical and economical reasons this screening programme should be hospital based with the aim to screen all babies prior to discharge. This type of screening programme is already operating successfully in 550 hospitals in the United States and one hospital in New Zealand.

It is proposed to establish the screening programme at National Women's Hospital in three overlapping stages. In the first stage all babies (approximately 1250 per annum, see Appendix I) within Newborn Services (NICU) will be screened using an Automated Auditory Brainstem Evoked Response system (AABR). Testing in a population at high risk for deafness, where babies are admitted for relatively long periods, will enable the establishment of the test procedures, training of the screeners, setting up of a database and developing and trialling protocols for follow-up. Once this stage is underway the screening programme will move to the Well Baby wards where babies with stays longer than two days will be screened. In the third Stage the screening programme will be extended to cover the babies who have left the hospital within two days of birth.

It is essential that a newborn hearing screening programme be established in New Zealand. Since early 1998 a group has been developing the protocols and procedures for a screening programme. In early 1999 Auckland Rotary became interested in assisting with the project and along with National Women's Hospital, funded a feasibility study to develop this Business Plan. The National Foundation for the Deaf is setting up a national Hearing Committee to facilitate the introduction of a national hearing screening programme. It is anticipated that the programme at National Women's Hospital would provide the information which will lead to guidelines for the development of a national programme.

The goal of our universal Neonatal Hearing Screening Programme is identification of hearing loss and appropriate intervention by six months of age.

Summary budget: The setting up costs for the implementation of Stage One of the Hearing screening programme at National Women's Hospital are approximately $141,440. For the initial setting up and running of Stages Two and Three the estimated costs are $219,874 and $383,687 respectively. Once the programme is fully implemented the ongoing cost of screening all of the babies born at National Women's Hospital is estimated to be $255,268. These costs cover staffing, equipment and consumables.

STAGE TWO:

Overall Objective: To perform hearing screening on every neonate staying two or more days on the postnatal wards at National Women's Hospital (approximately 2590 babies per year).

Commence: November 2000

Specific Objectives:

- *obtain additional funding for equipment and consumables and purchase equipment*
- *obtain further ethical approval for the larger group*
- *refine and implement follow-up procedures*
- *recruit and train additional screeners*
- *develop public awareness information programme*
- *screen babies and analyse data*

In Stage Two we intend to screen all babies born each year who stay at NWH two days or longer (as well as the 1250 in the NICU). The well babies will be tested by evoked otoacoustic emissions (EOAE) with a follow up by AABR for those babies who do not pass the EOAE test. This stage will require training and hiring of additional hearing screeners and additional purchase of equipment and consumables. These items are outlined in the budget. Additionally, it is anticipated that increased Community Healthcare providers will need to be involved in order to ensure that appropriate, timely and culturally sensitive follow-up occurs.

STAGE THREE:

Overall Objective: Universal Screening - to perform hearing screening on every neonate who is born at/admitted to National Women's Hospital, or falls into their region, by the time the child is six months of age (approximately 3440 babies per year).

Commence: July 2001.

Specific Objectives:

- *obtain additional funding for equipment and consumables and purchase equipment*
- *recruit and train additional screeners*
- *define tracking procedure for babies leaving hospital early*
- *establish links to community services*
- *establish a public awareness campaign*
- *screen babies and analyse data*

Approximately 3440 babies leave NWH before they are two days of age. Currently the optimal time for hearing screening is greater than two days, to reduce the chance of false positive results from vernix or other debris in the external ear canal or middle ear fluid. Thus a high proportion of these babies will have left hospital before an optimal screening period. The challenge, therefore, is to trace these children and screen them in the community. We intend to build on our experiences and contacts from the previous stages to develop procedures to screen these children. This will involve community-based programmes which will need to be sensitive to and seek advice on bicultural and multicultural issues.

Budget

The funds necessary to implement and then to maintain the staged Neonatal Hearing Screening Programme are given below with justifications. The equipment and consumable costs are exclusive of GST. Appendix III contains descriptions of the roles of the various staff required to run the programme. The reader should refer to Appendix IV for information as to how the Screening Staff costs and AABR and OAE consumable costs were determined.

The calculations below indicate the estimated total funding which is needed to implement and then continue to run the hearing screening programme. The contributions by Auckland Healthcare Audiology and National Women's Hospital for facilities, telephone, secretarial and administrative costs have not been included in the budget figures.

Note that it is difficult to predict exactly what the total costs will be, due to the evolving nature of the project. For instance, in Stage Three significant contributions by community-based staff will be necessary. It is possible that some costs (eg staff, travel and some equipment) will be Health Provider funded. As this is an area of uncertainty, it has not been factored in for stage three.

The budget information provided on the following pages can be summarised by the table and by the graph below and overleaf:

Stage	Staffing	Equipment	Consumables	Total
One	$57,678	$51,949	$31,813	**$141,440**
Two	$82,599	$79,883	$57,392	**$219,874**
Three	$132,343	$159,807	$91,537	**$383,687**
Ongoing	$132,343	$31,388	$91,537	**$255,268**

APPENDICES

APPENDIX I

Proposed Numbers of Babies Screened at Each Stage

Stage One - Babies within the NICU

Predicted annual admissions	*1360*
Lost due to death or transfer (to hospital outside of A+ health)	*110*
Total eligible for neonatal hearing screening at Stage One:	***1250***

Of the above 1250 babies it is predicted that around 560 will be transferred to the Postnatal Ward, so may need to be tested within that environment.

Stage Two - All Babies with Length of Hospital Stay (LOS) Greater than Two Days

Stage One babies eligible for screening	*1250*
Well Babies with LOS greater than two days	*2590*
Total eligible for neonatal hearing screening at Stage Two:	***3840***

Based on 1997, 1998 and 1999 admission data.

Stage Three – All Babies

Stage One babies eligible for screening	*1250*
Stage Two babies eligible for screening	*2590*
Well Babies with LOS of two days or less (transferred to other birthing centres or discharged home)	*3440*
Total eligible for neonatal hearing screening at Stage Three:	***7280***

NATIONAL APPLICATION FORM

FOR ETHICAL REVIEW OF INNOVATIVE PROCEDURES

Principal Ethics Committee AUCKLAND

Other Institutions to be involved: *The University of Auckland*

1. Title of the Innovative Procedure - *Newborn Hearing Screening*

2. Abstract. -

The early detection of hearing loss in children is vital to ensure access to speech and language for infants during the critical stages for language acquisition. Current methods of detection in infants rely upon identifying risk factors for deafness and this is not satisfactory. Further the average age of detection of significant hearing loss in New Zealand over the past 10 years is close to 21 months. This is far too late to intervene successfully. (See Appendix 1). The internationally recommended age for detection is by 3 months with intervention by 6 months.

Technology is now available to screen newborn infants' hearing successfully. The outlined programme plans to implement newborn hearing screening at National Women's Hospital in three staged phases (see Appendix 2). In Phase One the babies' hearing is screened using Automated Auditory Brainstem Response Testing (AABR) (See Appendix 3). We are seeking ethical approval for Stage One of the programme.

We are using this technique as a screening method for these babies because infants who are in the NICU frequently have hearing problems with involvement of the higher auditory pathways.

Babies who do not pass the screening protocol are passed on to an audiologist for further hearing evaluation. Infants who are found to have a hearing loss can then be fitted with hearing aids or Cochlear implants as soon as possible.

Hearing Screening progammes and the techniques used have been implemented successfully overseas (See Appendix 4). Hearing Screening has now been made compulsory in over 30 States in the USA. Following from overseas trends hearing screening will become a basic standard of care. We propose to adapt procedures used successfully overseas to the New Zealand environment.

There are Newborn hearing screening initiatives currently running in New Zealand. The initiative at Tarawhiti Healthcare has recently obtained HFA funding. This is using Otoacousitc Emissions, which is the screening technique we will be using in Phases 2 and 3 of the programme

Ms Oriole Wilson, M Aud, MNZAS
Audiologist Co-ordinator
Newborn Hearing Screening Project.
National Audiology Centre
98 Remuera Rd
Newmarket
Phone 520 -4009
Fax 522 1622
Email oriolew@ahsl.co.nz

Other Staff Involved

Ms Karen Anderson-Hawke
Neonatal Nurse Practitioner
National Women's Hospital
Greenlane Rd
Greenlane

Phone 630-9943 x3227
Fax 630-9753
Email karenah@ahsl.co.nz

Dr Ellen Mc Neil
Clinical Director
National Audiology Centre
98 Remuera Rd
Newmarket

Phone 520 4009
Fax 522 1622
ellenm@ahsl.co.nz

Dr Peter Thorne
Associate Professor
Head, Section of Audiology
University of Auckland
Park Rd, Grafton

Phone 3737 599 x 6314
Fax 3737 499
pr.thorne@auckland.ac.nz

4. Head of Departments

Dr Ellen Mc Neil
Clinical Director
National Audiology Centre
98 Remuera Rd
Newmarket

Phone 520 4009
Fax 522 1622
Email ellenm@ahsl.co.nz

Dr David Knight
Clinical Director
National Women's Hospital
Greenlane Rd
Greenlane

Phone 630-9943 X3197
Fax 630 9753
Email davidk@ahsl.co.nz

5. Name, address and position of independent clinician to whom this proposal may be referred if necessary: What about Judith Gravel?

6. Proposed starting date -

This programme will begin when

- *Ethical approval has been obtained*
- *Funding has been approved/obtained for programme running costs*

Funding has already been obtained for the purchase of the testing equipment.

We hope to begin within the next 6 months.

The hearing-screening programme will be introduced in 3 Phases (See Appendix2). We are seeking approval for Phase One.

7. 7.1 Have you performed this innovative procedure elsewhere?
7.1.1 *No*
7.1.2 *N/A*
7.1.3 *N/A*

7.2 Has the innovative treatment been carried out elsewhere by anyone else?

7.2.1 *This procedure has been used by many newborn hearing screening programmes in the USA and around the world. (See Appendix 4). AABR has been carried out in the Southern Health District, through Southland Hospital from 1992-1999.*
7.2.2 Hospital Audiologist and volunteers
7.2.3 On how many patients?

7.3 Results about the Safety and Efficacy of the Innovative Treatment

AABR is a completely safe non-invasive procedure. The American Academy of Pediatrics, The Australian Society of Otolaryngology Head and Neck Surgery LTD has endorsed this screening procedure. It has been mandated at a federal level in the USA and is now being implemented progressively in the States. At the time of writing it has been implemented in over 30 states.

8. Description of the proposed procedure.

In AABR the infant's hearing is screened while it in a settled state (preferably asleep). A soft disposable probe tip is placed in the baby's ear, which is connected to a sound transducer. Three disposable adhesive surface electrodes are attached to the baby's head. Sound is introduced into the baby's ear at a very low level (35 dbHL) and the hearing systems electrophysiological response to that sound is recorded. The equipment has a detection algorithm that compares the response recorded from the baby with a normal response pattern for babies. The equipment will then determine if a hearing response is present in the baby (a screening pass) or not (a screening fail).

9. Standard procedure used for the same clinical condition

The standard procedure from which the AABR is based is called Auditory Brainstem Response Testing. It is usually used for objective hearing evaluation to estimate hearing thresholds of clients who are unable to respond to conventional audiological testing. It is also used to evaluate the integrity of the auditory pathways from the ear to the higher brain centres.
The standard procedure is different from AABR in that the testing is not automated in the standard procedure. The clinician carrying out the standard procedure is able to have much more control over the testing conditions and uses their clinical skills to interpret the client's electrophysiological responses. In the automated test the test conditions are highly controlled and because the ABR is a very robust and reliable response it can be automatically judged against normal responses and thus used as a screening test. The AABR does not require the same

clinical interpretive skills as the standard test and can be carried out by a trained technician. It also takes a much shorter time 30-40 minutes compared with the standard test that is allocated 90 - 120 minutes.

10. What is the justification for using the new procedure, including the clinical indications for its use?

Hearing loss has a high prevalence in newborns compared to other conditions that are commonly screened for. Appendix 5 shows the prevalence of hearing loss in infants compared with these other conditions.

At present significant hearing loss is not detected until on average 21 months of age (median 17 months). New Zealand Deafness Detection Database figures 1989 - 1998. In the detection method currently used infants are referred for Audiological assessment if they show characteristics that put them at risk for hearing loss. This method - the high-risk register - is clearly not working. Overseas studies have shown it only has the potential to detect at best 50% of hearing losses, Appendix 6.

Appendix 1 contains information on the effect of late detection of hearing loss on speech and language development. Infants have critical periods for the acquisition of language and it is vital that the language centres in the brain be stimulated during these times. These deficits in speech and language development have serious educational and life consequences.

We are using this particular technique as a screening method for the babies in Phase One of the programme. Overseas studies have shown that infants who are in the NICU frequently have hearing problems that have involvement of the higher auditory pathways - auditory neuropathy. The other hearing screening technique commonly used -Otoacoustic Emissions would miss the hearing loss in these infants.

11. Benefits expected from the new procedure:

- *Reduction in age of detection of hearing loss in babies to 3 months from the current age of 21 months*
- *Dramatically improved coverage of babies from the existing methods used.*
- *Ability to begin intervention before 6 months of age*
- *Tracking of infants tested through the programme*
- *Potential to have national co-ordination of NBHS programmes*
- *Better ability to monitor and audit incidence of hearing loss.*

. 11.1 Improvements on current procedures?

- *Hearing loss detected at birth (see Appendix 1)*
- *Greatly improved coverage rate for hearing testing*
- *Currently the "At Risk" criteria are used at NWH to detect -for referral -babies who are at risk for hearing loss. This technique only has the potential to detect at most 50% of all babies with hearing loss. Appendix 6*
- *A study at NWH from 1995 -1998 of all the babies discharged from National Women's Hospital from the Special Care Units at risk for hearing loss (n=654) has shown that only 73% (n=480) of those eligible babies were actually referred.*

- *Thus of the infants discharged from National Women's NICU only 58% of the babies who fell in "at risk" group actually got an Audiological assessment*
- *The" at risk" categorisation as used at NWH fails to pick up most of the babies who havef a family history of hearing loss because theses babies are usually in the Well Baby wards. 20% of babies detected with Hearing loss in New Zealand have "Family History" as a risk factor.*

12. Risks associated with the new procedure:

- *The major risks associated with Newborn hearing screening programmes relate to the false negative and false positive screening outcomes.*
- *False positive outcomes can cause unnecessary anxiety for parents*
- *False negative outcomes can give reassurance that hearing is normal and thus delay identification of the hearing loss that has been missed.*
- *When Newborn Hearing Screening Programmes are in place rapidly progressive hearing losses in young infants can be detected later due to a false sense of security from the test results showing normal hearing at birth*

12.1 How are risks different from current procedures

- *Risks with current procedures relate to the failure of the present system to detect hearing loss in a timely manner.*
- *The current "at risk" protocol relies on the staff to select the babies for referral for audiological assessment. This has the risk as shown above that less than 50% of babies who are likely to have a hearing loss will ever get assessment.*
- *The current procedure is not a screening procedure in the true sense so there are no false positive or negative results. The testing process is a diagnostic procedure*

13. Staff Training

- *Neonatal Intensive Care Nurses will carry out the screening for phase one of the programme.*
- *The Audiologist Co-ordinator will develop a training package and monitor the programme.*
- *This training will be carried out at National Women's Hospital and at National Audiology Centre*
- *NAC has the model of both the Vision and Hearing Testers Training and monitoring Programme to use as a foundation for the Newborn Hearing Screening Programme.*
- *Permission is being sought from the Nurses Council to include NBHS as part of the nurses' role.*
- *Babies that are referred on from the screening programme will be tested by fully qualified audiologists at National Audiology Centre or their own local Hospital Audiology Department*

Innovative Devices:

14. Insertion of an innovative device

The screening procedure involves:

- *the positioning of a small probe with a disposable probe tip into the first few millimeters of the baby's external ear canal. A picture of the device is attached in Appendix 8.*
- *The infant also has 3 surface electrodes attached to their skin, one on the forehead and one on each mastoid*

14.1 Has the device been mechanically tested? *Yes*

14.2. If so, by whom, where and under what conditions?

Interek Testing Service, Des Plaines, Illinois. This service tested it to an American Standard for medical equipment UL 206-1 2nd edition and EN 60601-1-1 and EN 60601-2-26

14.2.1 What were the results of the mechanical tests?

The device has been tested for input, leakage current, dielectric, enclosure force, enclosure impact, handheld drop, temperature, and humidity. No changes were make as a result of the test. See specification sheet Appendix8.

14.2.2 Were any changes made to the device as a result of the mechanical tests?

No

Testing of innovative treatment in animals:

15. Has the innovative treatment been tested in animals? *No*

15.1 If yes, where and by whom? *NA*

15.1.1 What were the results *NA*

15.1.2 ***Auditory evoked potential testing as a diagnostic test has been used extensively with animals. The screening test is merely a variation on the test procedure and the results and normative data only relate to the newborn babies for which the screening procedure is designed.***

Patients

16. Location of Service.
On the present National Women's site the service will be located in the Paediatric Clinic Room, first floor.

17. Scope of programme
The hearing screen will be offered to all Newborn Services Unit babies when they are in a stable condition prior to discharge.

18. ***Hospital inpatients***

19. Number of patients

The hearing screening programme has a phased introduction. We are applying for ethics approval for Phase One of the programme. In Phase One we plan to test all the babies from the Newborn Services Unit prior to discharge when they are in a stable condition. This is approximately 1300 babies per year. We will run phase one of the project for 6-12 months before moving onto phase 2; this will therefore involve from 650 - 1300 babies.

Monitoring

1. Plan for monitoring the innovative treatment.

We intend to purchase a purpose designed hearing screening database software package. This tool will allow comprehensive monitoring of the outcomes of the programme. It is being used by statewide programmes in the USA to track babies and quality outcomes of the programme. Further information of this is contained in Appendix 9. In phase one of the programme we anticipate testing 650-1300 babies.

Data collection forms

2. Assessment of the initial safety and efficacy of the innovative treatment

This screening procedure is being widely used in the USA and has been used to screen the hearing of many hundreds of thousands of babies in the USA since the early 1990s. I attach in Appendix109 a copy of an article from the American Academy of Pediatrics that recommends the use of AABR testing for Newborn Hearing Screening.

3. Follow-up Care

When an infant has failed the hearing screening protocol they will be referred for diagnostic assessment and if a hearing loss is confirmed for provision of appropriate rehabilitative services. These services are will primarily provided by Auckland Healthcare Audiological Services or for some NSU graduates by their local hospital audiology service and the Advisors for Deaf Children who work for Special Education Services. Infants are referred by these professionals to ear nose and throat specialists for Oto-neurological assessment to try to determine the cause of the hearing loss. No additional cases of hearing loss will result from the implementation of the screening programme however the babies will be detected at a younger age and this will necessitate the staff working with these infants acquiring the skills necessary to work with very young infants.

23. How long will patient information relating to the innovative treatment be held?

As per the Auckland Healthcare policy for storage of clinical information

23.1 Responsibility for Data Storage

The data will be stored on the database referred to in 15 above, this will be physically situated at National Audiology Centre and will be the responsibility of the Audiologist Co-ordinator of the

Audit

24. Data that will be collected on patients

- *Personal information details will be collected in line with the NHI information system and National Women's personal information collection procedures.*
- *Results of hearing screening will be collected*
- *Information as to the possible cause of the hearing loss and other medical information relevant to the hearing loss*

25. ? Include any procedures to be conducted as part of the audit (eg, scan)

The audit will examine the outcomes of the screening programme and will look at issues of :
- *Clinical procedures*
- *Parental satisfaction*
- *Coverage rate*
- *Screening Outcomes*
- *Tracking performance of screening programme*
- *Attendance rate at diagnostic test session*
- *Appointment waiting times for diagnostic assessment*
- *Appointment waiting times for provision of rehabilitiation services*

An audit has been carried out of the present system of referral for hearing testing based on the use of the at risk register. The findings of this study are attached in Appendix 11. Additionally the deafness detection database records are held at National Audiology Centre, these provide the current information available on the state of hearing loss detection in New Zealand

After - At the completion of Phase one we will audit our records. I could ask Diane Webster if she would help us

25. How long will data relating to the audit be held?

The data will be held in accordance with Auckland Healthcare Policy on the storage of clinical information

26. Who will undertake the audit?

The audit will be carried out at the completion of Phase One of the project. The Audiologist Co-ordinator will compile the audit statistics and these will be given to an independent auditor see above

26. When will the audit be done, and how long will it take?

The audit will take place 9-12 months after the commencement of the screening programme

28. Will the audit results be published?

Yes

Future Use

29. What plans are there for long term use of the innovative treatment?

Ethical consent is being sought for Phase one of the programme. Appendix 2 outlines Phase 2 and 3 of the programme where the screening will be extended to include the well babies and later to include all babies born through National Women's Hospital. In phase 2 a different technique will be used to screen the hearing of the babies.

Budget

30. How is the innovative treatment funded?

At present the programme has received funding for the AABR machine and the part-time salary of the Audiologist Co-ordinator at National Audiology Centre and the Neonatal Nurse Practitioner at National Women's Hospital.

Funding is being sought from the Health funding authority for the balance of the costs required to run the programme. A costing for phase one is.
Staffing- $57,678.00
Equipment- $51,949.00
Consumables-$31,813.00
Audit- intangible
Total- $141,440.00
Costs of follow-up will be met under the budget of the local Audiology services of the infants that are tested. Most of these babies will fall under the responsibility of National Audiology Centre. There will be some additional costs over and above the standard treatment, these will be:

1.Screening Clinics – for families who are alerted by publicity about the programme and wish to have their Newborn babies hearing checked and who are part of our health catchment area but not part of the babies selected to take part in Phase One of the Programme.

30.1 To what extent are these costs additional to the costs of standard treatment?

The standard treatment at present covers the costs from diagnostic assessment part of the process. All the above costs are additional.

30.2 Will patients incur any costs additional to costs they would incur for standard treatment?

No

31. What financial provision has been made to cover the costs of audits and/or reviews of the innovative treatment?

See 30 above

32. Does anyone have a financial interest in the innovative treatment?

No

STAGE TWO:

Ethical Issues Arising from Innovative Treatment

33. *The ethical issues that will arise from implementing this programme in our opinion far outweigh the ethical issues surrounding non-implementation of the programme as highlighted in 2, 10 and 11 on this form. The issues arising from implementation of the programme are:*

- *Parental anxiety from false positive results*
- *Reassurance given to parents by false negative results which may delay detection and treatment*
- *Reassurance to parents whose infants may have a progressive or late onset hearing loss which may delay them seeking assessment for their children since they had passed the hearing screening*
- *Infants who are lost to follow-up*
- *The proposed programme will not give access to universal hearing screening to all newborns*
- *Feasibility of implementing a UNHS programme in the NWH and NZ context.*

Compensation and Insurance

Please note that if innovative treatment is to be the subject of a research study, Section 5 (8) of the ARCI Act will apply and the appropriate Statutory Declaration will have to be completed and supplied.

Informed Consent

Information sheets will be developed and written in lay person's language. A copy of the guidelines on the preparation of information sheets and consent forms is available from **The Administrator tel ([redacted] or email sandrah@hfan.govt.nz**

Declarations

Summary budget: The setting up costs for the implementation of Stage One of the Hearing screening programme at National Women's Hospital are approximately $141,440. For the initial setting up and running of Stages Two and Three the estimated costs are $219,874 and $383,687 respectively. Once the programme is fully implemented the ongoing cost of screening all of the babies born at National Women's Hospital is estimated to be $255,268. These costs cover staffing, equipment and consumables.

Auckland
Ethics Committees

650 Great South Road
Penrose
Private Bag 92512
Wellesley Street
Auckland
Phone (09) 520 9105
Fax (09) 520 9001
Email: sandra.haydon@hfa.govt.nz

18 July 2000

Ms Oriole Wilson
Audiologist Co-ordinator
Newborn Hearing Screening Project
National Audiology Centre
98 Remuera Road, Newmarket
Auckland

Dear Oriole

2000/152IN Newborn Hearing Screening

Thank you for attending the meeting of Committee Y on 12 July when your study was discussed.

The discussion covered : Risks and Benefits
Training
Overseas use
Mechanical testing
Consent issues

Ethical approval for this study has been given. The Committee has requested a copy of the audit when Phase 1 is completed. Please note that the Committee grants ethical approval only. If management approval from the institution/organisation is required, it is your responsibility to obtain this.

The Committee wishes you well with your study

Please include the reference number and study title in <u>all</u> correspondence & telephone queries.

Yours sincerely,

Pat Chainey
Administrator
Auckland Healthcare

Auckland Healthcare
Te Tuka Oranga O Tamaki Makau Rau

National Women's Hospital
Newborn Service and
National Audiology Centre

NAME: _____ HOSP. No.: _____

DATE OF BIRTH: ____ / ____ / ____

WARD/UNIT: _____

Please attach patient label here

CONSENT FORM HEARING

CONSENT FOR NEWBORN HEARING SCREENING

The Newborn Service is carrying out a screening programme to detect hearing impairment in newborn babies. This is so that if a hearing loss is found appropriate intervention can be started as soon as possible to minimise the effect of the hearing loss on the baby's speech and language development.

The hearing screen has been explained to me. I have received and read the information pamphlet. I have had the opportunity to ask questions and understand the answers I have been given.

I ..... (parent/guardian)

of baby ..... DOB .....

agree/do not agree to the AABR (Automatic Auditory Brain Response) screen being carried out on my baby and if necessary for a referral to my local audiology service.

Signature ..... Date .....

Name of staff member ..... Designation.....

Signature ..... Date .....

I understand that the results will be sent to the address I have given to National Women's Hospital and to my family doctor and/or Paediatrician.

Please tear here

Note

If parent declines screening test, please remove this section and send it without any identifying information to Neonatal Co-ordinator..... in order to track level of acceptance of this programme.

CR XXX

APPENDIX 6

National Women's

National Women's Hospital
Private Bag 92 189
Auckland
New Zealand
Telephone: 0-9-638 9909

Service: Newborn Services

Phone: 6389 909
Ext: 3263
Fax: 6309 753

26 April 2000

Marion Clarke
Chief Executive
Nursing Council of NZ
Wellington

Dear Marion

I am writing to seek approval and guidance concerning the training of experienced Neonatal Nurses (RN's) in a Newborn Hearing Screening Programme. This programme has been initiated by the National Audiology Centre (Auckland Healthcare Audiology Services and National Women's Hospital, Greenlane, Auckland) and is currently going through Ethics approval following discussions with the HFA. I enclose a brief summary of the project for your information.

The Newborn Hearing Screening Programme is divided into three stages and at the first stage we plan to screen the hearing of all Neonatal Intensive Care (NICU) admissions. We felt it was important that the screeners be experienced Neonatal Nurses familiar with preterm or unwell newborn infants and their families. The screening test that is most appropriate for these infants as they fall in an 'at risk' population, is the Automated Auditory Brainstem Response (AABR) test. This will be performed following consent during the infants recovery phase and/or just prior to discharge. The National Audiology Centre will undertake the training of three to four Neonatal Nurses who will be employed part time to perform the AABR hearing screening during allocated screening time (separate to their rostered duties).

We would appreciate your consideration of the appropriateness of training Registered Nurses in this extended role and any guidance you may be able to offer.

Thank you.

Yours sincerely

Karen Anderson-Hawke
Neonatal Nurse Practitioner/Lecturer

Te Kaunihera Tapuhi o Aotearoa
Nursing Council of New Zealand

5 July 2000

Karen Anderson-Hawke
Neonatal Nurse Practitioner/Lecturer
National Women's Hospital
Private Bag 92 189
AUCKLAND

Dear Karen

I am writing in response to your letter about the training of experienced Neonatal Nurses in a Newborn Hearing Screening Programme.

The role of the Nursing Council is to maintain public safety and to ensure that quality systems are in place to support this function. The proposal you presented in your letter has a sound base and although the Nursing Council would not formally approve the outlined programme the concept is supported.

One of the key considerations for Council would be the implementation of a quality monitoring process that ensures the teaching package and subsequent skills the nurses exit the programme with are continually monitored for effectiveness and appropriateness.

I hope this has been of assistance to you and wish you success with the upcoming venture.

Yours sincerely

Donna Gordon
Registrations Adviser