CHAPTER 5

RESEARCH DESIGN AND METHOD

Aim: To provide the research design and methodological approach implemented in conducting the empirical component of this study

5.1.   INTRODUCTION

Science refers to both a system for producing knowledge and to the knowledge produced by that system (Neuman, 1997:6,7). According to Bless and Higson-Smith (2000:3) the "scientific method of acquiring knowledge, also called scientific research, is a systematic investigation of a question, phenomenon, or problem using certain principles". Different sciences are not united by their subject matter but rather by their common method or way of acquiring knowledge (Bless & Higson-Smith, 2000:3).

Although the South African Department of Health emphasises Essential National Health Research (ENHR) (Department of Health, 1997:21) the literature review reveals an almost complete dearth of contextually relevant research on early detection of hearing loss and subsequent intervention in South Africa. Maternal and Child Health (MCH) clinics, which serve to provide comprehensive primary healthcare services (Dennill, King & Swanepoel, 1999:36-39), have never been investigated as a hearing-screening context. This lack of contextually relevant research, the importance of identifying and intervening early for hearing loss, and finally the recommendation of the South African year 2002 HSPS to implement MCH clinics as a screening context, provide the rationale for the current study. Investigating the utilisation of MCH clinics as hearing-screening context in South

Africa required the selection of an appropriate research design and method to obtain suitable empirical data to address the research problem.

Mouton (2001:55,56) provides an apt analogy to distinguish the research design from the research method. The process is compared to building a house with the research design representing the architectural design or blueprint for the house. The research design focuses on the end product and on what type of study is being planned and what kind of results are aimed at. The departure point is the research problem and it is concerned with the logic of the research and on what kind of evidence is required to address the research question adequately. The research method represents the actual construction process or methods and tools used to complete the house. It focuses on the research process and the kind of tools and procedures to be used (Mouton, 2001:56). The design and method selected for this study had to provide the plan and process instructions to answer the following question: ***Is an early hearing detection programme at MCH clinics in a developing, peri-urban, South African community a feasible option?***

This chapter discusses the selected research design as the general plan for addressing the research question of the study and also sets out the methodological approach to acquiring, recording, and analysing the empirical data.

5.2.   AIMS OF THE STUDY

The aims of the research study are as follows:

5.2.1. Main aim and sub-aims

The main aim of this study was to critically describe an early hearing detection programme at MCH clinics in a developing, peri-urban, South African community.

152

The following sub-aims were formulated in order to realise the main aim of the study:

1. To describe the MCH clinics as a screening context
2. To describe the population of infants and caregivers attending the MCH clinics
3. To describe the results of the High-Risk Register and test procedures
4. To describe the performance and efficiency of the screening protocol
5. To describe the interactional processes involved in the implementation and maintenance of a screening programme in MCH clinics

5.3.   CONCEPTUALISATION OF DESIGN AND METHOD

An exploratory descriptive design (Bless & Higson-Smith, 2000:41) implementing combined quantitative and qualitative research methods was selected to address the aims of this study (De Vos, 2002a:365). The quantitative and qualitative methods were jointly implemented using a dominant-less-dominant model of triangulation (Creswell, 1994:177,178). The selected research design and method is represented in Figure 5.1.

The research design is like a route planner providing a set of guidelines and instructions on how to reach the goal that has been set (Mouton, 1996:107) and has two main purposes. Firstly to solve the research problem by developing a strategy for obtaining empirical data that will answer the question or hypothesis posited. The second purpose is to eliminate or minimise the contamination of results by extraneous variables (Ventry & Schiavetti, 1980:65). The research method, however, is defined by Leedy and Ormrod (2001:100) as "merely an operational framework within which the data are placed so that their meaning may be seen more clearly" (Leedy & Ormrod, 2001:100). The design and method utilised in the current study are forthwith discussed.
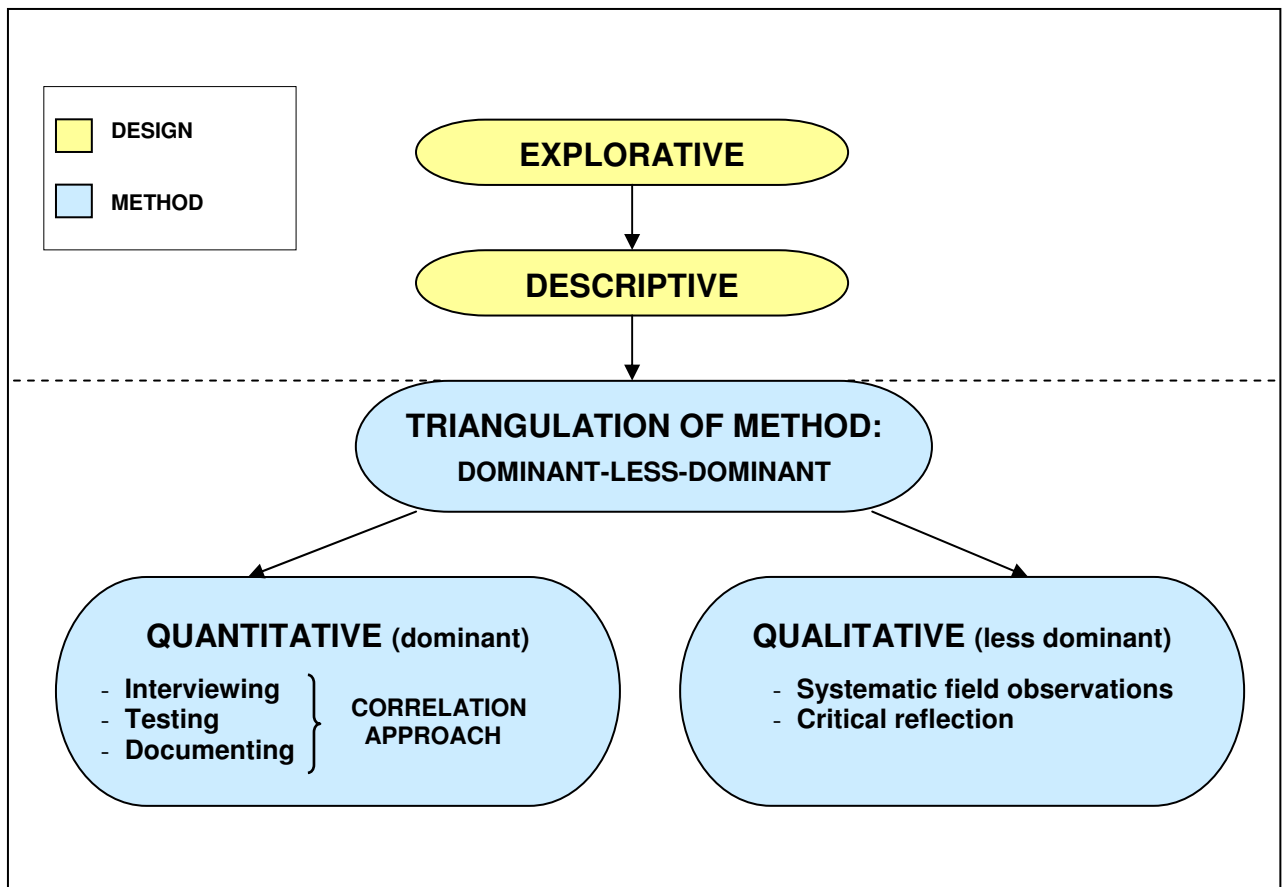
FIGURE 5.1 Research design and method of study

5.3.1. Research design

As illustrated in Figure 5.1 this study utilised an exploratory descriptive design. If an issue of investigation is new and little or nothing has been reported on it, the design is exploratory in nature (Neuman, 1997:19). According to Bless and Higson-Smith (2000:41) the "purpose of exploratory research is to gain a broad understanding of a situation, phenomenon, community or person" and the "need for such a study could arise from a lack of basic information in a new area of interest". The current study investigated a new hearing-screening context in Hammanskraal South Africa, a country and community with a dearth of contextually relevant research on NHS and therefore, is considered to be exploratory. This facet of the research aims to become conversant with basic

154

facts and to create a general picture of environmental and healthcare conditions (Fouché, 2002a:109). According to Mouton (2001:53) the answer to a *what* question represents the aim of an exploratory study and in this case it relates to "what benefits and challenges MCH clinics present for infant hearing screening in South Africa?"

Neuman (1997:20) argues that exploratory and descriptive research often come together in practice. A descriptive study, however, presents a picture of specific details of a situation, social setting or relationship focusing on *how* and *why* questions (Neuman, 1997:19,20; Mouton, 2001:54). Descriptive research may have a basic or applied research goal and can also be qualitative or quantitative in nature (Fouché, 2002a:109). In every case descriptive research is employed to provide an empirical picture of a situation by examining that situation as it is (Ventry & Schiavetti, 1980:41). The current study followed an applied research goal aiming to describe specific details of MCH clinics in Hammanskraal as screening context, the population attending these clinics, and the screening test and protocol performance. Robson (1993:10) classifies this type of research as "real world enquiry" with an emphasis on the substantive or practical importance of research results, solving problems and developing and testing programmes, interventions, and services.

5.3.2. Research method

Within this exploratory descriptive design a combination of the quantitative and qualitative methods was implemented as illustrated in Figure 5.1. Leedy and Ormrod, (2001:103) note that quantitative and qualitative research is not mutually exclusive and it is not unusual for quantitative researchers to also report on qualitative aspects of a study. Non-experimental quantitative data is not collected in a vacuum but in a specific environment or context with its own network of personal and procedural interactions and relationships. The quantitative measurement of data is nestled in these surroundings of routine activity and it is a description of these surroundings that requires a qualitative approach to observing phenomena (Plante, Kiernan & Betts, 1994:53). A combination

approach is often the only way to adequately encompass human beings in their full complexity. A single approach is limited in investigating phenomena in social science that are often tightly enmeshed (Mouton & Marais, 1990:169,170). By adopting an approach of convergence and complementarity De Vos (2002a:364) believe that greater insight into human nature and social reality may be attained. Posavac and Carey (1989:242) also suggest that mixing the two traditions may often be the best approach in social science providing a fuller or more comprehensive study.

A triangulation of method was used to combine qualitative and quantitative styles of research and data for the current study (De Vos, 2002b:342). A dominant-less-dominant design was selected as triangulation model as illustrated in Figure 5.1 (Creswell, 1994:173-190). This design presents the study within a single dominant paradigm with a smaller component of the overall design drawn from the alternative paradigm (De Vos, 2002a:366). The dominant paradigm for the current study was the quantitative approach and the qualitative approach served as the less-dominant paradigm. The advantage of this type of design is that it pursues a consistent paradigm picture (quantitative) whilst also probing additional information in an alternative paradigm (qualitative) (De Vos, 2002a:366). These two methodological approaches to the current study are discussed forthwith.

5.3.2.1.   Quantitative research method

Quantitative research in general terms is implemented to address questions regarding relationships among measured variables with the purpose of explaining, predicting, and controlling phenomena that will generalise to other persons and places (Leedy & Ormrod, 2001:101). The descriptive approach to quantitative research involves either identifying the characteristics of observed phenomena or exploring possible correlations among two or more phenomena (Leedy & Ormrod, 2001:191). This type of research does not attempt to change or modify the situation under investigation and is therefore not intended to detect cause-and-effect relationships (Leedy & Ormrod, 2001:191). The quantitative

156

paradigm was dominant in the current study. It investigated the population of caregivers and infants attending the MCH clinics and the performance of the screening tests and protocol.

Describing the performance of the screening tests and protocol implemented a correlation research approach (Mouton, 1996:192; Ventry & Schiavetti, 1980:48) within the quantitative method and descriptive design followed in this study. Correlation is concerned with the statistical relationship between two characteristics and does not in itself indicate causation (Leedy & Ormrod, 2001: 191). This correlational approach was implemented to compare the test measurements by considering criterion validity. This is the extent to which results of an assessment instrument correlate with another; presumably related measure (the latter measure is called the criterion) (Leedy & Ormrod, 2001:98).

The collection of the data was performed in four consecutive phases as arranged in the data collection sheet (Appendix B). The quantitative data collection phases were as follows:

- Compilation of biographical information and risk indicators
- High frequency immittance measurements
- Hearing screening with OAE and AABR according to specified protocols
- Diagnostic assessment of infants who referred on the screening protocol

Data collection may be performed using a variety of different methods that will correspond to the data sources (Mouton, 2001:104). The quantitative methods of data collection used for the current study and the type of data obtained is presented in Table 5.1.

TABLE 5.1 Quantitative data collection methods and type of data obtained

QUANTITATIVE DATA COLLECTION	
METHOD	**DATA OBTAINED**
- Structured interview and patient file	- Identifying information for population - Risk indicators for hearing loss
- Test measurements	- Hearing screening result (Pass/Refer) - Measure of middle-ear functioning - Diagnostic testing
- Structured documentation	- Follow-up return rate

The data obtained from these quantitative methods of data collection provided information regarding the population and the test and protocol performance.

5.3.2.2.   Qualitative research method

The qualitative approach was the less-dominant paradigm implemented for the current study as indicated in Figure 5.1. Qualitative research focuses on phenomena that occur in natural settings and involve studying phenomena in all their complexity aiming to portray the issue in its multifaceted form (Leedy & Ormrod, 2001:147). The descriptive approach to qualitative research involves revealing the nature of certain situations, settings, processes, relationships, systems, or people (Leedy & Ormrod, 2001:148). This paradigm aimed to describe the MCH as a hearing-screening context and to reveal the interactional processes involved in the implementation and maintenance of such a screening program. According to Neuman (1997:329) the qualitative approach captures and discovers meaning once the researcher becomes immersed in the data. The resulting data is in the form of words from documents, observations and transcripts and analysis proceeds by extracting themes of generalisations from

158

evidence and organising data to present a coherent, consistent picture (Neuman, 1997:329).

The qualitative methods of collecting data that were used for the current study and the type of data obtained are presented in Table 5.2.

TABLE 5.2 Qualitative data collection method and type of data obtained

| QUALITATIVE DATA COLLECTION	
METHOD	**DATA OBTAINED**
- Field notes (Mouton, 2001:107) - Critical reflection by fieldworkers immersed in the data	*Context:* Barriers and assets *Interactional processes*: Attitudes, support, contact, networking, collaboration, neonate/infant state

Field notes were made by the fieldworkers while participating in the fieldwork. After the data collection period the researcher and each research assistant, having been immersed in the data collection context, documented a critical personal reflection regarding the research process according to specified criteria (Appendix C). These two methods of data collection provided rich qualitative information regarding the research context and the interactional processes involved.

5.4.   RESEARCH CONTEXT

Two MCH clinics, called *Refentse* and *Eersterus,* in the Hammanskraal district, were selected as research context for collecting research data for the current study. The Hammanskraal district was selected as a community representative of large sections of the South African population. Hammanskraal comprises one of

nine districts constituting the city of Tshwane (Tshwane 2020 Plan, 2002:2). The city of Tshwane municipality is the local governing body of the District Health Services under the Gauteng provincial authorities (Tshwane 2020 Plan, 2002:73) and comprises a geographical area of the municipality is 2198 square kilometres (Municipal Demarcation Board, 2003). Figure 5.2 shows a map of the city of Tshwane indicating the semi-urban district of Hammanskraal approximately 55 km from the inner city of Pretoria.

The total population of Tshwane is 2.2 million (Tshwane 2020 Plan, 2002:28). The Hammanskraal district within Tshwane is home to, predominantly, black Africans with the majority of the population (52%) being males with a large percentage (37 %) of the population between 0 – 19 years of age (Tshwane 2020 Plan, 2002:28). Figure 5.3 presents the age distribution of the Hammanskraal district.
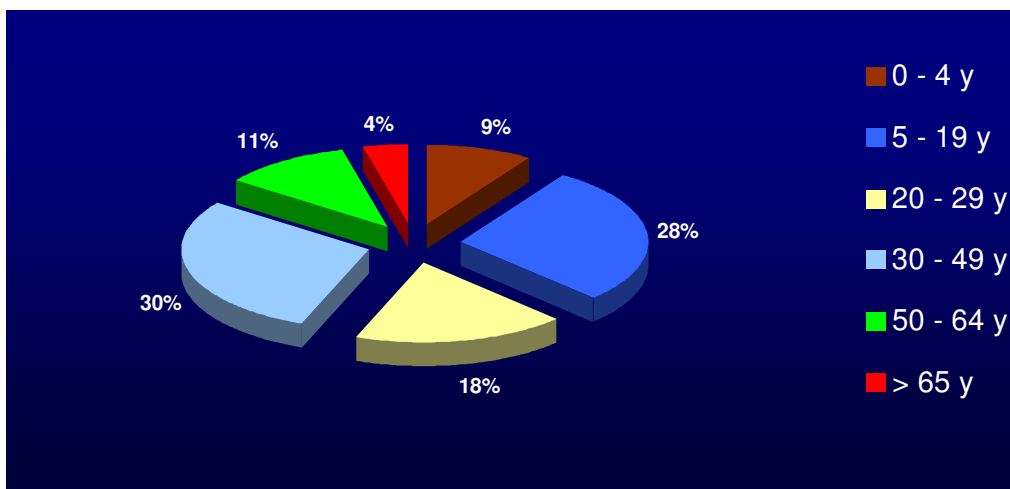
FIGURE 5.3 Age distribution of Hammanskraal population (Tshwane 2020 Plan, 2002:28)
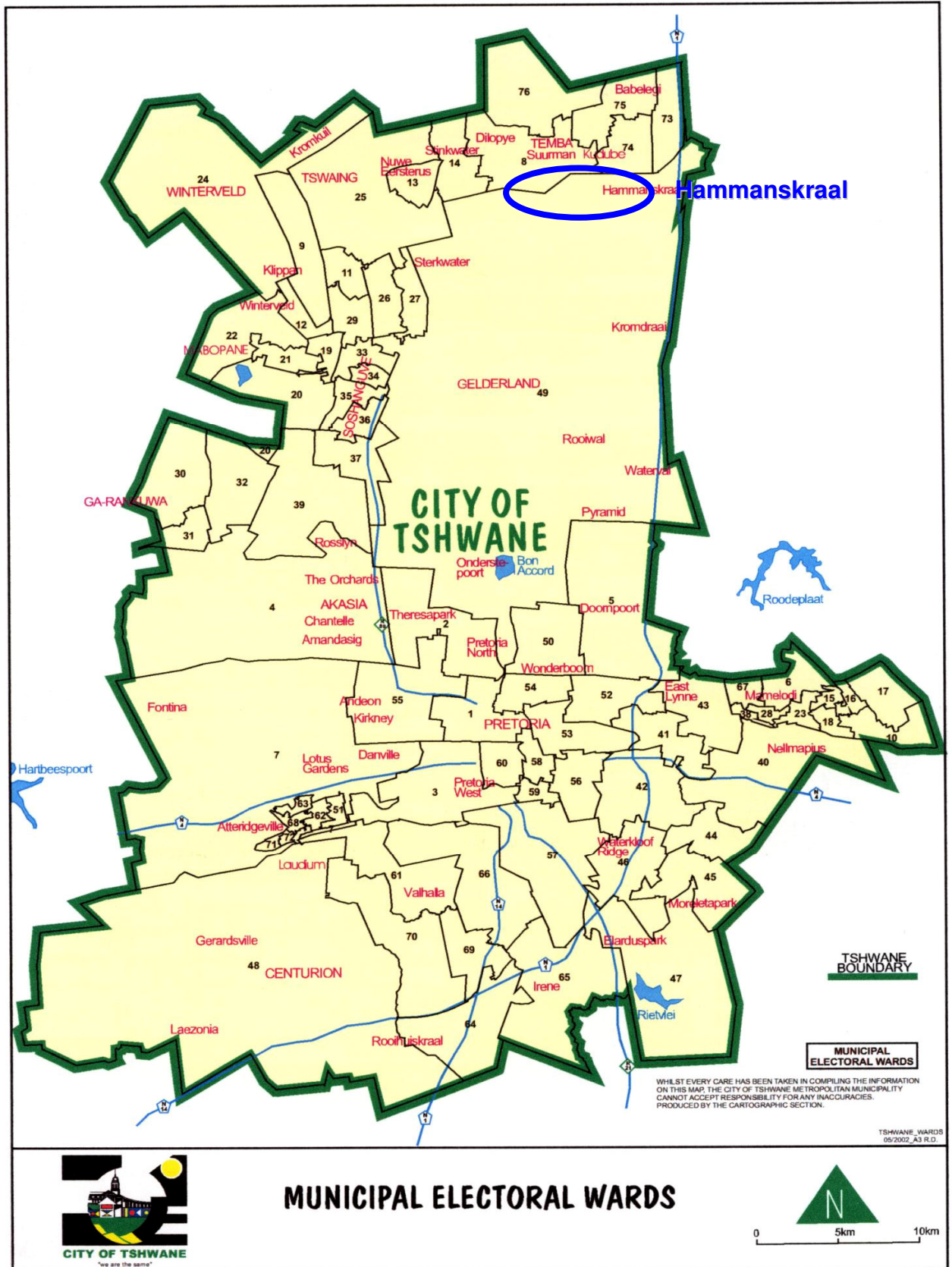
160

FIGURE 5.2 Hammanskraal on City of Tshwane map (Tshwane 2020 Plan, 2002:1)

Hammanskraal, along with three other districts, have the highest percentage (41%) of households earning less than R12 000 per annum in the city of Tshwane (Tshwane 2020 Plan, 2002:28,29). These same three districts, which include Hammanskraal, are also the poorest supplied of water in the house or on site. Only 50% of households in Hammanskraal have flush toilets and 30% of households are without electricity (Tshwane 2020 Plan, 2002:30). These poor living conditions and lack of income commonly increase malnutrition and lowered immunity (Tshwane 2020 Plan, 2002:28). The risk in these areas is high for Cholera and diarrhoeal diseases and generally children are at higher risk for developmental disabilities and delays such as hearing loss (Tshwane 2020 Plan, 2002:28).

Primary problems with the healthcare system in Hammanskraal can be summarised as: Problems due to a lack of maintenance; healthcare facilities not accessible in all areas; lack of facilities at clinics; all clinics not fully equipped; Primary Healthcare services are provided in a fragmented uncoordinated way; lack of comprehensive package of primary healthcare services at clinics; all staff not adequately trained to deliver comprehensive service; and a lack of required categories of staff to render a comprehensive service (Tshwane 2020 Plan, 2002:336). These challenges evident in Hammanskraal are representative of developing contexts in South Africa.

MCH clinics were selected for investigation as screening context because the Professional Board for Speech, Language and Hearing Professions' year 2002 HSPS (HPCSA, 2002:5) recommends it as one of three main hearing screening contexts to be utilised in South Africa. Currently, however, no research data is available on the positive and negative aspects associated with MCH clinics as such a context. The Refentse and Eersterus clinics were approximately 3 km travelling distance from each other which confines the demographic distribution of subjects to within close proximity; as most subjects travel by foot to the nearest clinic.

162

MCH clinics are an initiative of the Department of Health to ensure the provision of maternal and child health services to all, including immunisation, communicable and endemic disease prevention, screening of children, child healthcare and counselling (Dennill, King & Swanepoel, 1999:37). According to the Department of Health the restructuring of South Africa's health services from a largely curative-based and fragmented system to a more community-oriented one, based on primary healthcare principles, must emphasise the improvement of preventative, promotive and curative services for children and women (Department of Health, 1997:63). The Department of Health has committed itself to delivering free healthcare for pregnant women and children under the age of 6 years. This package of free services includes immunisation, health surveillance and screening, identification of children with special needs, and basic elements of care and treatment for children with chronic illnesses (Children in 2001, 2000:42).

MCH clinics are part of primary healthcare facilities that serve as birthing, immunisation, and general healthcare centres and are primarily managed by nursing staff (Reagon et al., 2004:9-15). The 6-week immunisation clinics are therefore one of the service-delivery infrastructures within the MCH clinic. Infants and young children accompanied by their caregivers attend these clinics daily during the week for maternal and child health services delivered by means of antenatal visits. Table 5.3 provides an example of the statistics for antenatal visits at the Refentse MCH clinic over a two-month period in 2002. Similar recordings were made at the Eersterus clinic.

TABLE 5.3   Maternal and Child health statistics for Refentse MCH clinic during March and April 2002 (Source: Head of Refentse clinic)

MATERNAL HEALTH (2002)	MARCH (cases)	APRIL (cases)
- First antenatal visits	92	118
- Follow-up antenatal visits	213	262
- Maternal death	0	0
- Live births	2	0
- Delivery to women < 18 yrs	0	0
- Live Births under 2500g	1	0
- Still births	0	0
- Referrals during labour	0	0
GROWTH MONITORING AND CHILD HEALTH (2002)		
- Entry in malnutrition reg. this month	2	1
- Severe malnutrition < 5 yrs – new	1	0
- Not gaining weight < yrs – new	2	4
- Diarrhoea < 5 yrs – new	32	31
- Lower respiratory infection < 5 yrs - new	240	320

5.5.   ETHICAL ISSUES

Ethics define what are or what are not legitimate, or moral, research procedures (Neuman, 1997:443) and whenever the focus of investigations is human beings ethical implications of what is proposed must be carefully considered (Leedy & Ormrod, 2001: 107). Any individual involved in research needs to be knowledgeable about the general agreements of what is proper and improper in scientific research (Babbie, 2001:470). According to Strydom (2002b:63) ethics "is a set of moral principles that are suggested by an individual or group, are subsequently widely accepted, and offer rules and behavioural expectations about the most correct conduct toward experimental subjects and respondents,

164

employers, sponsors, other researchers, assistants and students". Ethical guidelines therefore serve as important standards from which a researcher must evaluate his/her own conduct to protect the participants and subjects involved in a research study.

Ethical issues pertaining to the current study was considered according to the classification provided by Strydom (2002b:64) and are discussed as follows.

❑ **Harm to experimental subjects and/or respondents**

The researcher has an ethical obligation to protect subjects against any form of physical and/or emotional harm (Leedy & Ormrod, 2001:107). The collection procedures for the current study were non-invasive and to minimise any other possible emotional harm respondents were thoroughly informed verbally and in written format beforehand about the potential impact of the investigation. This information gave the research subjects the choice and opportunity to withdraw from the investigation if they wanted to (Strydom, 2002b:64).

❑ **Informed consent**

Informed consent has become a necessity instead of a luxury or impediment (Hakim, 2000:143). Research subjects must be informed about the nature of the study to be conducted, be given a choice of either participating or not participating and they must know that they have the right to withdraw from the study at any time (Leedy & Ormrod, 2001:107). To address this issue a verbal explanation of the nature of the research project and the required involvement of subjects were provided to all possible subjects. Two fieldworkers were fluent in more than three national languages and were able to convey all information in a language native to the subjects. This was to ensure that subjects comprehended the investigation and were consequently able to make a voluntary, well reasoned decision about their participation (Strydom, 2002b:65). A letter of informed consent, which was explained and provided to all subjects, supplemented this verbal explanation. After ensuring that subjects were

thoroughly informed they could indicate whether they wanted to participate and if so they were required to sign the informed consent form. In addition adequate opportunities were allowed for subjects to ask questions before the data collection commenced, during the collection of data and after the collection procedure was completed (Strydom, 2002b:65).

❑ **Violation of privacy/anonymity/confidentiality**

Any empirical research project conducted should respect the participants' right to privacy (Leedy & Ormrod, 2001:108). Confidentiality places a strong obligation on the researcher to guard the information whether it was specifically requested or not (Strydom, 2002b:68). During the current study subjects were informed that all information was confidential and no names would be taken. Caregivers were required to give direct consent for their own participation andthat of their infant in the study (Bless & Higson-Smith, 2000:100). To ensure subsequent confidentiality no subject's data was coupled to any names. Every research subject received a unique number, which was used to refer to his or her data.

❑ **Actions and competence of researchers**

An ethical obligation rests on researchers to ensure that they are competent and adequately skilled to undertake the proposed research project (Strydom, 2002b:69). The entire research project must run its course in an ethically correct manner to ensure accountability towards all colleagues in the scientific community (Babbie, 2001:475). To address this issue the researcher and fieldworkers were constantly reminded of his ethical responsibility throughout the composition of the research population, the sampling procedure, the implemented method, processing of the data, up to writing the research report (Strydom, 2002b:69). Competent and accountable data collection was ensured by using fieldworkers with previous experience in the research context and with the research materials and apparatus. In addition data was never collected by a single field worker but always in groups of at least two.

Ethical clearance for conducting the current study was obtained from the Research Proposal and Ethics Committee, Faculty of Humanities, University of Pretoria (Appendix F) and the Ethical Committee of the District Health Department of North West Province (Appendix G). Ethics committees are becoming accepted practice to be enforced by law in 2005 (Strydom, 2002b:75). The involved committees provided ethical clearance based on a review of the research proposal and a completed ethics application form submitted.

5.6.   RESEARCH PARTICIPANTS

Five fieldworkers and 510 pairs of research subjects, consisting of a caregiver and neonate/infant, acted as research subjects. The researcher and four research assistants served as fieldworkers in the collection of data for the current study whilst neonates/infants between 0 – 12 months and their caregivers who attended two MCH clinics in the Hammanskraal district during the extent of the research project were employed as research participants.

5.6.1.   Selection criteria

The following selection criteria were followed in selecting fieldworkers and subjects for this study.

5.6.1.1. Fieldworkers

To ensure a high degree of internal validity between the different fieldworkers a number of criteria had to be met (Leedy & Ormrod, 2001:103). Fieldworkers were selected according to the following criteria:

❑ **Tertiary qualification**
   Fieldworkers were required to have at least a bachelor's degree in audiology or a diploma in hearing therapy. A qualification in the hearing assessment and intervention sciences generally assures a higher degree of reliability and

commitment in conducting hearing screening tests (Northern & Downs, 2002:273).

□ **Screening experience**

Fieldworkers were required to have previous experience in screening neonates and infants for hearing loss consisting of at least one week's exposure. Screening experience can increase coverage rates and decrease false-positive results (Messner et al., 2001:128).

□ **Exposure to the Hammanskraal district**

Fieldworkers were required to have had previous clinical experience in the Hammanskraal district. Experience of the cultural and linguistic diversity and the socio-economic circumstances of the community, improves adaptation to and functioning in the selected context.

□ **Experience in cross cultural interviewing**

Fieldworkers were required to have had previous experience in conducting interviews with individuals from different cultures with different home languages. This ensures better collaboration with caregivers and nurses. One fieldworker was included for his experience in community work and his fluency in most of the national South African languages.

□ **Training in screening tests and screening protocol**

The fieldworkers were required to attend a two-hour training session in the use of the specific screening equipment used in this study. In addition, several demonstrations of the data collection procedure was performed in the field to ensure that each fieldworker was familiar with the equipment and test-protocol. Each fieldworker demonstrated a high level of competency, as observed by the researcher, before data collection commenced.

5.6.1.2. Subjects

Neonates/infants and their caregivers served as paired research subjects. Selection criteria were only specified for the neonate/infant, as all caregivers of infants adhering to the selection criteria were included. Caregivers were considered to be the person responsible for bringing the neonate/infant to the MCH clinic. The following criteria for neonates/infants were followed to select participants:

- **Age**

  Neonates and infants of 0 - 12 months were included. This age range was selected because the study aimed to describe the feasibility of an early hearing detection programme at MCH clinics and this range is in line with the challenge of identifying hearing loss by 12 months specified by Healthy People 2000 (Health People 2000, 1990:18).

- **Registered patient of maternal child health clinic**

  Participants had to be registered patients of the Refentse and Eersterus MCH clinic in the Hammanskraal district and a file had to be available for each participant. This ensured that the medical history is on file and other important information which the mother or caregiver may not be able to supply. These two clinics were selected because of their proximity to each other and to Pretoria and both centres provide services to significant numbers of infants representing typical developing contexts in South Africa.

5.6.2.   Selection procedure

The selection procedures for the inclusion of fieldworkers and research subjects are discussed in the following paragraphs.

5.6.2.1.   Fieldworkers

Three fieldworkers, apart from the researcher, were selected from post-graduate Communication Pathology students at the University of Pretoria who were available to act as research assistants. The fourth fieldworker had previously obtained a tertiary diploma in hearing therapy and was a final year undergraduate Communication Pathology student at the University of Pretoria at the time of data collection. This student participated in the research project as part of his fourth year research report.

5.6.2.2.   Subjects

Non-probability convenience sampling was used because the researcher had no means of forecasting or guaranteeing that each element of the population will be represented in the sample by taking subjects that are readily available (Leedy & Ormrod, 2001:218). All subjects were selected from the subjects (infants/neonates and their caregivers) awaiting other services at the MCH clinic according to the selection criteria, and during the times the researchers spent at the clinics. A letter describing the research project and stipulating confidentiality was made available to all caregivers and was carefully explained to the mothers by the fieldworker fluent in the African languages (Appendix D). After the mother or caregiver were informed regarding the research project they were required to provide informed consent before being included as a research subject (Appendix D). As far as possible neonates/infants who were restful or sleeping were selected because the screening procedures cannot be performed reliably on infants who are active or crying.

5.6.3.   Description of participants

The fieldworkers and research subjects are described forthwith.

170

5.6.3.1. Fieldworkers

The researcher and four assistants served as fieldworkers in the collection of data for the current study. All fieldworkers were competent in more than one language and two of the fieldworkers were competent in more than two languages, one of the fieldworkers being fluent in 8 native languages. A description of the field workers are summarised in Table 5.4

TABLE 5.4 Description of fieldworkers

NUMBER OF FIELD WORKERS	GENDER	AGE	QUALIFICATION
1 field worker	Male	25	Graduated M. Communication Pathology and registered for a D.Phil. Communication Pathology degree
3 field workers	Female	23 - 25	Graduated B. Communication Pathology and registered for a M. Communication Pathology degree
1 field worker	Male	33	Hearing Therapy Diploma Final year B. Communication Pathology student

5.6.3.2. Subjects

An interview schedule was conducted with the caregivers to acquire identifying information (Appendix B, section A). 510 infants and their caregivers where included in the study. Infant age ranged from 0 – 12 months and gender was equally distributed with 262 (51%) female and 248 (49%) male infants. The age of the mothers ranged between 15 – 43 years. A detailed description of the research subjects is provided in Chapter 6 as the biographical and descriptive data for the research subjects were collated to achieve sub-aim #2.

5.7.   DATA COLLECTION MATERIAL AND APPARATUS

The collection of data for the current study included material and apparatus for the collection of quantitative and qualitative data. These materials and apparatus are summarised in Table 5.5. A recording sheet was compiled on which all the variables of these material and apparatus were documented and an additional space was provided to document any observed difficulties (Appendix B). The material and apparatus are discussed as follows.

5.7.1. Interview schedule

The aim of the interview schedule was to compile a profile of biographical characteristics and risk indicators for hearing loss from the sample of subjects. The schedule constituted two sections which formed part of the recording sheet (Appendix B, section A & B) and was completed by interviewing the caregiver supplemented by information from the MCH clinic file. The first section consisted of biographical type questions and the second section was a risk indicator checklist for hearing loss. Two of the fieldworkers were fluent in African languages and interviewed the caregivers in their home language if they were not able to understand English or Afrikaans. In order to ensure cooperation and a positive attitude as well as to improve the reliability and validity of the results, the following aspects were taken into consideration during the compilation of the interview schedule (Leedy & Ormrod, 2001:202-204):

- Politeness, respect and cultural sensitivity was maintained in the wording of instructions and questions
- Questions were constructed to follow logically on each other
- Questions that are time saving were utilised throughout the questionnaire
- Questions referred to a single aspect for clarity

Each section of the questionnaire is discussed in the following paragraphs.

172

TABLE 5.5 Data collection material and apparatus

METHOD OF DATA COLLECTION		MATERIAL & APPARATUS	OBJECTIVE	JUSTIFICATION
QUANTITATIVE	Structured interview & extracting info from patient file	*Interview schedule*: 1. Biographical info 2. Risk indicator list *(Appendix B)*	1. To describe the research subject pairs 2. To identify any possible risk-factors for hearing loss	Direct face-to-face interviews and consultations were mainly used because it has the highest response rate (Neuman, 1997:167).
	Test measurement	*Middle-ear analyser*	To measure and record the variables of middle-ear functioning	A high 1000Hz probe tone was used because it provides more reliable results for infants <7months (Margolis et al. 2003:383)
		Combined *OAE & AABR screening device*	To screen for hearing loss. OAE is the first step screen and AABR is the second step	These two electrophysiological techniques are the only recommended techniques currently (JCIH, 2000:14)
		Diagnostic ABR	To assess the hearing status of neonates/infants who fail the 1st and 2nd screening visits	The ABR is recommended as the gold standard for evaluating hearing thresholds in infants >6months (JCIH, 2000:15)
	Structured documentation	*Recording sheet* *(Appendix B)*	To record if subjects return for a follow-up screen	This information was documented on a recording sheet to provide an accurate picture of the follow-up process (Mouton, 2001:104)
QUALITATIVE	Observation	*Field notes*	To record all observations regarding context (e.g. facilities, interruptions) and interactional processes (e.g. attitudes, support)	Ideal for presenting a comprehensive account of respondents and their contexts, events taking place, actual interactions, attitudes, perceptions and feelings (Strydom, 2002a:286).
	Critical reflection of fieldworkers	*Reflection sheet* *(Appendix C)*	To reflect and document the personal experiences of screening in MCH clinics in Hammanskraal in terms of the context and interactional processes	This type of report writing is important for researchers to note their own feelings speculations and perceptions by relying on memory (Strydom, 2002a:287)

5.7.1.1. Biographical information

Sub-aim #2 required a description of the research population and therefore biographical information regarding the caregiver and infant pairs were collected by the questions in this section of the interview schedule (Appendix B, section A). These questions were aimed at obtaining a general description of the research subjects in terms of age, gender, race, home language, family structure, housing, and income. This information also aided in the classification and statistical analysis of results. The format of this section of the interview was twelve closed questions aiming to obtain a general description of the research subjects in terms of age, gender, race, home language, family structure, housing, and income. Except for the two questions concerning the ages of the mother and infant all other questions had a number of options, ranging from two to seven, to choose from. Factual closed-ended questions, like these, were appropriate because attitudes and opinions were not being measured but rather objective information about the subjects, such as social background and related personal data (Bless & Higson-Smith, 2000:116). The use of closed-ended questions also do not require complicated recording and makes comparisons and quantification of results possible (Bless & Higson-Smith, 2001:119).

5.7.1.2. Risk indicator list

The second section of the questionnaire was a checklist for recording hearing loss risk indicators (Appendix B, section B). The list of risk indicators was compiled from the JCIH 1994 and 2000 position statements (JCIH, 2000). Table 5.6 presents the JCIH risk indicators and the risk indicator list compiled for use in the current study.

174

TABLE 5.6 List of risk indicators for infants 0-1 year as compiled from JCIH 1994 & 2000 lists

RISK INDICATORS: BIRTH – 28 DAYS (JCIH, 1994)	RISK INDICATORS: BIRTH – 28 DAYS (JCIH, 2000)	RISK INDICATORS: 29 DAYS – 2 YEARS (JCIH, 2000)	CURRENT STUDY: RISK INDICATOR LIST (Compiled from JCIH 1994 & 2000 lists)
a) Family history of childhood hearing loss b) Hyperbilirubinemia requiring exchange c) Congenital infections (TORCH) d) Craniofacial anomalies e) Birth weight < 1500 grams f) Bacterial meningitis g) Asphyxia (Apgar score of 0-4 at 1 minute or 0-6 at 5 minutes) h) Ototoxic medications, including but not limited to aminoglycosides, used in multiple courses or in combination with loop diuretics i) Mechanical ventilation lasting 5 days or longer j) Stigmata of other findings associated with a syndrome known to include a sensorineural and/or conductive hearing loss	a) An illness or condition requiring admission of 48 hours or greater to a NICU b) Stigmata or other findings associated with a syndrome known to include sensorineural hearing loss and or conductive hearing loss c) Family history of permanent childhood hearing loss d) Craniofacial anomalies, including those with morphological abnormalities of the pinna and ear canal e) In-utero infections such as cytomegalovirus, herpes, toxoplasmosis, or rubella	a) Parental or caregiver concern regarding hearing, speech, language, and or developmental delay b) Family history of permanent childhood hearing loss c) Stigmata or other findings associated with a syndrome known to include sensorineural or conductive hearing loss or Eustachian tube dysfunction d) Postnatal infections associated with sensorineural hearing loss including bacterial meningitis e) In-utero infections such as cytomegalovirus, herpes, rubella, syphilis and toxoplasmosis f) Neonatal indicators – specifically hyperbilirubinemia at a serum level requiring exchange transfusion, persistent pulmonary hypertension of the newborn associated with mechanical ventilation and conditions requiring the use of extracorpreal membrane oxygenation (ECMO) g) Syndromes associated with progressive hearing loss such as neurofibromatosis, osteopetrosis, and Usher's syndrome h) Neurodegenerative disorders, such as Hunter syndrome, or sensory motor neuropathies, such as Friedrish's ataxia and Charcot-Marie-Tooth syndrome i) Head trauma j) Recurrent or persistent otitis media with effusion for at least 3 months	a) *Family history of childhood hearing loss* b) *Hyperbilirubinemia levels requiring blood transfusion* c) *Congenital infections (in-utero)* *- Malaria and HIV was included as risks for SA population* d) *Craniofacial defects* e) *Birth weight < 1500g* f) *Bacterial meningitis* g) *Asphyxia (Apgar 0-4 at 1min and/or 0-6 at 5min)* h) *Ototoxic medications ? 5 days* i) *Persistent pulmonary hypertension / persistent fetal circulation. Prolonged mechanical ventilation ? 5 days* j) *Syndrome present* k) *NICU admittance and for how long*

The JCIH 2000 position statement recommend two lists of risk indicators for hearing loss (JCIH, 2000). The first list is for use in neonates from birth through 28 days where universal screening is not yet available. The second list of indicators is for use with neonates or infants who are 29 days through 2 years old and these indicators place an infant at risk for progressive or delayed onset sensori-neural hearing loss and/or conductive hearing loss (JCIH, 2000). Both of these lists have been updated, in accordance with new research evidence, from previous lists recommended by the JCIH, the last of which was put forward in 1994. Risk indicators for the current study were selected from risk indicators specified for neonates from birth through 28 days and for infants who are 29 days through 2 years old since neonates/infants used in the current study varied in age between 0 – 12 months.

In the JCIH 2000 position statement the list of indicators for neonates from birth through 28 days has included admittance to the NICU for 48 hours or longer as a risk indicator which was not previously included in the 1994 position statement. This inclusion has encompassed many of the previously specified risk indicators from the 1994 position statement into a single category. The previous risk indicators included by this new category are birth weight less than 1500 grams, asphyxia (Apgar score ≤ 3 at 5 minutes), mechanical ventilation for 5 days or longer, and most ototoxic medications used in multiple courses or in combination with loop diuretics (JCIH, 1994:7,8). Lutman, Davis, Fortnum and Wood (1997:266) also include this general category as an encompassing criteria in their shortened risk indicator list consisting of attendance in the NICU, family history of congenital hearing loss and presence of craniofacial abnormalities. This study included the 48-hour NICU risk indicator but also incorporated the previously specified risk indicators to compile a comprehensive profile of risk indicators for this sample.

Widespread in-utero infections that characteristic of South Africa were also added to the list and included HIV and malaria (Department of Health, 2000:3; Department of Health, 2001:2,3). HIV has become a pandemic in South Africa with 1 in every 9 South Africans being infected (Department of Health 2002:4;

176

UNAIDS, 2003:2). The children born of HIV/AIDS infected mothers are at increased risk for hearing loss due to significantly lower birth weights, increased vulnerability for acquiring infections such as meningitis and cytomegalovirus (Spiegel & Bonwit, 2002:128). HIV infected infants are also at a much greater risk of developing middle-ear infections, which leads to a conductive hearing loss and may even result in a sensori-neural hearing loss (Bam, Kritzinger & Louw, 2003:40; Matkin et al., 1998:153; Singh et al., 2003:2; Parving, 2002:255). Malaria is responsible for close to three million deaths each year with one child in the world dying thereof every 30 seconds (Department of Health, 2003:5). Malaria is particularly dangerous for pregnant women and the medications for treatment are ototoxic. (Department of Health, 2003:5; Claesen et al., 1998:482,483) Many regions of South Africa are malaria prone (Department of Health, 2003:4) and therefore this condition was included as a risk factor unique to the South African context.

The second list of risk indicators, specified by the JCIH (2000) for infants 29 days up to two years of age, was recommended for use with infants who passed the birth screen but nonetheless should receive audiological monitoring for the possibility of progressive or delayed-onset hearing loss. Cone Wesson et al., (2000) indicated that 1 of 56 infants identified with permanent hearing loss revealed clear evidence of late onset hearing loss by one year of age. The risk indicators for this infant included low birth weight, respiratory distress syndrome, bronchio-pulmonary dysplasia, and 36 days of mechanical ventilation. The value of this data however must be validated by additional studies using large samples of infants before risk factors for progressive or delayed onset hearing loss can clearly be defined (JCIH, 2000). One additional risk indicator, postnatal meningitis infections, from the second list proposed by the JCIH (2000) was added to the list of risk indicators used for the current study as meningitis is still a leading cause of sensori-neural hearing loss in infants and young children in developing countries (Northern & Downs, 2002:283).

The risk indicator questions were in the format of a checklist with 11 closed questions requiring a *yes*, *no*, or *information unavailable* choice. Four of these

questions had an additional question if a *yes* choice was made. The first question required yes and no responses to the different types of congenital infections whilst the following three questions related to descriptions of Apgar scores, type of syndrome present, and number of days spent in the NICU.

5.7.2. Middle-ear analyser

A GSI Tympstar™ (version 2) Middle-Ear Analyzer was used to record immittance measures. The GSI Tympstar™ was calibrated in January 2003 before research commenced and again after 300 subjects were evaluated. A second calibration was included to ensure that accurate and consistent measures were obtained throughout the data collection period as the equipment was transported to Hammanskraal with every visit. Disposable probes were used to record tympanograms from every infant. The data acquired with this instrument was recorded for each subject on the compiled recording sheet (Appendix B, section C).

5.7.2.1. Middle-ear analyser: test parameters

The test parameters for performing immittance measures are discussed according to the tympanogram measurements and the acoustic reflex measurements.

❑ *Tympanograms*

A high frequency probe tone of 1000Hz was utilised to measure Y-admittance tympanograms with a positive to negative pressure sweep of 200daPa as recommended for young infants (Holte et al., 1991:23). The maximum point on a recorded tympanogram was marked to obtain the uncompensated peak admittance value with the corresponding pressure value at this point.

❑ *Reflexes*

Ipsi-lateral reflexes at 1000Hz using a 1000Hz probe tone were recorded. Reflexes were determined at the lowest intensity eliciting a reflex response

178

with a deviation larger than 0.02. This deviation was required to be repeatable and indicative of growth at higher intensities and decrease in amplitude at lower intensities.

5.7.3. OAE/AABR screener

The GSI AUDIOscreener™ was used for Oto-Acoustic Emission (OAE) and Auditory Brainstem Response (ABR) screening measurements. This device is a handheld combination OAE/ABR unit does not require the use of a computer and uses a single probe to conduct OAE and ABR measurements. The system uses *real-ear* calibration to allow calibration within the test ear. Distortion Product (DP) OAE and click evoked ABR measurements are made with this device. Disposable probe tips were used for every neonate/infant.

The test parameters used for the GSI AUDIOscreener™ OAE and AABR are discussed in the following paragraphs.

5.7.3.1. OAE screener: test parameters

According to Rabbit-Park (2003:1) before acquiring OAE screening equipment it is important to ascertain whether the equipment has in ear stimulus calibration and to consider the OAE pass criteria for the manufacturer. At present there are no standardised criteria for pass and refer results and this matter is currently under investigation (Northern & Downs, 2002:287). It is therefore understandable that products with differing pass criteria affect the sensitivity and specificity of a screening programme differently (Rabbit-Park, 2003:1; Northern & Downs, 2002:287). Salata, Jacobson & Strasnick (1998:41) indicated that DPOAE screening specificity dropped from 94% to 68% to 38% in a sample of neonates using response levels of 5, 10, and 15 dB SPL, respectively. It is clear that more stringent pass criteria (higher response levels) will increase the sensitivity but increase the number of false positives whilst less stringent pass criteria will increase the specificity but increase the number of false negatives. The minimum

response level for most screening programs require a 3 dB or more response/noise floor difference to be considered acceptable.

The default screening protocol, setting 'DPOAE 2, was selected on the GSI AUDIOscreener™ for screening neonates/infants in this study. Five frequencies were assessed for each ear and a pass criterion was based on passing at least four of the 5 frequencies evaluated. The stimulus parameters are in agreement with the guidelines by the American Speech-Language-Hearing Association (ASHA, 1997) and are presented in Table 5.7.

TABLE 5.7 OAE stimulus parameters (DPOAE 2)

	2000Hz	3000Hz	4000Hz	5000Hz	6000Hz
L1/L2 ratio	65/55	65/55	65/55	65/55	65/55
F1 (Hz)	1750	2550	3250	4250	4950
F2 (Hz)	2100	3100	3950	4950	6000
Fdp (Hz)	1400	2000	2550	3550	3900
F1/F2	1.2	1.2	1.2	1.2	1.2

The recordings of DPOAE are based on a F2 centre method and the frequencies were measured in a downward order starting with the highest and ending at the lowest using a linear averaging method of analysis. The recording parameters for the different frequencies are presented in Table 5.8.

TABLE 5.8 OAE recording parameters (DPOAE 2)

	2000Hz	3000Hz	4000Hz	5000Hz	6000Hz
Level tolerance (dB)	2	2	2	2	2
Min S/N difference	6	6	6	6	6
Min DP level for pass (dB SPL)	-7	-8	-5	-7	-7
Minimum frames	128	96	64	64	64
Max time (s)	30	30	30	30	30

180

5.7.3.2. AABR screener: test parameters

The AABR does not require subjective interpretation of the ABR waveform but uses a template response pattern obtained from a large sample population of normal hearing newborns as a criterion against which online responses are compared (Northern & Downs, 2002:285). If the responses of the test infant fall within the normative values the equipment renders a *pass* decision; if the response pattern is significantly different to the template a *refer* decision is given.

The default AABR parameters for the GSI AUDIOscreener™ were used to collect data for this study. Stimulus parameters are presented in Table 5.9.

TABLE 5.9 AABR stimulus parameters

STIMULUS	Click
STIMULUS LEVEL	35 dB nHL
SPL – NHL DB LEVEL	37 dB SPL = 0 dB nHL
PERIODIC STIMULUS RATE	37/sec
POLARITY	Rarefaction
DURATION OF CLICK	0.10 msec
INTENSITY SCALE	dB nHL
OUTPUT	Monotic
INTENSITY	Starting intensity of 60 dB nHL

The default recording parameters for the AABR of the GSI AUDIOscreener™ are presented in Table 5.10.

TABLE 5.10 AABR recording parameters

TEST CONFIGURATION	Quick ABRprobe
ELECTRODE PLACEMENT	Mastoid (L&R) = ref & ground Fpz = Active
MAXIMUM IMPEDANCE	12 kOhms
MAXIMUM IMPEDANCE DIFF.	5 kOhms
LEVEL TOLERANCE	2 dB
LOW CUT OFF FILTER	100Hz
HIGH CUT OFF FILTER	1500Hz
µVolt REJECTION	30
MAX % REJECT	60
ANALYSIS METHOD	Overlap
Fsp THRESHOLD	3.2
MAXIMUM FRAMES	8000
NORMAL LATENCY	7.5 msec
NORMAL OFFSET	0.1 msec

5.7.4. Diagnostic ABR

The Biologic NavPro™ unit connected to a laptop computer was used to acquire ABRs. The equipment was calibrated in September 2002. The click stimuli were calibrated using a Larson Davis 824 connected to an IEC 318 artificial ear simulator by determining an averaged sound pressure for the frequency ranges 2 kHz - 4 kHz. Normal Hearing Level (nHL) for the click stimuli was established by testing a group of 20 normal-hearing adults. EAR 3A insert earphones were used with disposable ear tips.

The test parameters used for the Biologic NavPro™ ABR are discussed in the following paragraphs.

182

5.7.4.1. Diagnostic ABR: test parameters

A click stimulus was used to obtain a general description of hearing sensitivity specifically in the high frequency regions (Gorga, 1999:32). The stimulus parameters used by the Biologic NavPro™ ABR are presented in Table 5.11.

TABLE 5.11 Diagnostic ABR stimulus parameters

STIMULUS	Click
SPL – nHL DB LEVEL	37 dB SPL = 0 dB nHL
PERIODIC STIMULUS RATE	27/sec
POLARITY	Rarefaction
DURATION OF CLICK	0.10 msec
INTENSITY SCALE	dB nHL
OUTPUT	Monotic
INTENSITY	Starting intensity of 60 dB nHL

The recording parameters for the AABR of the GSI AUDIOscreener™ are presented in Table 5.12.

TABLE 5.12 Diagnostic ABR recording parameters

ELECTRODE PLACEMENT	Mastoid (L&R) = ref & ground Fpz = Active
MAXIMUM IMPEDANCE	6 Ohms
MAXIMUM IMPEDANCE DIFF.	2
LOW CUT OFF FILTER	100Hz
HIGH CUT OFF FILTER	3000Hz
µVolt REJECTION	40
MAXIMUM FRAMES	2000

5.8.   PILOT STUDY

According to Bless and Higson-Smith (2000:155) a pilot study is a "small study conducted prior to a larger piece of research to determine whether the method, sampling, instruments and analysis are adequate and appropriate". The pilot study is described in the following paragraphs.

5.8.1.   Aim

The aim of the pilot study was to evaluate the hearing screening test context (facilities and personnel relations), data collection apparatus and data collection procedures in terms of feasibility and practicality.

5.8.2.   Participants

Two subject groups served as participants to collect preliminary data. The first group consisted of the nursing staff (approximately six nurses for each clinic) at the Refentse and Hammanskraal MCH clinics. The second group of consisted of five pairs of caregivers and infants younger than six months of age.

5.8.3.   Material and apparatus

The material and apparatus used consisted of an interview schedule (Appendix B, section A & B) and an OAE screening device. The interview schedule was completed by interviewing the caregivers and by using the MCH clinic infant file. The GSI AUDIOscreener™ was used for OAE screening measurements. The device is a handheld combination OAE/ABR unit which does not require the use of a computer. The system uses *real-ear* calibration to allow calibration within the test ear. Distortion Product (DP) OAE measurements are made with this device.

5.8.4.   Procedure

The following data collection procedure was followed in the preliminary study:

184

- Three initial visits to the clinics were made to establish contact with the nursing staff and to discuss the screening procedure and requirements with the staff.
- The first two visits were made to the Refentse clinic and the third was made to the Hammanskraal clinic.
- Initially discussions were pursued during tea breaks when all the nursing staff was gathered together. The screening project was discussed and explained in terms of the period of testing, the actual test procedures, the importance of hearing screening, and it was made clear that it would not add an extra work load on nursing staff.
- After the project was discussed the facility requirements were discussed.
- A fourth visit was subsequently made to collect preliminary data on five pairs of subjects (caregivers and infants).
- The interview schedule was completed by conducting an interview with the caregiver and consulting the infant's file.
- After the interview was completed immittance measurements and an OAE screening were attempted in both ears.
- The default screening protocol, setting DPOAE 2, was selected on the GSI AUDIOscreener™ for screening neonates/infants in this study.
- Five frequencies were assessed for each ear and a pass criterion was based on passing at least four of the five frequencies evaluated. The stimulus parameters were in agreement with the guidelines by the American Speech-Language-Hearing Association (ASHA, 1997).

5.8.5. Results

The results are provided according to the aim of the pilot study.

❑ **Context**

This initial investigation provided insight into the functioning of the MCH clinics and assisted in establishing a suitable procedure for combining the regular MCH services with the hearing screening. Relationships with the nursing staff were established and a cooperative collaboration fostered to

facilitate effective and coordinated service delivery between the nursing staff and the research team. The nursing staff arranged an appropriate test room and the facilities were adapted (e.g. furniture, closed windows etc) to suit the interviewing of caregivers and the testing of infants. Both rooms at the respective clinics had appropriate ventilation, adequate seating and enough workspace to conduct all the relevant procedures.

❑ **Material and apparatus**

During the structured interview it was ascertained that some questions in the biographical information section were irrelevant to the aim of the current study and were taking up unnecessary time. The OAE battery life lasted for all testing and power points were available for the GSI Tympstar to be used for middle-ear measurements.

❑ **Data collection procedure**

Attempting to acquire immittance results with a 226Hz and 1000Hz probe tone was found to be too time-consuming and subjects became restless during the procedures. In addition, the standard 50-daPa/s pressure rate proved to be too time-consuming and this was changed to a default of pressure rate of 200-daPa/s. Collecting acoustic reflexes at two frequencies (500 & 1000Hz) in each ear proved to be too time consuming with infants becoming restless and agitated. The OAE measurements were successfully performed and the noise levels were appropriately low.

5.8.6. Implications

The pilot study resulted in the arrangement of an appropriate test environment and the refinement of the data collection material and procedures. Experiences from the caregiver interview resulted in the exclusion of certain questions from the biographical information due to time limitations and lack of relevance to the aim of the study. The immittance protocol was also changed from performing a 226Hz and 1000Hz probe tone measurement for all subjects to only using a 1000Hz probe tone due to the time constraints. The rate of pressure change

186

across the tympanogram was also increased to 200-daPa/s because the default 50-daPa/s was too slow. Acoustic reflex measurements were also reduced from two per ear (500 & 2000Hz) to only one high frequency probe tone reflex at 1000Hz. These changes led to the compilation of a data collection sheet (See appendix B). The final data collection protocol based on the pilot study used the following basic procedural sequence:

- Structured interview supplemented by MCH clinic infant file to gather identifying information and risk indicators for hearing loss
- Hearing screening according to the specified protocol
- Immittance measures were performed

The procedures for each of the data collection methods as performed after the pilot study is discussed in the following paragraphs.

5.9.   DATA COLLECTION PROCEDURES

All data was collected in Hammanskraal at the Refentse and Eersterus MCH clinics. The research was conducted over a five-month period from mid January to mid June 2003. The Refentse MCH clinic was visited on Mondays, Tuesdays, and Wednesdays whilst the Eersterus MCH clinic was visited on Thursdays and Fridays. Data collection was not done every day over the five-month period due to practical schedule considerations.

Quantitative and qualitative data collection procedures were implemented to collect the relevant data during this period. The quantitative data was collected from each caregiver-infant pair in four phases. Firstly, a structured interview with the caregiver supplemented by the infant file was used to gather biographical information and to complete a risk indicator list for hearing loss. This was done by the two fieldworkers who could speak various African languages. Secondly, immittance measures for both ears were performed to evaluate middle-ear functioning. Thirdly, a hearing screening protocol using OAE and AABR

187

technologies were used to screen both ears. The final data collection phase was a diagnostic ABR assessment. Only infants who did not pass the test protocol in phase three, however, were referred for a diagnostic ABR assessment.

Qualitative data was collected throughout the period in which quantitative data was collected at the respective clinics. Figure 5.4 provides an outline of the quantitative phases, alongside the qualitative processes, of data collection in the current study.

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┌─────────────────────────────────────────────────────────────────┐
│   QUANTITATIVE DATA                QUALITATIVE                     │
│   COLLECTION PHASES                DATA COLLECTION                 │
│  ╔═══════════════════╗          ╔══════════════════╗             │
│  ║        1.         ║          ║                  ║             │
│  ║ BIOGRAPHICAL INFO &║          ║                  ║             │
│  ║  RISK INDICATORS  ║          ║                  ║             │
│  ╚═══════════════════╝          ║     CONTEXT      ║             │
│           ↓                      ║                  ║             │
│  ╔═══════════════════╗          ║      AND         ║             │
│  ║        2.         ║          ║                  ║             │
│  ║  HIGH FREQUENCY   ║          ║   INTERACTIONAL  ║             │
│  ║IMMITTANCE SCREENING║         ║    PROCESSES     ║             │
│  ╚═══════════════════╝          ║                  ║             │
│           ↓                      ║                  ║             │
│  ╔═══════════════════╗          ║                  ║             │
│  ║        3.         ║          ║                  ║             │
│  ║  HEARING SCREENING║          ║                  ║             │
│  ╚═══════════════════╝          ║                  ║             │
│           ↓                      ║                  ║             │
│  ╔═══════════════════╗          ╚══════════════════╝             │
│  ║        4.         ║                                            │
│  ║DIAGNOSTIC ASSESSMENT║                                          │
│  ╚═══════════════════╝                                           │
└─────────────────────────────────────────────────────────────────┘
```
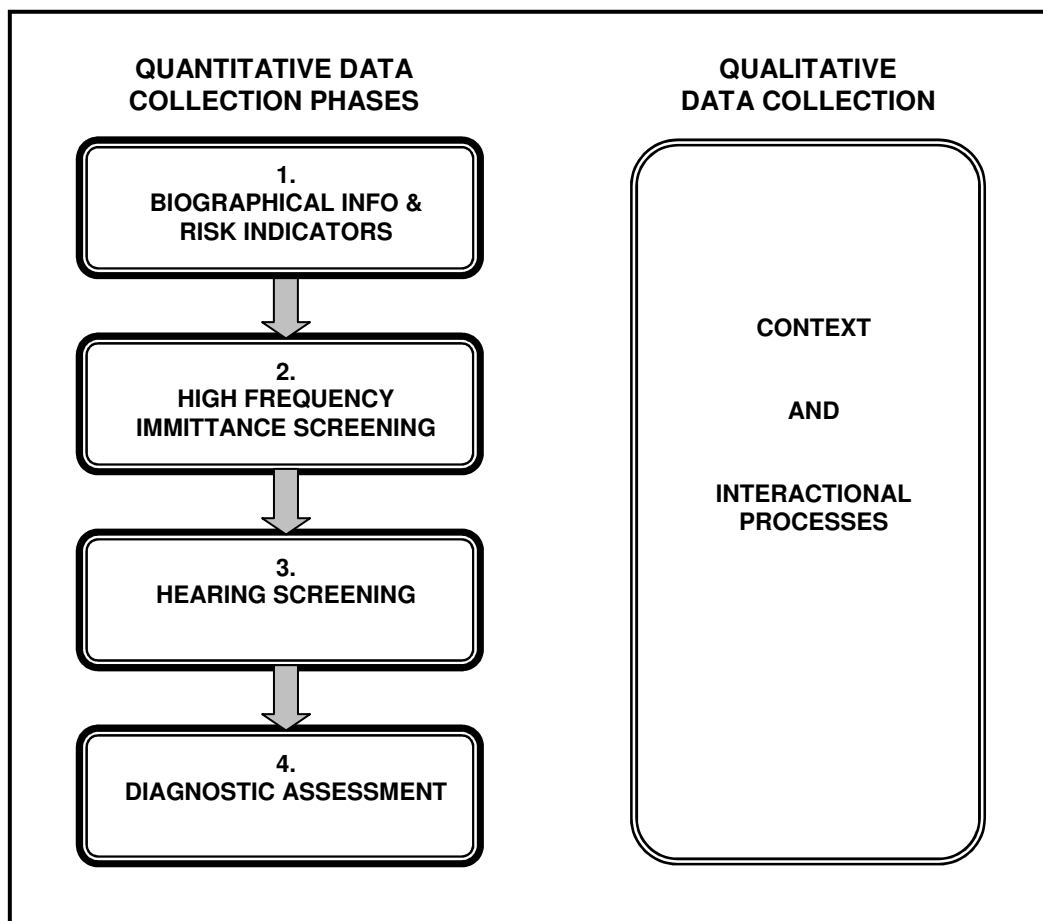
FIGURE 5.4 Quantitative and qualitative data collection procedures

The data collection procedures used to collect the quantitative and qualitative data will be discussed forthwith.

188

5.9.1.   Quantitative data collection procedures

The collection of quantitative data was divided into four phases, as described in the method section, with each phase containing its own set of collection procedures. These phases will be discussed individually in the following paragraphs.

5.9.1.1.   Phase 1: Biographical information and risk indicators

The biographical information and risk indicators were obtained using a structured interview supplemented by the file for the infant (Appendix B, section A & B). If the caregiver could not speak English or Afrikaans one of the two fieldworkers able to speak the other African languages completed the structured interview. The following procedure was used to obtain information:

- Caregivers and infants waiting in line for MCH care services were requested to bring their baby and his/her file into the hearing screening room
- The caregivers were instructed to bring their baby preferably if he/she is sleeping or quiet and restful
- Caregivers were informed about the procedure and further testing was only performed if informed consent was obtained (Appendix D)
- After the procedure was explained and informed consent obtained the mother was interviewed
- Biographical information regarding the caregiver and the child was obtained first after which questions were asked about the risk indicators that are present for the specific infant (Appendix B, section A & B)
- Two of the fieldworkers were able to speak one or more African languages and these were used if the caregiver could not understand English or Afrikaans.

5.9.1.2. Phase 2: High frequency immittance measurements

To avoid influence on a participant's performance or cooperation as the screening procedures progressed and to reduce order effects the immittance and hearing screening orders were randomised. Some infants were screened for hearing loss first followed by immittance and others were screened with immittance first followed by the hearing screening protocol. Immittance measures and hearing screening were performed on the neonate/infant after the interview. The immittance measurements were made for both ears in the testing room provided according to the following procedures.

- An appropriate sized probe tip was selected and the probe inserted in the infant's ear
- Once a good seal was attained 1000Hz probe tone tympanograms were recorded
- Two tympanograms were recorded for every ear; first a Y-admittance tympanogram followed by a simultaneous B-susceptance and G-conductance tympanogram
- The peak of every tympanogram was marked with a cursor thus providing the peak pressure (daPa) and peak compliance reading (mmho)
- If no peak was present this was recorded
- The tympanograms were followed by the recording of reflexes with a 1000Hz probe tone at a test frequency of 1000Hz
- Measurements were initiated at 70 dB HL and a reflex threshold seeking procedure of 10 dB up and 5 dB down increments followed. A maximum intensity of 110 dB could be obtained
- All results were printed for each subject

5.9.1.3. Phase 3: Hearing screening

Screening for hearing loss was based on the selection and development of a screening protocol to serve as directive guide for the collection of data. The
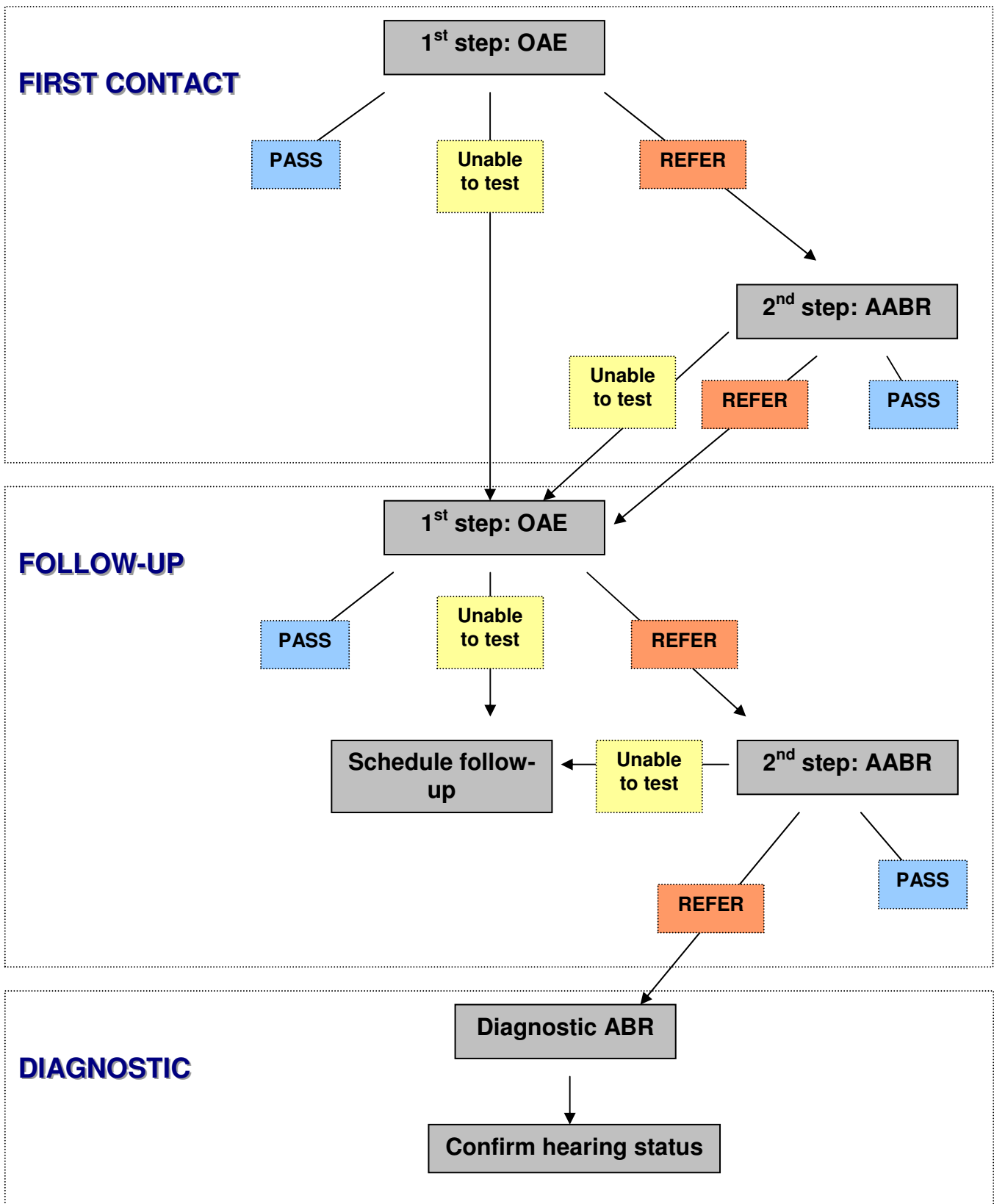
screening protocol is subsequently discussed followed by the data collection procedures used.
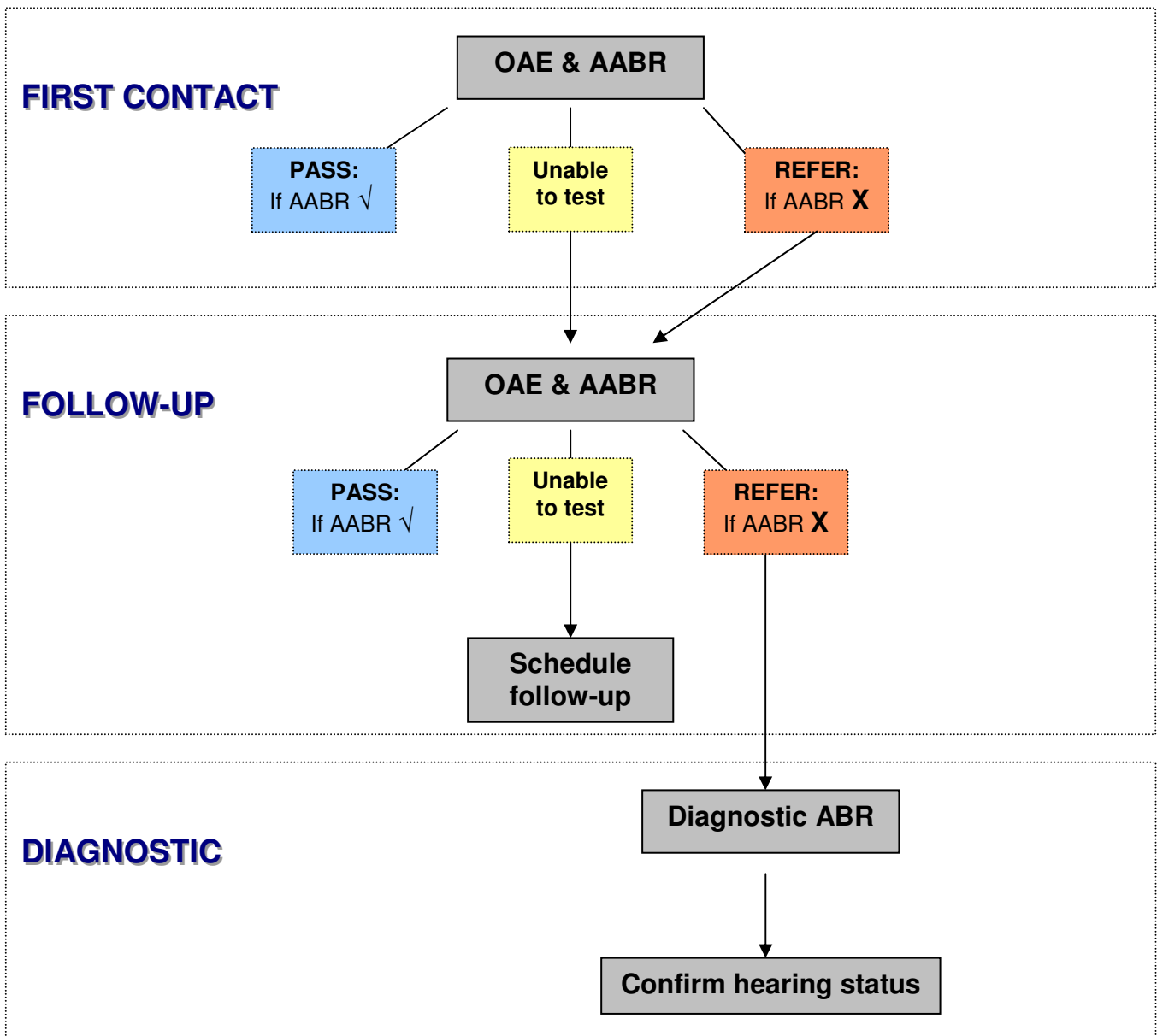
- **Screening protocol**

The screening protocol for this study was compiled for two populations of infants. The first screening protocol was implemented for all neonates/infants that were not NICU graduates and is presented in Figure 5.5. The second protocol was selected for all neonates/infants who were NICU graduates and is presented in Figure 5.6.

The referral criteria was the same for both protocols, a refer result in one ear determined an overall refer status for the subject. The first protocol was used to screen the majority of neonates/infants and involved a two-stage screening process with OAE as the initial screen and AABR as the second step screening method. This option was selected to limit the cost of disposable supplies that are required for AABR as the first screening procedure (Mehl & Thomson, 2002:6) and to serve as a possible prototype for screening practice in the South African public health sector. Additionally screening with OAE for well babies has a minimal risk of missing a neonate/infant with auditory neuropathy (Mehl & Thomson, 2002:6). The second protocol was used for all NICU graduates because this population has the highest incidence of auditory neuropathy and an AABR is recommended to reduce the risk of missing these infants (Mehl & Thomson, 2002:6). A summary of the Colorado newborn hearing screening project from 1999 – 2001 indicated that all infants identified with auditory neuropathy was from the NICU and that one out of every five NICU babies with hearing loss had auditory neuropathy (Mehl, 2002:1).

FIRST CONTACT

1st step: OAE

PASS

Unable to test

REFER

2nd step: AABR

Unable to test

REFER

PASS

FOLLOW-UP

1st step: OAE

PASS

Unable to test

REFER

Schedule follow-up

Unable to test

2nd step: AABR

REFER

PASS

DIAGNOSTIC

Diagnostic ABR

Confirm hearing status

FIGURE 5.5 OAE/AABR screening protocol #1

(For all neonates/infants except NICU graduates)

FIRST CONTACT

OAE & AABR

PASS:
If AABR √

Unable
to test

REFER:
If AABR **X**

FOLLOW-UP

OAE & AABR

PASS:
If AABR √

Unable
to test

REFER:
If AABR **X**

Schedule
follow-up

DIAGNOSTIC

Diagnostic ABR

Confirm hearing status

FIGURE 5.6 OAE/AABR screening protocol #2
(For NICU graduates)

Neonates/infants used in this study were between the ages of 0 – 12 months and thus presented with varying degrees of cooperation. If all test procedures could not be performed, or if a subject referred, a follow-up appointment was made and a letter provided with the date and time of the follow-up appointment (See Appendix B, section D).

- **Data collection according to screening protocol**

Hearing screening was performed on the neonate/infant in a randomised order with immittance measures conducted first in certain cases and hearing screening first in other cases. Both these procedures were performed after the initial interview was conducted. The collection procedure used for each protocol specified for the two populations is presented in the following paragraphs:

PROTOCOL #1 (For all neonates/infants except NICU graduates)

- The infant was placed in a comfortable position depending on state of wakefulness (in mother's arms or in a sleeping cot).
- The infant's ear was investigated and an appropriate sized probe tip selected and the probe inserted in the infant's ear.
- The OAE screening module on the AUDIOSCREENER™ was selected and testing commenced for the test ear; this procedure was repeated for the other ear.
- If the infant passed both ears no further testing was done and the results were recorded on the infant's file.
- If the infant did not cooperate a follow-up appointment was scheduled and a letter with the follow-up information provided.
- If a refer result was obtained, two additional recordings were made for that ear, if possible .
- If the second and third OAE result was still a refer, an AABR was attempted using the AUDIOSCREENER™.
- For the AABR three electrodes were attached at Fpz (active) and at A1 and A2 with the reference and ground switched between the two ears depending on the test ear and the probe remained in the infant's ear.
- If an infant passed the AABR for the ear which failed the OAE the overall result for the infant is a pass.
- If the AABR revealed a refer result or if an AABR could not be performed due to poor cooperation a follow-up appointment was scheduled and a letter provided with the follow-up information (Appendix E).

194

- During follow-up evaluation the procedure was repeated; if after completing the procedure an infant referred a second time a diagnostic evaluation was scheduled.
- If an infant did not cooperate for the follow-up appointment a second follow-up appointment was scheduled.

PROTOCOL #2 (For all NICU graduates only)

- The infant was placed in a comfortable position depending on state of wakefulness (in mother's arms or in a sleeping cot).
- The infant's ear was investigated and an appropriate sized probe tip selected and the probe inserted in the infant's ear.
- The OAE screening module on the AUDIOSCREENER™ was selected and testing commenced for the test ear; this procedure was repeated for the other ear.
- After the OAE procedure a AABR screening was performed for both ears using the AUDIOSCREENER™.
- For the AABR three electrodes were attached at Fpz (active) and at A1 and A2 with the reference and ground switched between the two ears depending on the test ear and the probe remained in the infant's ear.
- If an infant did not cooperate for the AABR screening a follow-up appointment was scheduled and a letter provided with the follow-up information.
- If an infant passed the AABR for both ears even if the OAEs referred the overall result was a pass and no more testing was scheduled.
- If the AABR revealed a refer result or if an AABR could not be performed due to poor cooperation a follow-up appointment was scheduled and a letter provided with the follow-up information (Appendix E).
- During follow-up evaluation the procedure was repeated; if after completing the procedure an infant referred a second time, a diagnostic evaluation was scheduled.
- If an infant did not cooperate during the follow-up appointment, a second follow-up appointment was scheduled.

5.9.1.4.   Phase 4: Diagnostic assessment

This phase was only recommended for those neonates/infants who were referred based on the results of the screening protocols used in phase three. The assessment was conducted using a diagnostic ABR instrument and was performed in the testing room provided at each clinic. The following collection procedure was followed during the conduction of this phase.

- ABR recordings were performed in a test room in the MCH clinic.
- Electrode discs of Ag/AgCI were fixed with electrolytic paste to the scalp at Fpz, A1 and A2. Fpz was the active electrode and A1 and A2 were switched between reference and ground depending on the test ear.
- Impedance values were kept below 3 000 Ohms.
- EAR 3A insert earphones used.
- Stimulation was presented monotically at a supra threshold intensity of 60 dB nHL starting with the left ear.
- The bioelectric activity was amplified with a gain of 100 000 and analogue filtered between 100 and 3 000Hz,
- A maximum of 2 000 recordings were averaged for each intensity although less averages were often adequate because of the low levels of ambient noise in the soundproof booth.
- A recording window of 0 – 15 ms was implemented for recordings (Hood, 1998; Bachmann & Hall, 1998),
- A noise level rejection level of 10 was used,
- Threshold was established in descending intensity steps of 10dB until no response was present. The minimum response level for each frequency in each ear was taken as the threshold,
- A latency-intensity function was taken to determine if a conductive component was present.
- This procedure was repeated for each ear.

5.9.2.   Qualitative data collection procedures

Qualitative field data was collected throughout the empirical research period. This was collected using field notes and critical reflections of the researchers' experiences. According to Neuman (1997:361) this type of field data consists of what researchers experience and remember recorded in a format that can be subjected to systematic analysis. This data collection aimed to describe the *context* (e.g. facilities, barriers and positive aspects) and *interactional processes* (attitudes, support, contact, networking, collaboration, and neonate/infant state) at the MCH clinics as related to the hearing screening of neonates/infants.

The following procedures were followed in the collection of qualitative data:

- The researchers were sensitised to watch and listen carefully in order to observe factors relating to the screening context and interactional processes.
- This was done throughout the five-month data collection period and within this time the researchers became the instruments absorbing all sources of information (Neuman, 1997:361).
- When an observation was made regarding the context or interactional processes this was documented in field notes.
- These notes were examined and elaborated on once the data collection for a given day was completed by the fieldworkers.
- After the five months of empirical data collection the researcher and each research assistant were required to do a critical reflection of their experiences during the period of collecting data at the respective clinics. This was conducted by considering certain questions to elicit specific responses (Appendix C).

5.10.   DATA PREPARATION PROCEDURES

The quantitative data was recorded onto a data collection sheet (Appendix B) which consisted primarily of numerical data whilst the qualitative observations were recorded in the form of descriptions according to field notes and critical descriptions (Appendix C) (Neuman, 1997:295). The quantitative data was in raw format on the data-recording sheet (Appendix B). This data was coded by two research assistants and checked for a second time to ensure that all data was correctly coded. This coding is done to organise the data into a suitable format for data capturing on digital format allowing analysis of the data (Neuman, 1997:295). The coded data on the recording sheets was entered into a computer programme (SAS) to allow for statistical analysis of the data.

The quantitative observations (Field notes and critical reflections) were compiled and grouped into topics or descriptions that were similar. The raw data was organised into conceptual categories to create themes or concepts that were used to analyse the data (Neuman, 1997:421). This type of coding is unlike coding quantitative data because the process is not just a clerical task but forms an integral part of the data analysis (Neuman, 1997:421).

5.11.   DATA ANALYSIS PROCEDURES

According to Neuman (1997:422) data analysis means to search for patterns in data. This involves examining, sorting, categorising, evaluating, comparing, synthesising, contemplating and reviewing the data (Neuman, 1997:422). The analysis procedures used in the current study is presented according to each empirical sub-aim in Table 5.13.

198

TABLE 5.13 Statistical analyses implemented for sub-aims

SUB-AIMS	METHOD	STATISTICAL PROCEDURE
#1 To describe the MCH clinics as a screening context	Qualitative	No statistical procedure Descriptive qualitative analysis
#2 To describe the population of caregivers and infants attending the MCH clinics	Quantitative	Descriptive statistics *(means and frequency variables describing selected characteristics of the subjects)*
#3 To describe the High-Risk Register and test procedures	Quantitative	Descriptive statistics Kruskal-Wallis H-test
#4 To describe the performance and efficiency of the screening protocol	Quantitative	Descriptive statistics Kruskal-Wallis H-test
#5 To describe the interactional processes involved in the implementation and maintenance of a screening programme in MCH clinics	Qualitative	No statistical procedure Descriptive qualitative analysis

Quantitative analysis relied primarily on statistics. After the quantitative data had been prepared for, and captured onto, digital format, statistical analyses were performed on the data set. The coded data represented on spreadsheets was analysed statistically using the SAS statistical package. Both *descriptive statistics,* which describe what the data looks like, and *inferential* statistics, which allow for making inferences about large populations by collecting data on relatively small samples, were used to investigate quantitative data for this study (Leedy & Ormrod, 2001:259).

199

Qualitative data analysis was performed as an integral part of the data preparation procedures. The preparation and analysis of qualitative data consisted of organising and grouping field note and critical reflection data into *context* (barriers and assets) and *interactional processes* (attitudes, support, contact, networking, collaboration, neonate/infant state) themes (Neuman, 1997:421). The steps conducted in analysing the qualitative data involved the following three steps.

- Units of relevance are identified
  The researcher identified units (e.g. phrases, sentences) relating to the aim of the study (Reid & Gough, 2000:75).

- Classification of themes
  The researcher identified major themes (Context and interactional processes) in the field notes and critical reflections. These sorted themes established a basis for further categorisation of the content (Reid & Gough, 2000:76).

- Categorisation of supporting material
  The units identified in step one were subsequently sorted according to the themes identified in step two. This categorisation formed an interpretive representation of responses (Reid & Gough, 2000:76).

5.12.   VALIDITY, RELIABILITY AND TRUSTWORTHINESS ISSUES

This study implemented both quantitative and qualitative research methods which differ in nature and purpose and require application of different quality criteria (e.g. validity, reliability, trustworthiness). The quality criteria applied for each of these methods are as follows.

5.12.1. Quantitative quality criteria

Quantitative methods were implemented for the recording of biographical and risk factors, and the measurement of auditory functioning. Validity and reliability issues were carefully considered to ensure that the study generated accurate and valid findings (Neuman, 1997:145). The steps taken to apply these quality criteria are discussed as follows.

- **Ensuring validity**

Validity refers to whether an instrument measures the concept in question and whether the concept is measured accurately (Delport, 2002:167). External validity simply refers to the "generalizability of the data, that is, the extent to which the results can be generalized from the study sample to the population of the people from which, presumably, the sample was drawn" (Ventry & Schiavetti, 1980:81). According to Leedy and Ormrod (2001:105), when research is conducted that has implications that extend far beyond the specific situation actually studied, more is contributed to humanities knowledge about the world. It is for this reason that this study aimed to increase its external validity according to two main criteria specified by Leedy and Ormrod (2001:105,106) namely, selecting a *real life setting* and allowing a *representative sample*. Both internal and external validity was considered in the current study in the following ways (Bless & Higson-Smith, 2000:126; Neuman, 1997:145).

- The MCH clinics in Hammanskraal are *real life settings* in use by the District of Health in Mpumalanga.
- A *representative* sample was acquired as mothers and their babies who came for routine visits were selected as research subjects.
- A third criteria for improvement of external validity, *replication in a different context*, was met to a lesser extent by selecting two clinics within the district, but replications were not made outside of the Hammanskraal area (Leedy & Ormrod, 2001:106).
- Since the interview schedule did not measure attitudes or perceptions and was supplemented by the MCH clinic file, recording only biographical facts

and risk indicators, a high degree of internal validity can be assumed (Delport, 2002:167).

- The validity of OAE/AABR hearing screening devices as measures of auditory functioning has been firmly established (Hall et al., 2004:415) (See Chapter 2).

■ **Ensuring reliability**

Reliability is defined as the accuracy of an instrument and the degree of consistency between two independently derived sets of scores (Delport, 2002:168). This means that information provided by the instrument does not vary as a result of the device itself. A high degree of reliability is necessary to ensure the final results can be trusted (Neuman, 1997:145). The following aspects were addressed to ensure reliable results were obtained:

- The reliability of the interview schedule was maintained by providing concise and simple instructions, limiting the length of the questions and by supplementing the interview with information from the MCH clinic files.
- The hearing screening and middle-ear assessment equipment was calibrated twice during the five-month data collection period to ensure reliable measurements (performance reliability) were being made.
- The reliability was further improved by ensuring that the same research group collected data throughout the study and always did so in a team of at least two field workers.
- Reliability was further maintained during the data analysis by having a single person coding the data on the data-recording sheet for consistency (Appendix B). Verifying the data for a second time validated the accuracy of the coding (Leedy & Ormrod, 2001:105).

5.12.2.   Qualitative quality criteria

Qualitative data collection constituted the less-dominant method of accruing data for the current study. This method of data collection was used to gain insight into the context and interaction processes of MCH clinics in Hammanskraal as a

hearing-screening platform. The quality criteria used for quantitative research (e.g. validity and reliability) is inappropriate for naturalistic or qualitative inquiry (De Vos, 2002b:351). Four quality criteria are specified to establish the trustworthiness of qualitative data (Lincoln & Guba, 1985:290). Table 5.14 presents these criteria and a working definition for each.

TABLE 5.14 Aspects of trustworthiness (De Vos, 2002b:351,352)

TERM	DEFINITION
CREDIBILITY	The goal of demonstrating that the inquiry was conducted in such a manner as to ensure that the context was accurately identified and described
TRANSFERABILITY	The goal of demonstrating the applicability of one set of findings to another context
DEPENDABILITY	The goal of accounting for changing conditions in the phenomenon chosen for study. Minimisation of idiosyncrasies in interpretation.
CONFIRMABILITY	The goal of demonstrating that the findings of the study could be confirmed by another study

The strategies employed during the current study to ensure these quality criteria are applicable on the qualitative method of this study were as follows.

❑ **Ensuring credibility**
- An in-depth and encompassing literature study was performed to ensure the credibility of the theoretical underpinnings of the study (Krefting, 1991:217).
- The aim and objectives of the research study were carefully constructed so that unambiguous goals were clearly stated (Reid & Gough, 2000:65).

- Combining the field notes and critical reflections including the experiences of four fieldworkers increases the credibility of the data (Reid & Gough, 2000:67).
- Conducting the naturalistic observations in two different MCH clinics increased the credibility of the data (Reid & Gough, 2000:67).
- During the extent of the research project the primary researcher reflect on the possible influence of his own background, perceptions, experience and interest on the interpretation of findings and was cautioned against bias as a result (Krefting, 1991:219).

❑ **Ensuring transferability**

- The transferability of the data was discussed for the quantitative data in this study but also applies to the qualitative data. Real life settings (MCH clinics) were implemented from a typical developing South African context and therefore does carry transferability toward other MCH clinics in developing contexts.
- Conducting the naturalistic observations in two different MCH clinics in the region also increases the transferability of the data because it involves more than just one setting (Reid & Gough, 2000:67).
- To allow informed transferability judgements to be made to other contexts detailed descriptions of the participants, data collection instruments, procedures and variables were provided (Krefting, 1991:221).

❑ **Ensuring dependability**

- A combination of data collection methods, including field notes and critical reflections, and a small number of researchers (n=5), allowing less variability, ensured a higher degree of dependability (Krefting, 1991:220).
- A careful description of the data collection, recording, analysis, and interpretation methods was provided to ensure accurate and justifiable judgements regarding the dependability can be made (Krefting, 1991:220).

204

❑ **Ensuring confirmability**

- The use of field notes and a structured critical reflection with sub-divisions for different topics provided an improved degree of confirmability (Reid & Gough, 2000:70).

- The researchers were cognitive of assuring an unbiased approach toward the data collection procedure and the inference of conclusions to satisfy the confirmability criteria (Reid & Gough, 2000:71).

The strategies above ensured a high degree of quality measures in terms of validity, reliability and trustworthiness in the present study.

5.13.   CONCLUSION

The need for contextual data has become imperative in light of the recommendations by the year 2002 HSPS produced the Professional Board for Speech Language and Hearing Professions of the HPCSA. This statement recommends MCH 6-week immunisation clinics as a primary context for implementing TNHS toward UNHS in 2010 (HPCSA, 2002:2). The empirical research of the current study was designed to investigate the use of these clinics as screening contexts in a representative South African community. Ensuring that a holistic representation of the clinics as screening facilities was accrued both quantitative and qualitative methods were used. These methods provided the means of investigating the context and interactional processes as well as providing insight into the demographics of the population served, screening test and protocol performance and programme efficiency. This type of information is pivotal to establishing evidence-based infant hearing screening programmes at MCH 6-week immunisation clinics suited to the developing contexts of South Africa.

5.14. SUMMARY

This chapter provided a thorough description of the procedures implemented in the research method to acquire the data according to the sub-aims, in order to address the main aim of the study. Evaluating the feasibility of an early hearing detection programme at MCH clinics in Hammanskraal was the driving force behind this project. The research design was described, followed by the selection criteria and description of subjects used in this study. The apparatus used, the collection of data and analysis thereof was discussed subsequently, followed by the data collection procedures according to the different techniques. The chapter was concluded by an overview of the data preparation and analysis procedures implemented and a discussion of ethical issues involved in the current study.