PAEDIATRIC HEARING LOSS IN SOUTH AFRICA: A SURVEY OF DIAGNOSTIC AUDIOLOGY PROCEDURES IN 3 SOUTH AFRICAN PROVINCES

by

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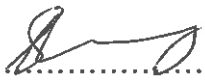
DECLARATION

I declare that this thesis is my own unaided work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



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Dedication

This thesis is dedicated to my grandparents who came to South Africa in search of a better life and thrived in the face of adversity. Their pursuit of knowledge and recognition of the importance of education is commendable.

M.A. (Mulliar Anki Reddy), my maternal grandfather, came to South Africa at 4 years of age and made his mark on the landscape of Indian education by building the Bayview School, as well as ensuring surrounding schools were able to access water. He provided education to a countless number of young Indian children.

This is the level of greatness that I aspire to.

PhD BY PUBLICATION

Senate standing order_S2015/1395 states that the preferred format of the report for Masters and PhD is by the publication model. According to Senate Standing Order S2011/2028 this should include 4 publications, as well as an introductory chapter and concluding chapter for each published article. This PhD thesis incorporates five publications in peer reviewed journals that make a significant contribution to knowledge within the field of paediatric audiology. As per the standing orders each article has an introduction and conclusion which outlines the goal of the article, links it to the previous article, as well as providing a link to the overall thesis.

Publications emanating from this research, as submitted for this PhD by Publication

1) Moodley, S. & Störbeck, C. (2015). Narrative Review of EHDI in South Africa. *South African Journal of Communication Disorders, 62* (1), Art #126, 10 pages
2) Moodley, S. (2016). Paediatric Diagnostic Audiology Testing in South Africa. *International Journal of Pediatric Otorhinolaryngology, 82,* 1-7.
3) Moodley, S. & Störbeck, C. (2016). Diagnostic Hearing Testing of Children 0-36 Months in 3 South African Provinces- Comparison of Audiology Records to HPCSA Guidelines (2016).
   International Journal of Pediatric Otorhinolaryngology, 91, 152-158
4) Moodley, S. & Störbeck, C. (2016). Sedation for Paediatric Auditory Electrophysiology in South Africa (2016). *South African Journal of Anaesthesia and Analgesia, 1*(1), 1-5.
5) Moodley, S. & Störbeck, C. (In press). EHDI Data Management in South Africa. *South African Journal of Information Management*

Abstract

Background: With 17 babies born with hearing loss every day in South Africa, there is a pressing need for systematic Early Hearing Detection and Intervention (EHDI) services. Progress is being made in the area of newborn hearing screening with studies to document the screening fora and processes appropriate for a developing country context. A systematic review of EHDI services in South Africa highlighted the need for comprehensive studies on diagnostic protocols and procedures in diagnosing paediatric hearing loss. There has also been a recognition of the ethical obligation to ensure equitable access to efficient and timely diagnostic and intervention services for children identified with hearing loss, regardless of their geographic or socioeconomic status.

Objective: The aim of this study was to document the current practice of audiologists in South Africa, with reference to paediatric audiology diagnosis, reporting of testing results, record keeping and data management in a closed sample set in 3 provinces of SA.

Method: This study utilised a retrospective record review process as well as a survey to identify the processes and procedures followed by audiologists in the diagnosis of paediatric hearing loss, across both the public and private sectors. The children who were part of the Home Intervention Hearing and language Opportunities Parent Education Services (HI HOPES) programme were selected using convenience sampling. The files of 230 children, who had diagnostic audiology records as part of the HI HOPES programme data were included as part of the sample for this study. Audiology reports and records were reviewed so as to gain an understanding of the diagnostic procedures used. Data were then compared to the HPCSA recommended guideline document to determine how diagnostic testing compared to testing procedures outlined in the guideline document. Finally, a survey to identify data management procedures followed by audiologists was sent to 40 public (n=21) and private (n=19) sector audiologists

Results: Data reflected in diagnostic audiology reports indicate differences in tests employed with paediatric clients across the regions of Gauteng, Kwazulu Natal and Western Cape, as well as across the public and private sectors. There is an increased use of electrophysiology measures across all the age ranges of paediatric clients. The

extensive use of electrophysiology on older children means there is an increased need for the use of sedation. The analysis of sedation information included in the diagnostic audiology reports indicated a need for evaluation of safety during sedation for diagnostic testing, as well as a need for development of sedation guidelines for auditory electrophysiology testing in South Africa.

The logging of diagnostic audiology data as well as sedation information in audiology reports also indicated that data is not always comprehensive. The survey showed that there is a need for efficient audiology data management and tracking systems to allow for evaluation of EHDI services, and for sharing of diagnostic information amongst professionals. Challenges with the implementation of online/electronic data management systems include those that are common to a developed world context (time and staff for data entry), as well as challenges unique to a developing country context (electricity access and internet connection).

Conclusion: Accuracy in paediatric diagnostic audiology is important as this step in the EHDI pathway is necessary for appropriate provision of amplification, communication methodology options and the influence on future education options and success. Paediatric diagnostic audiology in South Africa shows a lack of agreement with South African diagnostic guidelines in terms of tests employed, across the provinces of Gauteng, KZN and WC as well as across the public and private healthcare sectors. The incomplete sedation information on audiology reports indicates the deficiencies in accurate and comprehensive data recording. . Extensive studies across all provinces relating to all aspects of EHDI services (screening, diagnosis, intervention and data management) are necessary. Further studies on diagnostic practice and resources in South Africa will provide information on factors that are preventing adherence to South African guidelines as well as international best practice guidelines for paediatric diagnostic audiology, as well as information and resources that are needed for advancement and improvement of the field.

Keywords: Paediatric diagnostic audiology, hearing loss, EHDI, hearing screening

Introductory Chapter

Introduction

Hearing loss is the most prevalent sensory disorder amongst all people worldwide. The World Health Organisation (WHO) estimated the global prevalence of hearing loss (>40 decibel Hearing Level [dBHL]) to have more than doubled from 120 million people in 1995 to more than 278 million in 2005 (WHO, 2006). However, these WHO figures were based solely on hearing loss among the adult population. The WHO Burden of Disease Database previously only included adult hearing loss and regarded childhood hearing loss to be sequelae of other diseases, failing to recognise the pervasive effects of childhood hearing loss on all aspects of development (Olusanya, 2007). The WHO has recently collected statistics of 360 million people having disabling hearing loss (328 million adults and 32 million children) and has acknowledged the importance of early detection and intervention (WHO, 2015). Internationally there has been recognition of the benefits of early identification and intervention for children with hearing loss, with many international countries implementing newborn hearing screening programmes.

Hearing loss has an effect on the development of communication, language, socio-emotional, cognitive, perceptual and future academic and literacy skills. Late detection of hearing loss and subsequent delays in these areas of development results in poor education outcomes, reduced employability and increased dependence on state grants (Swanepoel, 2008). This highlights the importance of prioritizing early detection of and intervention for childhood hearing loss for long-term benefit. Government support and funding for the development and effective implementation of health and education policies will have an effect on the development of newborn hearing screening programmes and ensuring that all children are able to access these screening services (Swanepoel, 2008). In developing countries the government focus has primarily been on illnesses such as HIV and tuberculosis, with a historical lack of focus on prevention of childhood illnesses and preventative or early detection screening programmes.

Background and Rationale

The incidence of congenital hearing loss in developed countries is 2 to 4 per 1000 live births (White, 2004). An estimate of incidence in sub-Saharan Africa is around 6 per

1000 live births if socioeconomic and health conditions, as well as births occurring outside hospitals, are taken into account (Olusanya, Ruben & Parving, 2006).

However, data on congenital childhood hearing loss in developing countries is deemed to be of limited value (McPherson & Olusanya, 2008) since it is not known if hearing loss is congenital or acquired (due to the lack of infant screening programmes for early identification of hearing loss). This is further compounded by the high incidence of factors that could lead to a hearing loss being acquired, e.g. infections such as meningitis, the use of ototoxic medications to treat illnesses such as tuberculosis and the high rate of HIV in South Africa. These illnesses have an effect on overall child development, with an acquired hearing loss having the potential to result in further delays in development of speech and language.

Late identification of childhood hearing loss has an effect on overall childhood development. Studies have shown that due to the compromised access to language, children with hearing loss are likely to have difficulties with socio-emotional, cognitive and perceptual skills (Yoshinaga-Itano, 2003; Yoshinaga-Itano, 2004; Yoshinaga-Itano, 2014). Children with hearing loss have been shown to achieve typical developmental outcomes if the hearing loss is detected early and appropriate amplification and intervention services are provided before the age of 6 months (Yoshinaga-Itano, 2003). Adequate access to a language model and the increased opportunities for the development of effective communication and language skills results in an increased ability to develop cognitive, socio-emotional, perceptual and future academic skills. In addition to screening for early identification of hearing loss, there is a need for effective services in the diagnostic step of the EHDI pathway. Diagnosis is the link between early screening, and provision of early intervention services. An accurate diagnosis informs the provision of amplification, communication methodology and future education options.

The articles that follow include firstly, a historic overview of articles published within the field of EHDI in South Africa (Moodley & Störbeck, 2015) and secondly, a broad overview of procedures employed in the diagnosis of paediatric hearing loss (Moodley, 2016). Results showing the increased use of electrophysiology with older children then

indicated a need for an analysis of sedation information in the field of auditory electrophysiology (Moodley & Störbeck, 2016a).

In order to make the findings more practical, relevant and applicable to the South African context, this is then followed by an article determining how diagnostic audiology records compare to South African guidelines as set out in the HPCSA EHDI position statement (Moodley & Störbeck, 2016b).

Finally, since data management is an important part of monitoring and evaluation and research, the last article focuses on EHDI data management in South Africa.

Article 1: Moodley, S. & Störbeck, C. (2015). Narrative Review of EHDI in South Africa. *South African Journal of Communication Disorders, 62* (1), Art #126, 10 pages

Introduction to Article 1

Early detection of hearing loss is necessary for the establishment of appropriate individualised early intervention services, which includes access to communication and a language model. The link between screening and provision of early intervention services, to ensure deaf children have the opportunities for development on par with hearing children, is the accurate diagnosis of the hearing loss type and level. It is thus important that comprehensive high-quality screening as well as diagnostic services are available and accessible. In South Africa there is currently no policy in place to ensure newborn hearing screening. This lack of a national policy, therefore, leads to the reality that babies and children are usually identified late (van der Spuy & Pottas, 2008).

The importance of and a focus on early detection of hearing loss in a developing country context has been recognised in research. There have been a number of studies to determine how hearing screening is being conducted, availability of equipment and the best possible forum for conducting hearing screening (Theunissen & Swanepoel, 2008; Swanepoel, Hugo, & Louw, 2006; Friderichs, Swanepoel & Hall, 2012; Meyer, Swanepoel, Roux & van der Linde, 2012). In the context of the large number of screening studies, and community based infant screening being touted as the most cost effective and efficient for low-income countries (Swanepoel, 2010), there is a clear need for studies focusing on the next stage of the EHDI process: diagnosis. Studies on diagnostics, and the process after screening is completed, are necessary to ensure that the pathway from screening to diagnosis to intervention is a seamless, well-coordinated, efficient process, so as to ensure early provision of intervention services and prevention of a language delay. The following published article serves as a comprehensive introduction to the rationale for the study. A narrative review was conducted to determine the extent of research and the areas of focus in the field of paediatric diagnostic audiology.

The following published article thus served as a motivation for the study focus. The findings clearly showed that the area of diagnosis was a significant gap, emphasising

the validity and rationale for the study of diagnostic paediatric audiology in South Africa.

Narrative review of EHDI in South Africa

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Background: With 17 babies born with hearing loss every day in South Africa, there is a pressing need for systematic Early Hearing Detection and Intervention (EHDI) services. Progress is being made in offering newborn hearing screening and studies have been conducted to document these processes within South Africa. However, due to the lack of a national and holistic overview of EHDI services to date, an accurate picture of the current status of EHDI within the South African context is required.

Objective: To document and profile what has been published within the field of EHDI in South Africa over the last two decades (Jan 1995–Sept 2014) in order to gain a comprehensive overview of the current status and practice of screening and diagnosis in the field of paediatric hearing loss.

Method: A narrative review of peer-reviewed articles related to EHDI in South Africa was conducted by searching the EBSCOHOST, SCOPUS and JSTOR databases for the period January 1995 to September 2014.

Results: Results indicate that over the last two decades research and publications in the field of EHDI have increased considerably. These publications have revealed extensive knowledge related to paediatric hearing screening and intervention services in South Africa; however, this knowledge seems to be limited primarily to the provinces of Gauteng and the Western Cape. Furthermore, studies pertaining to diagnosis have revealed that, although much has been written on the scientific aspects on tools for diagnosis of hearing loss, there is a lack of comprehensive information on diagnostic protocols and procedures.

Conclusion: Despite the clear progress being made in South Africa in the field of early hearing detection and intervention, there is a need for comprehensive studies on protocols and procedures in diagnosing paediatric hearing loss. Finally, the narrative review revealed a clear need to ensure that development and growth in the field of EHDI is a national priority and extends beyond the two provinces currently showing growth.

Introduction

South Africa is estimated to have 16–17 babies with hearing loss born daily (Swanepoel, 2008) and despite having no legislation in place, awareness of the importance of early detection of hearing loss, followed by appropriate intervention, is growing. Early Hearing Detection and Intervention (EHDI) describes the pathway from infant screening for hearing loss to the subsequent process of diagnosis and intervention.

In response to the international drive for effective and early EHDI programmes, the Health Professions Council of South Africa (HPCSA) published a position statement in 2007. This statement describes internationally benchmarked indicators of screening at birth, amplification by three months and enrolment in early intervention by six months of age (as published in Joint Committee on Infant Hearing [JCIH], 2007) and then provides the South African benchmarks of screening by four months, appropriate amplification by six months and enrolment in an early intervention programme by no later than eight months of age (Health Professions Council of South Africa [HPCSA], 2007).

Universal newborn hearing screening and the subsequent early diagnosis of infant hearing loss is a new practice in South Africa when compared to international progress. In the USA as early as 1965, health, education and welfare departments recommended universal evaluation of hearing loss on a national level. Hearing screening has since become universal in the USA (every newborn is offered the option of having a hearing screening), with only 5% of newborns not having their hearing screened (Eiserman *et al.*, 2008). Although there is a system in place to ensure newborn hearing screening in the USA, the system is complex. Screening occurs at the birth hospital,

rescreening at a different outpatient facility, referral to an otorhinolaryngologist for amplification and referral to early intervention services (Russ, Hanna, DesGeorges & Forsman, 2010). Quality management, which includes record keeping and reporting to ensure a seamless transition from screening to diagnosis to intervention, is ensured through a good data management system (Finitzo & Grosse, 2003).

In the United Kingdom (UK), hearing screening forms part of their general screening regimen and is preceded by screening procedures for medical disorders such as haemoglobin disorders, metabolic disorders and neurogenetic disorders. By 2004, as part of the Universal Newborn Hearing Screening Programme in England, between 90% and 94% of mothers had been offered hearing screening for their newborn (Bamford, Uus & Davis, 2005). Prior to implementation of universal hearing screening in the UK, studies were conducted on the likely impact of screening on paediatric audiology services. The readiness of paediatric audiology services to deal with referrals from newborn hearing screening and the proficiency of audiologists in the accurate diagnosis of and intervention for paediatric hearing loss were determined (Uus, Bamford, Young & McCracken, 2005). These studies informed the feasibility of the screening programmes as well as the training needs of audiologists involved in paediatric audiology screening and diagnosis. It also informed the development of guidelines for screening and diagnosis.

The implementation of effective hearing screening programmes as outlined in developed countries requires numerous resources and financial investment A number of conceptual and research articles have recognised the impracticalities inherent in attempting to implement developed world models of hearing screening in a developing country (Swanepoel, Delport & Swart, 2004; Swanepoel, Hugo & Louw, 2005a), and recommendations highlighted the need for further research in the areas of using alternative screening forums (Swanepoel, Hugo & Louw, 2005b, 2006) for effective implementation of Universal Newborn Hearing Screening (UNHS) in South Africa.

Although numerous screening programmes have been implemented in hospitals and local South African communities, research to report on the outcomes are isolated and broader studies describing a collated overview of the general knowledge base and status of EHDI in South Africa are missing. Furthermore, areas in which there are gaps in knowledge have not been systematically presented nor has there been an outlining of strengths and weaknesses of EHDI systems and identification of areas where additional research is necessary.

A review of published studies on EHDI in South Africa was therefore needed to gain a comprehensive understanding of the current practice and status of newborn screening and diagnosis of paediatric hearing loss.

Research methodology

Research design

This study, whilst sharing much in common with the systematic review in terms of an academic database search with clear parameters (Liberati *et al.*, 2009), is descriptive rather than evaluative and therefore a narrative review. The overall aim of a narrative review is to 'tell the story' and thus provide an overall description of the current knowledge base and national activity within the field of EHDI as evidenced in the published research.

In telling the story about the publications, the aims of this narrative review are:

1. To detail the number of peer-reviewed papers on EHDI in South Africa from January 1995 to September 2014 and to classify the articles according to type of publication: a conceptual or research article or a letter to the editor.
2. To describe the main and secondary focus of each paper in order to get an overview of the work that has been done in the field within this time-frame.
3. To outline the chronological progress within the field of early hearing detection and intervention over the period of twenty years, January 1995 to September 2014.

Data collection

An electronic academic-database search of EBSCOHOST, SCOPUS and JSTOR databases was conducted using a combination of search terms related to the general EHDI topics of screening and diagnosis of paediatric hearing loss in South Africa. The two search parameters required that all the articles had to be peer-reviewed – thereby excluding theses and dissertations – and published between January 1995 and September 2014 (Table 1).

Of the 759 articles identified using the search terms across the three databases as noted above, 83 were identified as

TABLE 1: Description of the search results identifying articles for the narrative review.

Procedural steps	Number of reports	Description
a) Database search results	759	3 databases (EBSCOHOST, JSTOR and SCOPUS), 9 search strategies
b) Database search results –duplicates omitted	676	83 duplicates from the 5 searches were omitted
c) Database results examined for scope of review	41	676 titles and keywords were examined for relevance to the review topic. Where there was uncertainty about relevance abstracts were reviewed. 635 articles were omitted – 634 not relevant to topic and 1 citation
d) Time frame for review identified as from 1995 to September 2014	35	6 articles were omitted due to being published before 1995
e) Identification of additional reports relevant to review	8	Reference lists of articles reviewed to identify additional relevant articles
f) Reports included in review	43	Articles forming part of the final systematic review

duplicates. The remaining 676 articles were examined for relevance and 635 were omitted as being irrelevant. An additional six were omitted as they were published before 1995. The 35 remaining articles were studied and reference lists were reviewed in order to identify any additional relevant articles, from which eight were identified. A final total of 43 peer-reviewed articles were included in the narrative review. Masters and PhD dissertations, as well as the HPCSA Position Statement were excluded from the review, as they are not peer-reviewed academic articles.

Data analysis

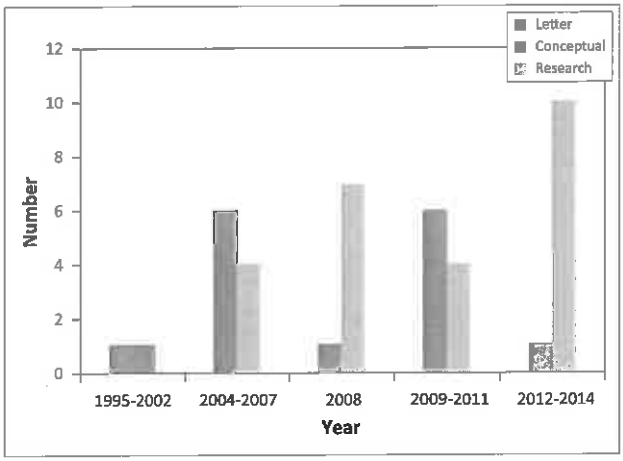
Articles were classified according to: (1) type of publication, whether it was conceptual, editorial or a research paper; (2) year of publication in order to determine chronological progression of EHDI in South Africa; and (3) primary and secondary focus of the publication. If the majority of the article related to a specific area, it was classed as the primary focus. If some reference was made to a specific area, but was not the main topic, it was classed as the secondary focus.

Results

43 peer-reviewed articles were identified in the field of EHDI in South Africa for the period January 1995 to September 2014. These included 15 conceptual articles, 26 research articles and two letters to journal editors. In classifying the papers by their primary and secondary areas of focus, the following four categories arose: (1) screening, which includes the process and forum for identification of hearing loss; (2) diagnosis, which involves the comprehensive testing and classification of the hearing loss; (3) intervention, which refers to the fitting of amplification and referral to early intervention services and (4) data management, which includes reference to the follow-up and referral network. A summary of the 43 papers can be found in Appendix A.

The analysis revealed that almost 60% (n = 24) of the papers focused on screening as their primary focus and just under 30% (n = 11) focused on diagnosis, whilst the remaining six focused on intervention (n = 5) and data management respectively (n = 1). Two articles (Swanepoel, 2006; Swanepoel & Störbeck, 2008) could not be classified into one of the four areas, as one was an article describing the profession of audiology and the other was an overview article describing EHDI knowledge (Table 2).

When considering the chronological pattern that emerged over the 20 years of publications, the research increased considerably over time (see Figure 1), with the first 8 years



Note: Article type (n=43)

FIGURE 1: The chronological pattern.

(1995 – 2002) showing no empirical research, the second eight-year period (2004 – 2011) showing a growth in conceptual papers and research papers with the largest growth in research occurring in the last 3 years (2012 – 2014).

The period of 1995–2002 showed minimal focus on the area of EHDI, with just two publications: one being a letter to the journal editor discussing the feasibility of introducing universal newborn hearing screening in South Africa (1995) and the other being a conceptual article discussing the Auditory Steady State Response (ASSR) as a tool for diagnosis of paediatric hearing loss.

More conceptual than research articles were published between 2004 and 2007. The focus of these articles was mainly on hearing screening forums and the importance of early identification and intervention for paediatric hearing loss. In 2008 a number of research articles dedicated to the proceedings of the first EHDI in Africa conference (held in 2007) was published in a special edition of the *International Journal of Audiology*. Between 2009 and 2010 the focus of the articles then shifted to a summary of the current status of EDHI services in South Africa and the introduction of a pilot screening programme implemented in one province of South Africa. The 2011–2014 period focused on alternative screening forums as well as retrospective reviews of audiology records to determine current practice.

Discussion

The 43 articles included in the narrative review will be discussed chronologically, with reference to specific themes within each time period.

TABLE 2: Area of focus for articles included in narrative review.

Primary focus	Secondary focus					
	Screening	Diagnosis	Intervention	Data management	No secondary focus	Total
Screening	-	-	6	2	16	24
Diagnosis	-	-	1	-	10	11
Intervention	-	-	-	-	5	5
Data management	1	-	-	-	-	1
Total	1	0	7	2	31	41

It is only in the new millennium (2000 onwards) that research in the field of EHDI has shown considerable growth in South Africa with studies in the specific areas of screening and early intervention. In 1993, the US National Institute of Health (NIH) Conference addressed the issue of late identification of hearing loss and made the recommendation of universal newborn hearing screening (NIH Consensus Statement, 1993). This led to a meeting at the Departments of Otolaryngology, Logopaedics and Neonatal Paediatrics at the University of Cape Town in South Africa. The conclusion of this meeting was that UNHS in South Africa was not feasible due to the lack of proof of effectiveness of hearing screening and the workload impracticality (Prescott, 1995).

Further research in this area then showed a decline until 2002, when general scientific research to determine the effectiveness of the ASSR in diagnosis of hearing loss in infants was conducted by South African authors (Swanepoel, Schmulian & Hugo, 2002).

The year 2004 also saw the importance of early identification and intervention for paediatric hearing loss being well recognised, with five conceptual articles (Swanepoel, 2006; Swanepoel, Delport & Swart, 2007; Swanepoel, Delport *et al.*, 2004; Swanepoel, Louw & Hugo, 2007; Swanepoel *et al.*, 2005a) and seven research articles relating to this topic published between 2004 and 2007. Research during this period focused mainly on the use of immunisation and maternal health clinics as forums for screening of hearing loss in infants (Olusanya & Okolo, 2006; Swanepoel, 2006; Swanepoel, Hugo & Louw, 2005a; Swanepoel *et al.*, 2005b, 2006; Swanepoel, Louw *et al.*, 2007), screening uptake at a private healthcare clinic (Swanepoel, Ebrahim, Joseph & Friedland, 2007) and one article focusing on the generic topic of the ASSR being a reliable measure of threshold estimation for children with severe to profound hearing loss (Swanepoel *et al.*, 2002). Initial research in the field of EHDI from 2002 to 2007 focused mainly on an alternative screening forum that could be used in public health and the uptake of the offer for newborn hearing screening in private health. The use of screening methods, diagnostic data specific to South African practice and data management were gap areas in the research.

The areas of research and South African specific knowledge in the field of EHDI were highlighted when the first EHDI Africa conference was held in South Africa in 2007. A special supplement of the International Journal of Audiology (IJA) was dedicated to the publishing of proceedings from conference presentations. The introductory editorial article (Swanepoel & Störbeck, 2008) highlighted the increased concern and advocacy on the topic of paediatric hearing loss and EHDI on the African continent. Important findings from research in this special IJA supplement in terms of audiology included the lack of resources and personnel, as well as the need for resources and training in implementation of screening in the public health sector (Theunissen & Swanepoel, 2008), and in the fitting of paediatric amplification (Strauss & Van Dijk, 2008). The importance of the parents in the EHDI process and the role of the audiologist in providing on-going support and guidance (Swanepoel & Almec, 2008; Van der Spuy & Pottas, 2008), as well as the need to focus beyond screening and consider the importance of cultural, linguistic and accessibility factors in intervention (Störbeck & Pittman, 2008), was also addressed. Additional articles during this period focused on the scientific aspects of using the ASSR in the diagnosis of hearing loss (Swanepoel & Ebrahim, 2009; Swanepoel, Ebrahim, Friedland, Swanepoel & Pottas, 2008) and were not based on issues related specifically to the South African context. This period of research showed an expansion of earlier research in that there was a consideration of contextual factors related to staffing in the public health sector, the role of the audiologist in fitting of amplification as well as providing support. This included the importance of culture, linguistics and access to services in early intervention. However, there was still a lack of a focus on screening methods and effectiveness, South African specific diagnostic practice and data management.

The period of 2009–2010 produced a number of conceptual/review articles relating to the implementation of newborn hearing screening, early intervention and the importance of a follow-up referral network (Copley & Friderichs, 2010; Pillay, Moonsamy & Khoza-Shangase, 2010; Swanepoel, 2009; Swanepoel, Störbeck & Friedland, 2009). Research topics during this period focused on targeted screening and follow-up (Kanji, Khoza-Shangase & Ballot, 2010) and audiological management following meningitis (Khoza-Shangase & Rifkind, 2010). The need for screening and diagnostic protocols for children with a high risk of acquired hearing loss due to illnesses such as meningitis is unique to the African situation. Conclusions included the need for improved knowledge of hearing screening and early intervention among professionals as well as parents (Kanji *et al.*, 2010; Khoza-Shangase, Barratt & Jonosky, 2010).

This highlights the importance of focused studies taking into account all aspects of the situation in Africa, including the professional knowledge of all specialists involved in the EHDI process, as well as the impact of ear infections and illnesses such as meningitis on acquired hearing loss. Data management and cross-disciplinary diagnostic data are clearly lacking in South African studies within the time period of the review.

Studies up until the 2009–2010 period focused mainly on the public healthcare sector, and thus provided little indication of EHDI services available to the 15% of the population that use private healthcare services. In 2011 and 2012 a survey of hearing screening practice in the private healthcare sector was conducted on a national level (Meyer & Swanepoel, 2011; Meyer, Swanepoel, Le Roux & Van der Linde, 2012). The inadequacy of hearing screening services in the private healthcare sector, the need to improve knowledge of hearing screening among professionals, as well as the need for a centralised data management and follow-up system was highlighted. In the public sector, a pilot screening programme

using nurses as screening personnel in clinics in a single province of South Africa, the Western Cape, was implemented (Friderichs, Swanepoel & Hall, 2012). Conclusions from this programme were that follow-up is improved if there is a dedicated EHDI coordinator, and that screening coverage rates could be improved if screening was implemented at midwife obstetric units. The conceptual article outlining the many roles nurses can play in the EHDI process (Moodley & Störbeck, 2012) was contradicted by the pilot screening programme findings that for successful implementation of UNHS there needs to be dedicated EHDI personnel (Friderichs *et al.*, 2012). This was further corroborated by a study in another province (Gauteng), where it was found that nurses do not adhere to documenting and recording screening protocols as proposed by the National Department of Health (Joubert & Casoojee, 2013). Whilst these studies acknowledge data management and follow-up as important factors, there is limited focus on the use of data management systems within the South African context. The use of midwife obstetric units (MOUs) as alternative screening forums is advancement on the studies earlier in the decade relating to the use of alternative screening forums. However, screening methods and the effectiveness related to this is an area that has still not been extensively studied. Until this period, South African specific diagnostic data and practice has not been researched.

More recent research activities (from 2012) have focused on retrospective and, less commonly, prospective review of audiology records. The prospective studies focused on using audiology records to determine the impact of risk factors for hearing loss in low birth-weight babies (Kanji & Khoza-Shangase, 2012) and a study of children with serous otitis media in one province (Tiedt *et al.*, 2013). Findings from these studies correlated with previous findings of the late identification of hearing loss, audiology staff shortage, as well as that South African context specific risk factors should be developed if targeted screening is to be used for early identification of hearing loss. For targeted screening to be successful it is important for parents and healthcare professionals to recognise risk factors and that these children have access to hearing screening. Following findings that parent knowledge of hearing loss is poor, research conducted indicated that a contributing factor is the poor quality and readability of information pamphlets (Joubert & Githinji, 2014) and that parents refuse screening due to costs, as well as a lack of knowledge of the importance of hearing screening (Swanepoel, Scheepers & Le Roux, 2014). Whilst the focus of studies has moved on to investigate parent knowledge of hearing loss and screening and factors related to this, the main focus remains on screening of hearing loss. Even within the review of audiology records, there is a lack of comprehensive information on the process of diagnosing paediatric hearing loss in South Africa.

Studies following from screening to diagnosis, and the outlining of research related to diagnostic procedures and protocols, have only recently been conducted internationally (Larsen, Munoz, DesGeorges, Nelson & Kennedy, 2012; Munoz, Nelson, Goldgewicht & Odell, 2011). South African specific information related to diagnosis within the 2013/2014 period included two studies of retrospective audiology record analysis (Khoza-Shangase & Michal, 2014; Swanepoel, Johl & Pienaar, 2013). Whilst both these studies provide important initial information on diagnostic procedures, Swanepoel *et al.* (2013) focused on types of hearing loss related to risk factors and the diagnosis of auditory neuropathy spectrum disorder in a university clinic, whilst Khoza-Shangase and Michal (2014) focused on types of hearing loss, age of identification, amplification, intervention and a brief summary of diagnostic audiological evaluation in South African state hospitals. Neither of these studies provided an understanding of the process followed in diagnosis of type and level of paediatric hearing loss so as to allow for the progression to the next steps of EHDI, namely early intervention services and amplification. Previous South African studies related to diagnosis have focused on using the ABR and ASSR for the diagnosis of severe to profound hearing loss (Swanepoel & Ebrahim, 2009; Swanepoel, Hugo & Roode, 2004; Swanepoel *et al.*, 2002), age of diagnosis of hearing loss in South Africa (Butler *et al.*, 2013; Van der Spuy & Pottas, 2008), reports on diagnosis of hearing loss in state hospitals (Swanepoel, 2008) and protocols for audiological management following meningitis (Khoza-Shangase & Rifkind, 2010).

A study on audiology equipment and protocols used for paediatric assessment and hearing aid fitting highlighted the lack of both equipment as well as evidence-based guidelines for assessment in South Africa (Teixeira & Joubert, 2014). Developed countries have focused on putting policies and procedures in place to ensure early detection of childhood hearing loss and prompt initiation of early intervention services. Screening has become a standard of care, with studies on diagnosis being conducted to improve the diagnostic process. There is agreement on the need for standardisation and improvement of diagnostic services across developed countries.

The South African journey of research into EHDI services from 1995–2014 highlights the progress made in outlining the implementation of paediatric hearing screening services in a developing world context. The need for education of parents and professionals on the importance of early screening, the practical aspects of implementing screening programmes and the importance of South African specific risk factors being recognised was clearly highlighted. After the period of the review end date (September 2014) a further three articles were published in the field of EHDI in South Africa. One article focused on procedures and protocols for hearing screening at immunisation clinics in two South African provinces (Petrocchi-Bartal & Khoza-Shangase, 2014) whilst the other two focused on diagnosis and intervention for paediatric hearing loss (Le Roux, Swanepoel, Louw, Vinck & Tshifularo, 2015; Stroebel & Swanepoel, 2014). One focused on the parental experience of the diagnostic process for children with auditory neuropathy (Stroebel & Swanepoel, 2014) and the other focused on the risk profile and a summary

of diagnostic procedures for children receiving cochlear implants (Le Roux *et al.*, 2015).

Comprehensive research and evaluation of paediatric diagnostic audiology services and the procedures to be followed in the diagnosis of paediatric hearing loss in South Africa has emerged as a gap in the field. The use of tools such as the ASSR for diagnosis of paediatric hearing loss is an area of scientific knowledge for South Africa. However, comprehensive studies on diagnosis of paediatric hearing loss are lacking. The use of diagnostic tools and how they relate to the use of evidence-based guidelines for diagnosis of paediatric hearing loss, as well as the development of South African specific diagnostic guidelines (as was the case for recognition of the need for South African specific risk factors for screening), are areas for development and expansion.

An area of strength in EHDI research in South Africa is inclusive information on implementation of screening at different forums within the public and private healthcare sectors. The progress in development of South African specific risk factors with targeted screening as an option, as well as the need for the education of parents and professionals on the importance of hearing screening is clearly laid out. Whilst there is an acknowledgement of staff and equipment shortage for implementation of screening in the public health sector, there is not as much comprehensive information on the private health sector. An area that is also lacking is one that focuses on screening methods used and the effectiveness thereof. Related to this is what seems to be a lack of prioritisation of data management in the South African context, as few studies related to data management have been conducted

Limitations of this study include the fact that, as a narrative review, the study did not consider qualitative aspects of the research such as study sample or size, nor did it evaluate the research for possible bias or weakness in the individual studies. Additionally, the search, though exhaustive, did not include an independent researcher for verification.

Conclusion

South Africa has taken many strides in growing the knowledge base of the field of EHDI, and has recognised and tried to overcome challenges in the implementation of EHDI services by researching and identifying alternative forums for screening, parent reasons for refusing screening and the availability of early intervention services. However, studies are mainly conducted in, and related to the context within, the Gauteng and Western Cape provinces of South Africa. Additionally, a large portion of the research is mainly focused on the screening process, with some studies into the usefulness of ASSR as a diagnostic tool and record reviews related to diagnostic procedures.

The research has shown that South Africa lacks a nationally agreed battery of tests and protocols for diagnosing hearing loss for infants and babies, and although a draft document on diagnostic guidelines for the paediatric population has been released for comment by the HPCSA, (Swanepoel, 2012), no process has yet been put into place to take it further. In addition, the current practice of audiologists in the diagnosis of paediatric hearing loss has not been fully explored or documented. Since accurate diagnosis is necessary for appropriate amplification and intervention and screening has been the primary focus to date, there is a need for studies focusing on the diagnostic process. The development of diagnostic practice guidelines appropriate for use in a developing country context will go a long way towards improving the EHDI process in Africa.

Studies looking at the development of universal screening, diagnosis and intervention across both the public and private healthcare systems will provide much needed information on all aspects of EHDI in a developing world context.

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Competing interests

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Authors' contributions

This article is a write-up of part of S.M.'s (University of the Witwatersrand) PhD., with C.S. (University of the Witwatersrand) being the academic supervisor. The research process (including data collection and analysis) was completed by the first author, while the writing of the article was a collaborative process.

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Appendix 1 starts on the next page →

Appendix

Appendix 1: Database and search strategy details

Search strategy	Identifiers	Database	Number of articles
Articles related to early hearing detection and intervention in South Africa	Early hearing detection AND "South Africa"	Ebscohost Web-Academic Search Complete JSTOR SCOPUS	4 5 21
	Hearing loss AND "South Africa"	Ebscohost Web-Academic Search Complete JSTOR SCOPUS	15 313 123
Articles focusing on screening for paediatric hearing loss in South Africa	hearing screening AND "South Africa"	Ebscohost Web-Academic Search Complete JSTOR SCOPUS	8 9 57
Articles focusing on diagnosis of paediatric hearing loss in South Africa	" hearing loss" AND "diagnosis" AND "South Africa" in title "diagnosis of paediatric hearing loss" AND South Africa" Diagnosis of hearing loss" AND "South Africa" "Diagnosis of hearing loss" "Diagnosis of deafness	Ebscohost Web-Academic Search Complete JSTOR SCOPUS	96 33 75

Appendix 2 : Summary of articles included in review

	Title	Year of Publication	Article Type	Article focus
1	Should routine screening of neonates for deafness be introduced in SA	1995	Letter to journal editor	Discussion of international introduction of UNHS and whether this should be introduced in SA
2	The effectiveness of the auditory steady state response in diagnosing hearing loss in infants	2002	Conceptual	A review of the Auditory Steady State Response as a procedure for the diagnosis of hearing loss in infants
3	Universal newborn hearing screening in South Africa: a First-World dream?	2004	Editorial	The importance of early hearing detection and intervention in both a first world and developing country context is outlined
4	Auditory steady state response for children with severe to profound hearing loss	2004	Research	The clinical usefulness of the Auditory Steady State Response in estimating behavioural thresholds for children with severe to profound sensorineural hearing loss
5	Implementing infant hearing screening at maternal and child health clinics: Context and interactional processes		Research	A qualitative description of the context and interactional processes observed at two maternal and child health clinics in a single province of South Africa
6	Infant Hearing Screening in the Developing World: rethinking First World Models	2005	Conceptual	The lack of feasibility of first world models of screening before hospital discharge is explained, and alternative screening forums and protocols proposed.
7	Audiology in South Africa	2006	Conceptual	The history and development of audiology as a profession in South Africa is presented
8	Infant hearing screening at immunization clinics in South Africa	2006	Research	510 infants enrolled at a clinic hearing g screening programme were analysed in terms of DPOAE coverage, high frequency tympanometry, and follow-up screening appointment attendance
9	Early hearing detection at immunization clinics in developing countries	2006	Conceptual	Description of the importance of early hearing detection and intervention as standard part of neonatal care in the developed world. Practical and culturally appropriate options for EHDI are being explored in developing countries
10	Newborn hearing screening in a South African private health care hospital	2007	Research	A retrospective study of data from a screening programme at private hospital in Gauteng.
11	A novel service delivery model for infant hearing screening in developing countries	2007	Conceptual	A service delivery model for the implementation of infant hearing screening in developing countries is proposed
12	Equal opportunities for children with hearing loss by means of early identification	2007	Editorial	Evidence for the importance of early hearing detection and intervention, nationally and internationally is presented
13	EHDI Africa: Advocating for infants with hearing loss in Africa	2008	Editorial	An introduction to articles related to conference proceedings from "Building Bridges in Africa", the first EHDI Africa international conference held in South Africa in 2007
14	Early hearing detection and intervention services in the public health sector in South Africa	2008	Research	The status of newborn infant hearing screening in the public sector (44 of 86 speech therapy and audiology departments). Diagnostic procedures used at 13 sites and data management at 12 sites is presented
15	Infant hearing loss in South Africa: age of intervention and parental needs for support	2008	Research	Questionnaire surveys and focus groups conducted with parents of children diagnosed with hearing loss
16	Early intervention in South Africa: moving beyond hearing screening	2008	Research	Data of 32 infants registered in a home-based early intervention programme is outlined
17	Maternal views on infant hearing loss and early intervention in a South African community	2008	Research	A survey of 100 mothers attending an immunization clinic in Gauteng, regarding their views and attitudes on infant hearing loss, was conducted
18	Hearing instrument fitting of preschool children : Do we meet the prescription goals	2008	Research	Comparison of hearing instrument output values at 65 and 90dBSPL input signals fitted to preschool children to targets prescribed by DSL*m* across the frequency range.
19	Auditory steady-state responses to bone conduction stimuli in children with hearing loss	2008	Research	Investigation of bone conduction ASSR thresholds in children with normal hearing and various degrees of hearing loss
20	Auditory steady-state response and auditory brainstem response thresholds in children	2009	Research	Comparison of ASSR and ABR thresholds in 48 infants with varying degrees and type of hearing loss.
21	Identifying infant hearing loss - never too early, but often too late	2009	Editorial	The importance of prompt referral of children for hearing testing and the process of early identification is outlined
22	Early hearing detection and intervention in South Africa	2009	Conceptual	Review of the evidence and status of infant hearing loss and early hearing detection and intervention services in South Africa
23	Early detection of infant hearing loss in South Africa: editorial	2009	Editorial	A summary of the current status of EHDI in South Africa, together with evidence of the importance of developing infant hearing screening programmes on a wider scale
24	Paediatric meningitis and hearing loss in a developing country : Exploring the current protocols regarding audiological management following meningitis	2010	Research	Retrospective review of medical records of 47 children admitted with a diagnosis of meningitis to 2 academic hospitals in the Gauteng province.
25	Hearing screening follow up return rate in a very low birth weight project: A retrospective record review	2010	Research	Retrospective analysis of records of patients with low birth weight to determine the follow-up return rate in a hearing screening programme
26	An approach to hearing loss in children	2010	Conceptual/ Review	Difficulty on diagnosis of hearing loss in young children is outlined. The Ivan Toms Infant Hearing Screening Programme in Cape Town is presented as a pilot project for future UNHS programmes in South Africa
27	Protocols for early audiology intervention services: Views from early intervention practitioners in a developing country	2010	Research	Identification of the protocols and practices for early intervention in Gauteng government hospitals and how they compare to principles for effective early intervention
28	Bridging the gap between early identification and intervention in the paediatric population with hearing impairment	2010	Conceptual	Description of the development of the Wits Hearing Aid Bank to bridge the gap between identification of hearing loss and actual intervention.

Appendix 2 continues →

Appendix 2 (Continues...): Summary of articles included in review

	Title	Year of Publication	Article Type	Article focus
29	Newborn hearing screening in the private health care sector - a national survey	2011	Research	Hearing screening procedures implemented at and challenges in implementing screening in the private health care sector of South Africa
30	Clinical Status of the Auditory Steady-State Response in Infants	2011	Conceptual	The strengths and limitations of the ASSR for use with infants as well as the role of the ASSR in the paediatric test battery is presented.
31	Efficacy of a community based infant hearing screening program utilising existing clinic personnel in Western Cape South Africa	2012	Research	Evaluation of a UNHS programme with nurses trained as screening personnel at clinics in the Western Cape
32	Childhood hearing loss and risk profile in a South African population	2012	Research	Retrospective record review of 100 patient files to determine the hearing loss and associated risk profile of children diagnosed at a paediatric referral clinic
33	The occurrence of high risk factors for hearing loss in very low birth weight neonates: a retrospective exploratory study of targeted hearing screening	2012	Research	Determining the type and frequency of risk factor for hearing loss, as a backdrop for the argument for or against targeted hearing screening
34	Early detection of infant hearing loss in the private health care sector of South Africa	2012	Research	A national survey of EHDI services in the private healthcare sector of South Africa
35	The role of the neonatal nurse in early hearing detection and intervention in South Africa	2012	Conceptual	The multiple roles nurses play in the early identification and intervention of children with hearing loss is outlined
36	Age of diagnosis for congenital hearing loss at Universitas Hospital, Bloemfontein	2013	Research	A retrospective, descriptive study to determine the age of diagnosis of hearing loss in the Free State province
37	Hearing screening record keeping practices at primary healthcare clinics in Gauteng	2013	Research	Review of hearing screening and record keeping practices at 20 primary healthcare clinics in Gauteng, south Africa
38	Paediatric chronic suppurative otitis media in the Free State province: Clinical and audiological features	2013	Research	A prospective study of the audiological, ontological and bacteriological findings of children (113 ears) with chronic serous otitis media at an academic hospital in the Free State province
39	Quality and readability of information pamphlets on hearing and paediatric hearing loss in the Gauteng Province, South Africa	2014	Research	The quality and readability of information pamphlets relating to hearing loss at hospitals in the Gauteng province were evaluated (n=21)
40	Why parents refuse newborn screening and default on follow up screening a South African perspective	2014	Research	A retrospective record review of 2 universal newborn hearing screening programmes to determine parent reasons for screen refusal and follow-up default
41	Why parents refuse newborn hearing screening in South Africa?	2014	Response to letter to editor	A response to a letter to the editor regarding the article "Why parents refuse newborn screening and default on follow up screening a South African perspective"
42	Early Intervention in Audiology: Exploring the Current Status from a Developing Country Context	2014	Research	Retrospective record review of the files of 70 patients between birth and 3 years from 3 state hospital audiology clinics in Gauteng
43	Availability of audiological equipment and protocols for paediatric assessment and hearing aid fitting in Gauteng, South Africa	2014	Research	A cross-sectional survey to determine the availability of audiological equipment and protocols for paediatric assessment and hearing aid fitting was conducted in the Gauteng province

Conclusion

The significant progress within the field of EHDI in South Africa in terms of research, as well as practice, became evident in the extensive literature search for the compilation of the narrative review. This narrative review process and analysis highlighted the dearth of studies that have a focus on paediatric diagnostic audiology and EHDI data management in South Africa. Furthermore, protocols for diagnosis within the paediatric population in South Africa have not yet been fully explored. In order for efficient EHDI services to be developed by ensuring there is an effective and well-developed transition from identification of the hearing loss (through screening) and provision of appropriate early intervention services, there is a need for comprehensive studies on diagnosis. Diagnosis has been shown to be important to realise the benefits of early identification through screening initiatives, as accurate diagnosis informs amplification and intervention option Studies on the procedures and protocols that are being followed, factors that are preventing adherence to international best practice guidelines and resources needed for further development and implementation of the EHDI pathway.

Research on paediatric diagnostic audiology is thus important to determine the resources, challenges and modifications necessary for implementation of EHDI programmes in a developing world context. The HI HOPES early intervention longitudinal database provided access to a sample of children with diagnostic audiology data that allowed for analysis of diagnostic procedures and protocols.

Article 2

Moodley, S. (2016). Paediatric Diagnostic Audiology Testing in South Africa. *International Journal of Pediatric Otorhinolaryngology, 82,* 1-7.

Introduction to Article 2

Paediatric diagnostic testing is a specialised field that requires the expertise of an audiologist. It involves the use of a specialised test battery, each component of which contributes information that allows for diagnosis of the hearing loss. Different diagnostic tests assess different components of the auditory system. Each test contributes a component to understanding the process of hearing for each individual and where there is a breakdown in the auditory system (outer/middle/inner ear and cochlear/retrocochlear). The results of each test complement each other and provide the audiologist with a means of differential diagnosis of type and degree of hearing loss.

Accurate performance of the diagnostic testing (behavioural and electrophysiology) and precise interpretation of results from diagnostic tests is important for classification of the hearing loss. The diagnosis allows for appropriate fitting and programming of amplification devices, as well as determining the choice of communication modality options. The success of EHDI programmes is determined by the number of children correctly identified with a hearing loss and referred for diagnostic services, and the number of children accessing diagnostic services (JCIH, 2007). This can be further extrapolated to include the number of children with an accurate diagnosis of the degree and type of hearing loss.

For the evaluation and quality assurance of EHDI programmes there is a need for the accurate recording of paediatric hearing screening and diagnosis testing results in a data management system. South Africa does not have a national data management system. The HI HOPES early intervention programme has a comprehensive longitudinal dataset of children diagnosed with hearing loss. This provided a sample of children for whom diagnostic audiology records could be accessed. A retrospective record review of diagnostic audiology records for children referred to the HI HOPES programme within a specified time period across the three provinces of Gauteng, Kwazulu Natal and Western Cape (cross-sectional study) was conducted.

This paper outlines the reporting measures used in paediatric diagnostic audiology as well as highlights the tests employed by paediatric audiologists when conducting a diagnostic evaluation.

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Paediatric diagnostic audiology testing in South Africa

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ABSTRACT

Introduction: With the increased emphasis on the importance of early identification of paediatric hearing loss within developing countries such as South Africa and Nigeria there has been a recognition of the ethical obligation to ensure access to timely diagnostic and intervention services for children identified with hearing loss; regardless of their geographic or socioeconomic status. There are limited studies on diagnosis of paediatric hearing loss in a developing world context.
Objectives: The objective of this study was to determine processes used for diagnosis of paediatric hearing loss in South Africa, across the private and public healthcare sectors, and to profile the age of testing for each component of the diagnostic test battery.
Methods: Diagnostic audiology testing data of 230 children enrolled in an early intervention programme was analysed to profile the reporting of diagnostic audiology testing as well as diagnostic audiology procedures employed. Results were analysed according to province as well as healthcare sector to compare diagnostic services across regions as well as healthcare sectors.
Results: The differences in audiology practice and tests employed with paediatric clients across the regions of Gauteng, Kwazulu Natal and Western Cape indicates that services across regions and across the public and private sector are not equitable. Each region is equally unlikely to complete a full, comprehensive diagnostic evaluation on paediatric clients. The age of testing highlights the increased age of diagnosis of hearing loss.
Conclusion: Paediatric diagnostic audiology is a section of Early Hearing Detection and Intervention services that requires attention in terms of the appropriateness of procedures as well as equity of services. Further studies on diagnostic practice and resources in South Africa will provide information on factors that are preventing adherence to international best practice guidelines for paediatric diagnostic audiology.

1. Introduction

The prevalence of hearing loss in newborns has been recorded as 2 to 4 per 1000 live births in developed countries and 6 per 1000 in developing countries [1]. These statistics indicate an estimated 17 babies born with hearing loss daily in South Africa [2]. In order to ensure that hearing loss is identified as soon as possible after birth, with referral and intervention shortly thereafter, the Early Hearing Detection and Intervention (EHDI) pathway was instituted, with many international countries adopting the Joint Committee on Infant Hearing (JCIH) [3] recommendation of screening for hearing loss by 1 month of age, diagnosis of hearing loss by 3 months and referral to early intervention services by 6 months. The EHDI system ensures that the transition from screening to diagnosis to intervention is managed effectively. This drive towards early identification and subsequent early intervention has as its goal typical developmental outcomes for children with hearing loss.

Within the EHDI pathway internationally, the primary focus to date has been on the implementation of newborn screening programmes and the statistics relating to number of children screened, screening procedures and data management within screening programmes [4–8]. However, beyond this screening process, where USA is reporting a 96% coverage rate for screening of all newborns [9], few studies relating to the diagnosis of paediatric hearing loss have been published [10–13]. A systematic review of research related to the EHDI pathway in South Africa indicates a mirroring of this international trend [14]. Research focussing on the procedures followed for diagnosis of paediatric hearing loss in a developing country context is an area that is lacking in evidence-based research. Also lacking are studies related to data management and sharing of results from screening and diagnostic audiology testing [14].

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The goal of a diagnostic assessment is to determine the type, degree and configuration of hearing loss in each ear [15]. Internationally, specific protocols and guidelines exist for both the screening process [3] and for the diagnostic testing of children within specific paediatric age groups [15]. In this regard South Africa has the Health Professions Council of South Africa (HPCSA) document on guidelines for screening [16], drawn primarily from the international protocols. However protocols for diagnostics within the paediatric population in South Africa have not yet been fully explored. South Africa has (through the Health Professions Council of South Africa) released a draft document on diagnostic guidelines for the paediatric population, for comment by audiologists [17]. This is an indication of the impetus to move forward in establishing guidelines for ensuring consistency and accuracy in diagnosis of paediatric hearing loss, as the next step in the EHDI pathway. With the increased emphasis on the importance of early identification of paediatric hearing loss within developing countries such as South Africa and Nigeria [18–24], there has been a recognition of the ethical obligation to ensure access to diagnostic and intervention services for children identified with hearing loss, regardless of their geographic or socioeconomic status [25].

International best practice for diagnosis of paediatric hearing loss includes the JCIH [2] guidelines relating to paediatric diagnostic testing for the 0–5 year age group. South Africa lacks a nationally agreed upon battery of tests and protocols for diagnosing hearing loss for infants and babies and a lack of comprehensive studies relating to the practice of paediatric diagnostic audiology.

The current study aims to describe the documented audiology procedures used for diagnosis of paediatric hearing loss for children enrolled in an early intervention programme in Gauteng, Kwazulu Natal and Western Cape. The objectives of the study are to:

(1) document the reporting procedures employed by audiologists for recording and reporting on diagnostic testing of paediatric clients, and
(2) document the tests used for diagnosis of paediatric hearing loss including evaluation of the middle ear, and use of behavioural testing and electrophysiology testing (including the ages at which these tests are used).

2. Methods

A retrospective record review of the patient files of 711 children referred to the HI HOPES Early Intervention programme from September 2006 to December 2011 was conducted. Children identified with hearing loss are referred to the programme to receive home-based, family-centred early intervention. All identifying information from the paediatric audiology records have already been removed by the early intervention programme and a coding system for tracking and storage of information for data analysis is used. This ensures privacy and confidentiality of data. Parents have signed consent forms providing permission for accessing all data, including paediatric audiology records, to be used for research purposes. University of the Witwatersrand Ethical Clearance (Medical) Board provided ethical clearance for a comprehensive survey study and the University of the Witwatersrand Ethical Clearance (Education) Board provided permission for the study of all data and records relating to the early intervention programme.

2.1. Study population

The research population recruited through nonprobability convenience sampling comprises of 711 deaf and hard of hearing children enrolled in an early intervention programme in South Africa, who had diagnostic audiology testing conducted in one of three provinces (Gauteng, Kwazulu Natal and Western Cape) in South Africa. This research forms part of a longitudinal study of 160 variables profiling children with hearing loss enrolled in the HI HOPES early intervention programme during this period [26]. The sample comprised of 131 males (57%) and 99 (43%) females. The average age of initial testing for 167 children where age is provided is 36.5 months (SD ± 23.6, range 1–142 months). For the remaining 67 children the age at which initial diagnostic testing was conducted is not available due to this information not being included in the reports or diagnostic testing information included with the referral documents.

2.2. Procedures

The files of the children enrolled in the early intervention programme between September 2006 and December 2011 were examined to obtain audiology records. Audiology records were drawn from the files and reviewed. Information pertaining to diagnostic audiology testing was logged onto a data collection sheet specially designed to collate and facilitate analysis of the diagnostic audiology data. Variables included reporting format, middle ear assessment (tympanometry and acoustic reflex testing), behavioural testing method and age (air and bone conduction), and electrophysiology testing method and age (air and bone conduction). Demographic data included province in which testing was conducted and healthcare sector (public or private health).

Collated data from the data collection sheet was transferred to an excel sheet to electronically capture all details included in the reports so as to systematically document and analyse the information.

2.3. Data analysis

Data analysis techniques included basic descriptive statistics (average values, standard deviation, frequencies and percentages). Data was grouped and analysed according to the variables of private vs. public practice and the province in which the practice is located to determine the variation in diagnostic practice with respect to these variables.

Hypothesis testing (chi-square) using a significance level of 5% allowed the determination of whether there is a statistically significant difference between the private and public sector for specific variables [27].

3. Results

Of the 711 children referred to the early intervention programme between September 2006 and December 2011, audiology reports of 230 children (32% of the total referrals) were available. Reports were obtained either from parent records or directly from the referring audiologist. With logging of references to previous testing included in the reports, as well as reports from additional testing sessions for some children, audiological data includes reference to 390 audiology testing sessions.

3.1. Reports

Of the 230 children where there is some reference to diagnostic testing in the early intervention programme records, 121 children had a single assessment session only, 76 children had 2 assessment sessions, 23 had 3 assessment sessions and 7 had 4 assessment sessions. Three children each had 5, 6 and 9 assessment sessions

respectively. This amounts to a total of 390 audiology testing sessions. Assessment data included 262 audiology testing sessions (67%) in Gauteng, 94 (24%) in Kwazulu Natal and 34 (9%) in the Western Cape. In terms of healthcare sector 319 (82%) reports were from the public sector, 51 (13%) were from the private sector and 20 (5%) were from university audiology departments (education and training sector).

The public/private healthcare split for each province is consistent with the 86% public health and 14% private health use reported in Theunissen and Swanepoel [28].

Assessment records comprised of: (1) formal reports detailing the different aspects of testing, protocols used and results of the tests completed, (2) assessment summaries in which a list of tests completed at different testing sessions is listed, (3) assessment templates which included filling in results on a template of all tests that could be completed as part of the test battery, (4) an audiogram with notes written on the sheet or (5) a referral letter/email that provided a list of testing completed. Referral letters lacked the comprehensiveness and details of a formal report. Electrophysiology reports included a report with testing completed filled in on a template or a report template generated by the Biologic evoked potential equipment. Formal reports provide comprehensive details of the testing, and results and recommendations for further management. The use of templates and summaries provided less comprehensive information and often just indicated whether a procedure had been completed. The indication of dates of when testing was completed for specific aspects of a template or summary was not always clear. The biologic evoked potential report generates a summary of the testing parameters in terms of stimulus type and rate. Details in terms of responses and results or recommendations and management could be typed in or handwritten on the template generated.

Of the 390 assessments done on the sample of children 269 (69%) had some form of a written record, while for 121 (31%) (Fig. 1) information was obtained from: (1) reference to testing in subsequent reports or (2) electrophysiology reports detailing the previous attempts at behavioural testing.

Of the 269 written records 102 (38%) were in the form of a formal comprehensive report and 23 (9%) were in the form of an ABR/Biologic evoked potential report template. The remaining 144 (54%) records were comprised of assessment summaries, hospital assessment templates, audiograms with notes, a template for referral to HI HOPES, and a referral letter or email stating the testing procedures completed.

A test of significance in terms of provision of a formal report indicates a significant difference ($p = 0.04$), with the private sector more likely to provide a formal report of results obtained from audiology testing.

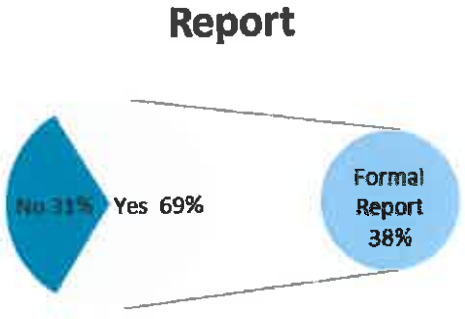

Fig. 1. Diagnostic reporting.

3.2. Diagnostic assessment

The information from the different report formats provided information on the different tests used in the diagnostic assessment. Diagnostic testing comprises of a test battery which includes (1) assessment of the middle ear system (tympanometry and acoustic reflexes), behavioural testing which is the actual physical response of the child to a sound stimulus and electrophysiology testing which includes objective testing procedures which does not require an overt response from the child to a sound stimulus. The test battery is used for differential diagnosis of the type, degree and configuration of the hearing loss. Electrophysiology testing may be included, depending on whether the child can be conditioned to consistently respond to a frequency specific sound stimulus and accurate thresholds obtained. A complete evaluation of the auditory system will include middle ear testing (tympanometry and acoustic reflex measures), air conduction frequency specific threshold testing and bone conduction frequency specific threshold testing.

The following results are presented for the total of 230 children and outlines whether tests in each specific category were completed for the total sample at any of the assessment sessions conduced.

3.2.1. Tympanometry

The initial test in a diagnostic assessment (after completion of an otoscopic examination) is tympanometry. Assessment of middle ear compliance and pressure through the use of tympanometry testing (a measure of the admittance changes in the tympanic membrane with applied air pressure [29]) allows for determination of the ability of the middle ear system to conduct sound through the air conduction pathway.

For the 230 children in the research sample, 4 children were unable to have a tympanometry assessment completed due to an atresia and 3 had cerumen or discharging ears. For the remaining 223 children, 40 (18%) did not have a tympanometry assessment, 163 (73%) have a record of a completed tympanometry measure and 20(9%) it was unable to be determined if a tympanometry measure was completed due to this information not being stated in the reference to previous testing included in reports.

Since tympanometry only provides an indication of the pressure and compliance of the middle ear system, an acoustic reflex measure is a necessary addition to tympanometry to provide an indication of the functioning of the middle ear system. The acoustic reflex is useful in diagnostic evaluation of infants as a present reflex adds support to a classification of normal middle ear function, can be used for ruling out conditions such as auditory neuropathy and sets the upper limit for auditory threshold (as a reflex will never be elicited at a level that is below the actual auditory threshold) [30]. 223 children were eligible to have an acoustic reflex measure completed (4 children had a microtia/atresia and 3 were stated to have either cerumen or discharging ears). 72 (32%) of these 223 children had an acoustic reflex measure completed in addition to the tympanometry, and thus had a complete assessment of the functioning of the middle ear system.

A breakdown of acoustic reflex testing in terms of healthcare sector indicated that the private sector conducts slightly more acoustic reflex testing than the private sector. However, a chi-test yielded a p-value of 0.18, indicating that the difference was not statistically significant.

After evaluation of the middle ear system, diagnostic testing proceeds to determine the degree and configuration of hearing loss across the frequency spectrum. Behavioural testing includes the subjective evaluation of the child's response to sound using age-appropriate behavioural testing methods, while electrophysiology testing is the objective evaluation of the auditory system and brain in response to a sound stimulus.

3.2.2. Behavioural

Behavioural testing involves the evaluation of the child's physical response to a sound stimulus and thus requires overt cooperation and participation from the child. It is dependent on appropriate equipment e.g. visual reinforcement materials for VRA, as well as audiologists skilled in conditioning a child to respond to tones and in accurately detecting response to sound. In this sample of audiology records objective behavioural testing included noisemakers, air conduction testing and bone conduction testing.

3.2.2.1. Noisemakers. Noisemakers are not frequency specific and provide an indication of whether a child responded to a toy/object that makes a sound within a frequency range. Noisemakers are used in contexts where equipment for obtaining frequency specific information is not readily available.

For 14 children noisemakers were used as an assessment tool for the initial evaluation. The ages of these children ranged from 7 to 62 months with an average age of 23 months (SD ±15.5). 2 of the 14 children had an additional disability.

3.2.2.2. Air conduction testing. Air conduction testing involves the child responding to sound presented to the ear through free-field speakers, earphones or insert phones.

Of the 230 children in the research sample air conduction testing was used as an assessment tool and results provided for 140 children. Age of testing is available for 107 children, with the age range as well as province and healthcare sector breakdown shown in Table 1.

Although (in this sample of children enrolled in an early intervention programme) the public sector is likely to start using air conduction testing on younger children, the average age of testing for the private sector is almost half of that in the public sector (Table 1). This indicates that electrophysiology thresholds for classification of degree and level of hearing loss hearing loss is more likely to be accurately verified with behavioural thresholds at an earlier age in the private sector.

When analysed according to province, it is evident that behavioural air conduction testing is not routinely conducted at younger ages (under 24 months) in any of the provinces. The age of pure tone air conduction testing in the WC (average 31.1 months, SD: ±13.6) is lowest and Kwazulu Natal the highest (average 56.2 months; SD: ±28.8). Both the private and public sector age of testing is well above the HPCSA (2007) recommendation of diagnosis by 6 months.

3.2.2.3. Bone conduction testing. Frequency specific bone conduction testing is necessary for accurate classification of the type of hearing loss. The child responds to frequency specific sounds presented via a bone conductor.

Of the 230 children that are part of the research sample, bone conduction testing was recorded for 22 children (9.5%). The age of first completion of pure tone bone conduction testing was available for 16 children (average: 56 months; SD: ±26.3; minimum: 10 months; maximum: 113 months). All children who had behavioural bone conduction testing completed were in the public sector.

Average age of bone conduction testing was higher in KZN than Gauteng. Although the average age in the Western Cape was very much younger, it was based on an *n* value of only 2. These data could be indicative of lack of adherence to a test battery for diagnosis and classification of hearing loss or poor data management in terms of accurate recording of assessment measures completed.

3.2.3. Electrophysiology

In addition to behavioural air and bone conduction threshold measures, electrophysiology is part of the test battery for confirmation of thresholds, as well as for assessment of the integrity of the neurological auditory pathway. 171 of the 230 children (74%) had some form of electrophysiology testing.

3.2.3.1. Auditory Brainstem Response. ABR can serve as a peripheral neurodiagnostic tool as well as a tool for estimation of auditory thresholds. The usefulness as a thresholding tool is for prediction of the pure tone audiogram in subjects who are not able to actively cooperate in providing a response with behavioural testing [31]. In the paediatric population this includes infants, as well as older children with a disability that makes detection of behavioural responses difficult.

154 children (67%) had at least a single Auditory Brainstem Response air conduction measure completed. Age of the test being conducted is not available for 12 children as the test was referenced in a referral letter and no date or age of testing was provided. The age of testing for the remaining 142 children is presented in Table 2 (average: 35.3 months SD: 22.7 months; minimum: 1 month; maximum: 142 months).

The largest number of auditory brainstem air conduction measures was completed in the 5–24 month age range.

When analysed according to province and sector, it is evident that the KZN private sector has the lowest average age of ABR air conduction testing while the KZN public sector has the highest average age.

Three children had ABR bone conduction measures completed. Two children with atresia were assessed with BC ABR only and one child (with atresia) had ABR BC in addition to the ABR AC and ASSR. All ABR BC measures were completed in the GT province, 2 in the private sector and 1 in the public sector. Average age of ABR BC testing was 21 months (SD ±14 months).

Table 1
Behavioural air conduction diagnostic testing.

Behavioural air conduction										
Age group	GT Public	KZN Public	WC Public	GT Private	KZN Private	WC Private	GT Univ.	KZN Univ.	WC Univ.	Total
Birth to 4 months	1 (1.5%)	–	–	–	–	–	–	–	–	1 (1%)
5–24 months	6 (8%)	4 (10.5%)	3 (23%)	5 (56%)	–	–	1 (25%)	–	–	19 (13.5%)
25–36 months	12 (16.5%)	2 (5%)	5 (39%)	2 (22%)	1 (100%)	–	3 (75%)	1 (100%)	–	26 (18.5%)
37–60 months	25 (34%)	11 (28%)	3 (23%)	1 (11%)	–	–	–	–	–	40 (28.5%)
>60 months	12 (16.5%)	9 (23%)	–	–	–	–	–	–	–	21 (15%)
Unknown	17 (23.5%)	13 (33.5)	2 (15%)	1 (11%)	–	–	–	–	–	33 (23.5%)
n	73 (100%)	39 (100%)	13 (100%)	9 (100%)	1 (100%)	–	4 (100%)	1 (100%)	–	140 (100%)
Average	45.2	56.2	31.1	24	–	–	27.3	–	–	43.9
Std Dev	18	28.8	13.6	9.6	–	–	4.5	–	–	22
Range (months)	4–101	10–121	9–52	13–23	–	–	22–33	–	–	4–121

Table 2
ABR air conduction diagnostic testing.

ABR air conduction										
Age group	GT Public	KZN Public	WC Public	GT Private	KZN Private	WC Private	GT Univ.	KZN Univ.	WC Univ.	Total
Birth to 4 months	1 (2%)	3 (8%)	1 (5%)	1 (6%)		–	–	–	–	6 (4%)
5–24 months	15 (24%)	3 (8%)	9 (45%)	10 (62.5%)	2 (50%)	–	5 (36%)	–	–	44 (28.5%)
25–36 months	18 (29%)	6 (16%)	6 (30%)	3 (19%)	1 (25%)	–	3 (21%)	–	–	37 (24%)
37–60 months	15 (24%)	14 (37%)	2 (10%)	2 (12.5%)		–	4 (29%)	–	–	37 (24%)
>60 months	6 (10%)	10 (26%)	–	–	–	–	2 (14%)	–	–	18 (11.5%)
Unknown	7 (11%)	2 (5%)	2 (10%)		1 (25%)	–	–	–	–	12 (8%)
n	62 (100%)	38 (100%)	20 (100%)	16 (100%)	4 (100%)	–	14 (100%)	–	–	154 (100%)
Average	35	48.4	25	14	22.3	–	37.4	–	–	35.3
Std Dev	18.8	28.4	11.7	11.3	6.7	–	25.7	–	–	22.7
Range (months)	3–101	1–142	4–48	2–38	18–30	–	5–96	–	–	1–142

3.2.3.2. Auditory Steady State Response. Auditory Steady State Response (ASSR) is an auditory evoked potential that is periodic in nature, in direct relation to the periodic nature of the auditory stimulus applied [32]. ASSR is more objective than ABR as it does not require the audiologist to determine replicability and location of peak waves.

76 children had an ASSR conducted in addition to the ABR measure and 17 children had only an ASSR completed. This amounts to a total of 93 ASSR measures completed. Age of completion of ASSR testing according to province and sector is detailed in Table 3. The age of testing for 4 children is unknown due to date of testing not being included on the reports. The KZN public sector is most likely to conduct ASSR testing, with an increased range and average age of ASSR testing. The youngest average age of ASSR testing is in the Gauteng private sector.

4. Discussion

Studies in South Africa have focused on screening of paediatric hearing loss. A recent study on age of diagnosis in a single province in South Africa concluded that hearing loss was diagnosed significantly earlier in children who had newborn hearing screening [39]. However, tests used for diagnosis of hearing loss were not included as part of this study. The opportunities and possibilities for screening in resource constrained settings, as identified by Petersen and Ramma [40], does not include any mention of diagnosis once hearing loss is identified through screening. Due to the continued lack of focus on diagnosis, this study focused on this gap in knowledge in the EHDI pathway in South Africa by investigating the diagnosis of paediatric hearing loss (including reporting, tests completed and age of completion of each diagnostic procedure).

The geographic spread of the research sample includes 3 provinces that make up more than 50% of the population and is representative of the population statistics in terms of public and private healthcare sectors. The 13% private and 87% public (82% public hospitals and 5% university audiology departments) is very similar to the healthcare sector spilt of 86% public and 14% private sector reported by Theunissen and Swanepoel [28]. The high average age of initial testing as well as the large range is indicative of the disparities in services for identification of hearing loss as well as the lack of newborn programmes and thus late age of identification of hearing loss.

The difference in the provision of audiology services across healthcare sectors is evident in terms of the range of reporting types, with a large number of public institutions using assessment templates and summary records and the private sector being more likely to provide formal reports detailing procedures and results from testing. This is evidence of the shortage of staff at public hospitals as has been previously reported [28], and could result in compromised quality of care across the sectors. The primary function of record keeping is the support of patient care [33], and data sharing between different professionals involved in management of the child's hearing loss. The understanding that geographic and socioeconomic barriers should not have an effect on quality of services [33] means that quality of services (and data for evaluation of services) should be equitable across healthcare sectors as well as provinces.

The importance of data management and recording is highlighted by the number of children requiring additional audiology sessions due to middle ear infections requiring referral to an ENT specialist. A factor that is important in a third world context where ear infections are common amongst the paediatric population, is the availability of ENT specialists for referral and treatment, should this be necessary. This will have an effect on diagnostic appointments, as ear infections will have an effect on accuracy of electrophysiology testing as well as behavioural audiology testing results. It is also therefore important that the test battery include all tests for differential diagnosis and classification and accurate reporting thereof.

Table 3
ASSR diagnostic testing.

ASSR testing										
Age group	GT Public	KZN Public	WC Public	GT Private	KZN Private	WC Private	GT Univ.	KZN Univ.	WC Univ.	Total
Birth to 4 months		2 (5%)	1 (5%)	1 (6.5%)	–	–	–	–	–	4 (4%)
5–24 months	3 (20%)	2 (5%)	6 (32%)	9 (60%)	2 (50%)	–	1 (50%)		–	23 (25%)
25–36 months	2 (13%)	4 (11%)	8 (42%)	4 (27%)	1 (25%)	–	1 (50%)	1 (100%)	–	21 (23%)
37–60 months	8 (53%)	20 (54%)	2 (10.5%)	1 (6.5%)	–	–	–	–	–	31 (33%)
>60 months	1 (6.5%)	9 (24%)	–	–	–	–	–	–	–	10 (11%)
Unknown	1 (6.5%)	–	2 (10.5%)	–	1 (25%)	–	–	–	–	4 (4%)
n	15 (100%)	37 (100%)	19 (100%)	15 (100%)	4 (25%)	–	2 (100%)	1 (100%)	–	93 (100%)
Average	39.4	49.9	26.1	20.5	22.3	–	24.5	–	–	39.1
Std Dev	13.6	25.6	11.5	10.2	6.7	–	3.5	–	–	21.2
Range (months)	4–66	1–142	8–48	2–37	18–30	–	22–27	35	–	1–142

The number of children having a tympanometry measure completed (72%), of which 33% had an acoustic reflex measure completed, indicates the small percentage that had a complete evaluation of the middle ear system, and for whom assistance with confirmation of thresholds and differential diagnosis of auditory neuropathy was possible.

Diagnostic guidelines recommend physiologic assessment of younger children (using auditory evoked potentials, such as the ABR), with behavioural assessment such as VRA being applicable from 5 months of age [15].

With an increase in age and as the child's response to sound becomes clearer and easier to measure and quantify, behavioural testing is used more frequently as part of the diagnostic process. However, electrophysiological testing, including the Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR), are often used as objective confirmation of results from behavioural testing. For behavioural evaluation of response to sound, 14 children (6%) had an assessment of their response to noisemakers.

Noisemakers are an unreliable assessment of hearing and do not provide any diagnostic information. Neither frequency specific nor ear specific information is obtained using this method. From the age of 6 months a child can be conditioned to respond to frequency specific behavioural testing.

In the USA, for children over 6 months of age most audiologists are comfortable using behavioural audiometry to monitor hearing levels and gain from amplification [35]. In South Africa this may not be the case. There appears to be more use of electrophysiology testing for children up to 4 years of age. Whether this is because of a lack of equipment for VRA, difficulty with conditioning of clients or because of audiology training courses will have to be determined. In addition, bone conduction testing was completed on only 22 (9.5%) of children in the sample. had bone conduction testing completed. For 90.5% of children in this sample the diagnosis and classification of hearing loss was based on an incomplete assessment process. A possible reason for assessments being incomplete is the number of appointments required for accurate behavioural testing results to be obtained. In a busy public hospital, there is a need to fit in as many appointments as possible, and for results to be obtained quickly. Electrophysiology testing may thus be a more feasible option in terms of time constraints.

However, Hyde [34] states that 'estimation of threshold' when using tone-pip ABR is dependent on tester accuracy, stimulation and recording parameters, baby management, test strategy and tactics as well as the audiologist's caseload. Other important factors related to electrophysiology testing, as found in the Larsen et al. [12] study include the use of sedation for electrophysiology, availability of support personnel for sedation, protocols for sedation in terms of parent consent and the effect of sedation for electrophysiology on waiting times for diagnostic appointments. The contrast of the KZN public sector having the highest average age of ABR AC testing, while the KZN private sector had the lowest average age is indicative of the differences in audiology services across the private and public sectors.

93 children had ASSR testing for estimation of thresholds, with 17 of these children having had ASSR testing without ABR testing. The accuracy of the threshold estimation is dependent on the age of the subject as well as the actual behavioural threshold, with the ASSR being on average 23–31 dB greater than the behavioural threshold in young children [36]. ASSR accuracy can be improved by extending the duration of the recording [37], but when testing infants and children this may not always be possible. In addition, for children who did not have an ABR measure there was no evaluation of the neurological system before the use of ASSR for thresholding purposes.

Don and Kwong [38] caution that although electrophysiological response to sound and auditory perception are both as a result of electrical activity in the brain, auditory perception is measured using an overt motor response to sound while electrophysiology measures synchronised neural activity in the auditory system. Physiologic testing using auditory evoked potentials (AEPs) is not a direct measure of hearing and should be complemented with behavioural testing as a measure of the actual response to sound.

5. Conclusion

Diagnostic audiology is an important component of the EHDI pathway in that it provides the link between screening and further management and intervention for the child with a hearing loss. The difficulty is in obtaining accurate diagnostic information for the paediatric population where there is a need for both objective testing (electrophysiology) and subjective confirmation of the child's actual physical response to sound. The test battery for paediatric diagnostic audiology thus has to provide information for accurate differential diagnosis. This has shown to be a challenge internationally, with South African paediatric audiology having its own unique challenges (in addition to limited comprehensive studies in this specific area). This study highlighted the late age of diagnosis, lack of use of a comprehensive test battery for diagnosis and increased use of electrophysiology testing on older children due to being unable to condition children for behavioural testing. These are issues that require further investigation.

The differences indicated in this study across the regions of Gauteng, Kwazulu Natal and Western Cape indicates that services across regions and across the public and private sector are not equitable. Each region is equally unlikely to complete a full, comprehensive diagnostic evaluation on paediatric clients. While opportunities and novel ideas for screening have been identified, further research is necessary to determine if South Africa is ready to cope with the resources, personnel and logistics necessary for accurate and timely diagnosis of paediatric hearing loss.

It is only once the process of diagnosis, audiological management and intervention are in place that the benefits of early screening will be evident.

This study was limited to audiology records of children referred to an early intervention programme (referral to which is not mandated by legislation and is at the discretion of the audiologist) and limited to 3 provinces. Further national studies are necessary to get an accurate depiction of diagnostic procedures employed. An understanding of the diagnostic procedures used and how they relate to the South African situation (in terms of healthcare, equipment, staff and linguistic issues), will provide information on factors that are preventing adherence to international best practice guidelines for paediatric diagnostic audiology and allow for contemplation of how these challenges can be overcome.

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Conclusion

From analysis of the diagnostic audiology records that were available for 230 children, it was evident that there is no standard reporting method in the field of diagnostic audiology in South Africa. The differences and lack of equity in diagnostic audiology practice across the regions Gauteng, Kwazulu Natal and Western Cape was highlighted. Each region is equally unlikely to complete a full, comprehensive diagnostic evaluation on paediatric clients.

The increased age of testing, as well as increased use of electrophysiology on older children, in addition to the lack of equity of services were highlighted as challenges needing attention in South Africa. These variations are noted, despite South Africa having a guideline document outlining recommended tests to be completed for paediatric diagnostic testing.

Since there is no accountability and tracking system in place to assess the performance and effectiveness of EHDI programmes, there is no way to determine the compliance with recommended guidelines as set out in the HPCSA (2007) EHDI position statement (for diagnosis of children aged 0-36 months). The next part of this study focused on the tests used in the diagnosis of hearing loss for 171 children that fell within this age range.

Article 3

Moodley, S. & Störbeck. C. (2016). Diagnostic hearing testing of infants aged 0-36 months in 3 South African provinces - Comparison of audiology records to HPCSA guidelines. *International Journal of Pediatric Otorhinolaryngology, 91,* 152-158.

Introduction to Article 3

Development of and adherence to recommended practice guidelines is aimed, among other things, at improving quality of care, and enhancing service provider accountability (Hyde, 2010).

Internationally, the importance of ensuring accurate diagnosis and subsequent early intervention as a follow on from birth screening, to ensure children with hearing loss have equal opportunities for development, led to the development of the American and British diagnostic guidelines. However, the reality (in terms of actual practice and procedures used for diagnosis of paediatric hearing loss) is that the guidelines are not always adhered to.

South Africa developed the HPCSA EHDI position statement (including guidelines for screening and diagnostic testing for the 0-36 month age group), modelled closely on the American JCIH (2000) position statement. As indicated in Article 1 (Moodley & Störbeck, 2015) there are limited studies related to diagnostic practice and data management. Additionally, adherence to HPCSA diagnostic guidelines has not been extensively researched. Following on from Article 2 indicating the increased age of testing and the limited use of a comprehensive test battery, this paper looked at how the current processes followed in diagnosis of paediatric hearing loss compares to the HPCSA guidelines for diagnostic audiology testing for the 0-36 month age group.

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Diagnostic hearing testing of infants aged 0–36 months in 3 South African provinces – Comparison of audiology records to HPCSA guidelines

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ABSTRACT

Introduction: Within the Early Hearing Detection and Intervention (EHDI) pathway, which includes the processes of screening, diagnosis and intervention for paediatric hearing loss, paediatric diagnostic audiology involves a battery of specific tests and procedures. International studies have highlighted a golden standard for diagnosis of paediatric hearing loss as based on the Joint Committee of Infant Hearing (2007) diagnostic guidelines, closely resembling the HPCSA diagnostic guidelines. There are limited South African studies on the processes and protocols followed in diagnostic paediatric audiology.
Objectives: This study aims to provide a comparison for how the tests used for diagnosis of paediatric hearing loss in South Africa (within both the public and private healthcare sectors) compare to the HPCSA recommended diagnostic guidelines.
Methods: A retrospective record review of paediatric clients with hearing loss (recruited through non-probability convenience sampling) was conducted. This study is part of a longitudinal study of 711 deaf or hard of hearing children referred to the HI HOPES early intervention programme from September 2006 to December 2011. Diagnostic data from audiology reports of 117 children between 0 and 36 months were coded and analysed.
Results: Large variation was found in the tests included in the diagnostic audiology reports. For 22 children (19%) a comprehensive test battery was used. Health Professions Council of South Africa (HPCSA) recommended guidelines for diagnostic testing were not followed in any of the records analysed. Components of the HPCSA recommended test battery most frequently omitted was bone conduction testing. For both electrophysiology and behavioural testing, there was limited frequency specificity information. This exclusion of information is evidence of deficiencies in data recording and management, as well as having an effect on accuracy of classification of degree and type of hearing loss.
Conclusion: There are gaps in age-appropriate assessment protocols, which will have an effect on accurate differential diagnosis of paediatric hearing loss. Reasons for not including all testing components of the HPCSA recommended guidelines, as well as the possibility of developing guidelines more relevant to a developing world context, should be explored. There might be a need for. The impact of South African specific factors that have an effect on provision of accurate paediatric diagnostic audiology services should be determined.

1. Introduction

Within the field of paediatric audiology, the Early Hearing Detection and Intervention (EHDI) pathway includes a battery of specific tests and procedures used in the process of screening, identification and diagnosis of paediatric hearing loss, followed by the provision of the required early intervention services. Once children are screened (using quick and efficient techniques such as Automated Auditory Brainstem Response (AABR) and/or otoacoustic emission (OAE) screening) and referred for further testing, diagnosis is the next step in the EHDI pathway. The diagnostic process is more technical, requiring specialised equipment and the services of a qualified audiologist to conduct and interpret results

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from diagnostic testing procedures. An accurate and timely diagnosis is necessary for appropriate amplification, planning of early intervention services and future education options [1].

The importance of ensuring accurate diagnosis and subsequent early intervention as a follow on from birth screening, to ensure equal opportunities for development for children with hearing loss, led to the development of the American and British diagnostic guidelines.

The British guidelines for the audiological assessment of babies referred from the newborn screening programme (Guidelines for the Early Audiological Assessment and Management of Babies Referred from the Newborn Hearing Screening Programme Version 3.1) [4] include a comprehensive guide on the order of testing, technical aspects of ABR testing as well as selected case studies of testing situations. The American guidelines (Joint Committee on Infant Hearing Year 2007 Position Statement: Principles and guidelines for early hearing detection and intervention) [5] includes a summary of comprehensive assessments that should be completed on infants birth to 6 months of age, as well as infants and toddlers from 6 to 36 months of age.

In South Africa, the HPCSA (2007) [6] Early Hearing Detection and Intervention Position Statement was closely modelled on the JCIH (2000) [7] position statement and includes a section on recommended tests to be used for diagnosis of paediatric hearing loss in the 0–6 months and 6–36 months age ranges (Table 1).

Different diagnostic tests in the recommended test battery assess different components of the auditory system. Each test contributes a component to understanding the process of hearing for each individual, and where there is a breakdown in the auditory system (outer/middle/inner ear and cochlear/retrocochlear). The results of each test complement each other, provide a means of cross-check of results and a means of differential diagnosis of type and degree of hearing loss.

Development of and adherence to recommended practice guidelines (including the NHSP (2013), JCIH (2007) and HPCSA (2007) diagnostic guidelines) is aimed, among other things, at improving quality of care, and enhancing service provider accountability [8], as well as ensuring diagnostic accuracy. While clinical guidelines for diagnosis are in place internationally, the reality in terms of actual practice and procedures for diagnosis of paediatric hearing loss is that the guidelines are not always adhered to [9].

A recent review of EHDI services in South Africa [15] highlighted the limited studies related to diagnostic practice and data management in South Africa. The procedures and tests used in paediatric diagnostic audiology practice in South Africa have not been determined, as to date there have been isolated small-scale region specific studies [10–14]. A study on audiological practice post HPCSA position statement [16], based on diagnostic data of a small sample (four children), found that there were gaps in age appropriate assessment protocols.

2. Objective

Due to the limited research on paediatric audiology diagnostic testing in South Africa, this study was conducted to determine firstly the current practice for the diagnosis of paediatric hearing loss, and secondly to determine how the practice of diagnostic audiology across the public and private healthcare sectors in three provinces compares to HPCSA recommended guidelines.

The objectives of the study were to:

1) Outline the comprehensiveness of paediatric diagnostic audiology testing across the public and private healthcare sectors and determine any differences.
2) Document the age of and frequency specificity of electrophysiology testing across the public and private healthcare sectors
3) Document the age and frequency specificity of behavioural testing across the public and private healthcare sectors

3. Methods

3.1. Research design

A retrospective record review of 711 deaf and hard of hearing infants was conducted. The sample (recruited through non-probability convenience sampling) was from the longitudinal

Table 1
Recommended tests for diagnosis of paediatric hearing loss [Based on HPCSA (2007) [6] EHDI Position Statement].

0–6months		6–36 months	
Evaluation	Tests	Evaluation	Tests
Child and family history Electrophysiology testing- (used for obtaining thresholds in this age group)	Case history information - ABR/ASSR using frequency specific stimuli - Diagnostic OAEs	Child and family history Physiologic measures at initial evaluation and subsequent evaluations as necessary (for conformation of thresholds from behavioural testing)	Case history information - OAE - ABR - ASSR
Middle ear functioning	- Tympanometry with high frequency probe tones of 660 or 1000 Hz (preferably 1000 Hz, - Bone conduction ABR/ASSR, and/or pneumatic otoscopy - Acoustic Reflex Thresholds		
Behavioural (for confirmation of thresholds obtained from electrophysiology)	Observation of the infants behavioural response to sound Parental report of emerging communication and auditory behaviours	Behavioural evaluation (used for obtaining thresholds in this age group). Screening of communication and language milestones	Behavioural response audiometry according to child's developmental age; visual reinforcement or conditioned play audiometry - Speech detection and recognition measures - Parental report of auditory and visual behaviours. Appropriate communication and language screening tools

Abbreviations - ABR- Auditory Brainstem Response, ASSR – Auditory Steady State Response, OAE- Otoacoustic Emissions.

dataset of children referred to the HI HOPES early intervention programme from September 2006 to December 2011.

3.2. Sample characteristics

Diagnostic audiology information was available for 32% (n ¼ 230) of the 711 children ranging in age from 1 to 142 months. This study focused only on diagnosis of hearing loss for children between 0 and 36 months of age, yielding a sample size of 117 of the 230 children. Of the 117 children, 5% (n ¼ 6) were in the 0–6 month age range and 95% (n ¼ 111) were between 7 and 36 months.

The geographic spread of the research sample includes three of the nine provinces, namely Gauteng, Kwazulu Natal (KZN) and the Western Cape (WC), where HI HOPES services were available during the period of the study. These three provinces make up more than 50% of the South African population and are representative of the population demographics in terms of public and private healthcare sectors [17]. Provincial breakdown of the sample showed that 63% (n ¼ 74) were from Gauteng, 19% (n ¼ 22) from KZN and 18% (n ¼ 21) from WC. The ethnicity breakdown includes 68% Black (n ¼ 80), 12% Coloured (n ¼ 14), 8% Indian (n ¼ 9) and 12% White (n ¼ 14) children. The gender breakdown of the sample is 48% female (n ¼ 56) and 52% male (n ¼ 61).

17% (n ¼ 20) had audiology testing conducted in the private healthcare sector, whereas 74% (n ¼ 87) were from the public healthcare sector, and 9% (n ¼ 10) were tested at University Audiology departments.

3.3. Procedures

Each child's file was examined to obtain audiology reports that included diagnostic testing information which was then logged onto an excel sheet. Variables logged included all diagnostic audiology tests completed for each child, age of testing, as well as province and healthcare sector.

Based on the tests completed for each individual child, the data were categorised into one of four groups. The groups were based on four categories (partial, incomplete, comprehensive and JCIH recommended) used in a USA study on diagnostic testing [9]. However, this grouping as used by Munoz, Nelson, Goldgewicht & Odell [9] was amended to account for the possibility that frequency specificity of electrophysiology testing might not be included in reports and rather looked at whether components of testing were included. The South African HPCSA guidelines as opposed to the JCIH guidelines were used. The grouping for this study is shown in Table 2, together with the implications of inclusion and exclusion of specific components of the test battery.

3.4. Data analysis

Initial data analysis involved an overview of diagnostic audiology tests completed. Data were initially analysed according to whether electrophysiology testing was completed, to determine the regularity of use of electrophysiology testing methods. Data were then further analysed to indicate frequency specificity of the electrophysiology testing and behavioural testing.

Data analysis included basic descriptive statistics indicating frequencies and percentages. Data were grouped and analysed according to the variables of private vs. public practice and the province in which the practice is located to determine the variation in diagnostic practice with respect to these variables.

3.5. Ethical considerations

This study is part of a larger, longitudinal study on audiology as well as demographic information on a dataset of children with hearing loss enrolled in an early intervention programme in South Africa. Parents have signed consent forms providing permission to access all data, including paediatric audiology records, to be used for research purposes. To ensure privacy and confidentiality of data, all identifying information from the audiology records were replaced with a coding system for tracking and storage of information.

Table 2
Categories of testing (adapted from Munoz, Nelson, Goldgewicht & Odell, 2011).

Category	Tests included	Tests omitted	Implications
Partial testing	Air conduction -behavioural OR Air conduction -electrophysiology	Bone conduction 2 or more of Tympanometry Reflexes Speech testing	Omitting bone conduction as well as tympanometry or reflexes means there is no indication of middle ear status. The possible impact of a conductive component on thresholds is not determined
Incomplete testing	Air conduction -behavioural Tympanometry	Bone conduction No more than 2 of Reflexes Electrophysiology Speech testing	Behavioural air conduction and tympanometry will indicate the level of loss as well as middle ear status. Omission of bone conduction means there is no verification of type of hearing loss. Omission of electrophysiology and speech testing means there is no cross check of behavioural results
Comprehensive testing	Tests recommended in HPCSA position statement (with exception of tests omitted)	Bone conduction OR electrophysiology Reflexes OR speech testing	Omission of bone conduction but inclusion of electrophysiology provides a means of classification of type of hearing loss as does omission of electrophysiology but inclusion of bone conduction. Omission of electrophysiology as well as acoustic reflexes takes away the means for differential diagnosis of auditory neuropathy. Omission of electrophysiology and speech testing means there is no verification of behavioural testing results
Testing recommended by HPCSA	Air and bone conduction -behavioural Air and bone conduction -electrophysiology Tympanometry Reflexes Speech testing		Accurate differential diagnosis of degree and type of hearing loss, with cross-check and verification of results

The University of the Witwatersrand Ethical Clearance Board provided permission for the study of all data and records relating to the early intervention programme.

4. Results

Results from this study will highlight the key issues of diagnosis based on inclusion of tests for accurate classification of the degree and type of hearing loss, as per HPCSA recommended diagnostic guidelines. In addition, the results will focus on the frequency specificity for electrophysiology and behavioural testing, as well as the ages at which electrophysiology and behavioural testing were conducted.

4.1. Comprehensiveness of testing

The audiology testing information provided for the 117 children included in this study were assessed for comprehensiveness of the test battery used for diagnosis. The completeness of testing based on the four categories, as indicated in the section on procedures, is outlined in Table 3. This initial analysis does not include the criteria of frequency specific information, but only assesses the inclusion of tests in the battery for diagnosis of hearing loss.

While 19% (n ¼ 22) of diagnostic audiology testing in this sample included a comprehensive test battery, HPCSA recommended guidelines were not followed in any of the 117 infants' diagnostic testing. Components of the HPCSA recommended test battery most frequently omitted was bone conduction testing (n ¼ 114). Within the three provinces and two healthcare sectors "partial testing" was the most frequent category.

4.2. a) Age of electrophysiology testing

Ninety four of the 117 children (80%) had air conduction electrophysiology testing included as part of the diagnostic battery. The age of air conduction electrophysiology testing is included in Table 4.

The KZN public and WC public sectors start conducting electrophysiology testing at a younger age than the private healthcare sectors in their respective provinces. The Gauteng public and private sectors conducts the majority of testing in the 25–36 month age range.

Three children (two with atresia) had bone conduction electrophysiology testing. All three children were from Gauteng, two from the public healthcare sector and one from the private healthcare sector. Average age of BC testing was 18 months (±8.9).

4.3. b) Frequency specificity of electrophysiology testing

The frequency specificity of electrophysiology testing is outlined in Table 5.

Only 3 (3%) children had all frequencies from 250 Hz to 8000 Hz completed. Nine children had only 1 frequency completed (10%) with the large majority being 39 (41%) where two and three frequencies were used. 26 children (28%) had electrophysiology testing based on tone burst information. There were no details of frequency specificity for 13 children (14%) who had electrophysiology testing.

Bone conduction frequency specificity included a click ABR for two children and frequencies of 500 Hz and 8000 Hz tone burst information included for one child.

4.4. a) Age of behavioural testing

Air conduction behavioural testing was included in the diagnostic test battery of 60 children (51%) in this sample. The age and provincial breakdown of behavioural testing is outlined in Table 6.

For twelve children (20%) the age of behavioural testing was not provided. The statistics on behavioural testing are thus limited to the 48 children where this information is available.

Behavioural testing was used for one child in the birth to 4 month age range, indicating very limited use of behavioural observation audiometry in this sample.

The Gauteng private sector has the lowest average age of behavioural testing, with the KZN public sector conducting behavioural testing in the 5–24 month age range. However, KZN public sector also has the largest percentage (73%; n ¼ 8) of children where the age of behavioural testing was not provided. Behavioural testing was included in the test battery of only one child each in the KZN private sector and KZN university sector. The WC public sector conducts behavioural testing most frequently in the 25–36 month age range.

Table 3
Comprehensiveness of testing.

Diagnostic testing categories	Public (n ¼ 87)			Private (n ¼ 20)			University (n ¼ 10)			Total (n ¼ 117)
	Gauteng (n ¼ 48)	KZN (n ¼ 18)	WC (n ¼ 21)	Gauteng (n ¼ 17)	KZN (n ¼ 3)	WC (n ¼ 0)	Gauteng (n ¼ 9)	KZN (n ¼ 1)	WC (n ¼ 0)	
Partial	31 (64.5%)	12 (67%)	14 (67%)	11 (64.5%)	3 (100%)	–	6 (67%)	1 (100%)	–	78 (66.5%)
Incomplete	9 (19%)	2 (11%)	3 (14%)	2 (12%)	0 (0%)	–	1 (11%)	0 (0%)	–	17 (14.5%)
Comprehensive	8 (16.5%)	4 (22%)	4 (19%)	4 (23.5%)	0 (0%)	–	2 (22%)	0 (0%)	–	22 (19%)
HPCSA recommended	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	–	–	0 (0%)	–	0 (0%)

Table 4
Age of AC electrophysiology testing.

Age of AC electrophysiology	Public			Private			University			Total
	Gauteng (n ¼ 35)	KZN (n- ¼ 15)	WC (n ¼ 16)	Gauteng (n ¼ 7)	KZN (n ¼ 3)	WC	Gauteng (n ¼ 8)	KZN (n ¼ 1)	WC	N¼(94)
Birth to 4 months	0 (0%)	2 (13.5%)	1 (6%)	1 (6%)	0 (0%)	–	0 (0%)	0 (0%)	–	4 (4%)
5–24 months	15 (43%)	5 (33%)	9 (56%)	8 (50%)	2 (67%)	–	5 (62.5%)	50 (0%)	–	44 (47%)
25–36 months	19 (54%)	8 (53.5%)	6 (38%)	7 (44%)	1 (33%)	–	3 (37.5%)	1 (100%)	–	45 (48%)
Unknown	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	1 (1%)
Average Age	24.2	22.6	22.5	18.6	22.3	–	20.4	–	–	22.4
Std Dev	8.3	11.1	9.7	9.4	6.7	–	9	–	–	9.3
Range	7–36	1–35	4–36	2–34	18–30	–	5.-31	–	–	1–36

Table 5
Frequency specificity of air conduction electrophysiology testing.

Missing frequency components electrophysiology (Hz)	Public (n ¼ 66)			Private (n ¼ 19)			University (n ¼ 9)			Total (n ¼ 94)
	Gauteng (n ¼ 35)	KZN (n ¼ 15)	WC (n ¼ 16)	Gauteng (n ¼ 16)	KZN (n-3)	WC	Gauteng (n-8)	KZN (n ¼ 1)	WC	
All completed	0 (0%)	3 (20%)	0 (0%)	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	3 (3%)
8000	3 (9%)	3 (20%)	0 (0%)	3 (19%)	0 (0%)	–	0 (0%)	0 (0%)	–	9 (10%)
250, 8000	2 (5.5%)	5 (33%)	10 (63%)	10 (63%)	3 (100%)	–	0 (0%)	0 (0%)	–	30 (32%)
500, 8000	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	1 (1%)
250, 4000	0 (0%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	–	0 (0%)	0 (0%)	–	1 (1%)
250, 2000, 4000	0 (0%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	–	1 (12.5%)	0 (0%)	–	2 (2%)
250, 4000, 8000	0 (0%)	1 (7%)	1 (6%)	0 (0%)	0 (0%)	–	1 (12.5%)	0 (0%)	–	3 (3%)
2000, 4000, 8000	2 (5.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	2 (2%)
250, 1000, 2000, 4000	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	–	4 (50%)	0 (0%)	–	4 (4%)
No frequency specificity (clicks)	21 (60%)	3 (20%)	1 (6%)	0 (0%)	0 (0%)	–	1 (12.5%)	0 (0%)	–	26 (28%)
No details	6 (17%)	0 (0%)	4 (25%)	1 (6%)	0 (0%)	–	1 (12.5%)	1 (100%)	–	13 (14%)

Table 6
Age of air conduction behavioural testing.

Age of AC behavioural testing	Public (n ¼ 48)			Private (n ¼ 7)			University (n ¼ 5)			Total (n ¼ 60)
	Gauteng (n ¼ 29)	KZN (n ¼ 11)	WC (n ¼ 8)	Gauteng (n ¼ 6)	KZN (n-1)	WC (n ¼ 0	Gauteng (n-4)	KZN (n ¼ 1)	WC (n ¼ 0)	
Birth to 4 months	1 (3.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	1 (2%)
5–24 months	9 (31%)	3 (27%)	2 (25%)	4 (67%)	0 (0%)	–	1 (25%)	0 (0%)	–	19 (31.5%)
25–36 months	16 (55%)	–	5 (62.5%)	2 (33%)	1 (100%)	–	3 (75%)	1 (100%)	–	28 (46.5%)
Unknown	3 (10%)	8 (73%)	1 (12.5%)	]0 (0%)	0 (0%)	–	0 (0%)	0 (0%)	–	12 (20%)
Average age	26.2	16.7	27.9	22.5	–	–	27.3	–	–	25.4
Std dev	7.6	5.9	9.3	8.8	–	–	4.5	–	–	7.7
Range	4–35	10.-21	9–36	13–34	–	–	22–33	–	–	4–36

Bone conduction behavioural testing was completed for 3 children, all from the public healthcare sector (with two in the Western Cape and one in Kwazulu Natal). The average age of bone conduction behavioural testing was 22.3 months (±13.1).

4.5. b) Frequency specificity of behavioural testing

The frequency specificity of behavioural testing was not included in reports for 48% (n ¼ 29) of this sample (Table 7). As with electrophysiology testing this lack of information is evidence of poor data recording and management as well as having an effect on accuracy of classification of degree and type of hearing loss. All frequencies from 250 Hz to 8000 Hz is completed for only 17% (n ¼ 10) of this sample.

5. Discussion

Diagnostic audiology is the component of the EHDI pathway that provides the link between screening and further management and intervention for the child with a hearing loss. Accurate diagnostic evaluation is necessary for amplification options, programming of hearing aids, and communication methodology options. The test battery for paediatric diagnostic audiology thus has to provide information for accurate differential diagnosis. The challenge is in obtaining accurate diagnostic information for the paediatric population where there is a need for both objective testing (electrophysiology) and subjective confirmation of the child's actual physical response to sound. This has shown to be a challenge internationally, with South African paediatric audiology having its own unique challenges including difficulty conditioning children due to linguistic and cultural differences, data management difficulties, staff and equipment challenges as well as limited comprehensive studies in this specific area.

Diagnostic audiology is composed of a comprehensive system for assessment of each component of the auditory pathway. Each test provides an important part of a cross-check for assessing and evaluating results from each diagnostic procedure employed, as well as providing a means for accurate classification of the degree and type of hearing loss. Standardisation of procedures and tests and inclusion of information in records is important so that other

Table 7
Frequency components not included- Air Conduction- Behavioural testing.

Missing frequency components (Hz) behavioural air conduction	Public (n ¼ 48)			Private (n ¼ 7)			University (n ¼ 5)			Total (n ¼ 60)
	Gauteng (n ¼ 29)	KZN (n ¼ 11)	WC (n-8)	Gauteng (n ¼ 6)	KZN (n ¼ 1)	WC (n ¼ 0)	Gauteng (n ¼ 4)	KZN (n ¼ 1)	WC (n ¼ 0)	
250	1 (3.5%)	–	–	–	–	–	–	–	–	1(2%)
8000	2 (7%)	2 (18%)	1 (12.5%)	–	–	–	–	–	–	2 (8%)
250, 2000.	–	–	–	1 (17%)	–	–	–	–	–	1 (2%)
250, 8000	2 (7%)	–	2 (25%)	1 (17%)	–	–	1 (25%)	–	–	6 (10%)
4000,8000	1 (3.5%)	1 (9%)	1 (12.5%)	–	1 (100%)	–	–	–	–	4 (7%)
500,8000	–	–	–	–	–	–	–	1 (100%)	–	1 (2%)
All completed	7 (24%)	1 (9%)	–	2 (33%)	–	–	–	–	–	10 (17%)
Could not condition	2 (7%)	–	–	–	–	–	1 (25%)	–	–	3 (5%)
No details	14 (48%)	7 (64%)	4 (50%)	2 (33%)	–	–	2 (50%)	–	–	29 (48%)

service providers are able to accurately interpret information and provide comprehensive services [20] (Campbell & Hyde, 2010). The inclusion of behavioural and electrophysiology testing procedures is thus important to provide an objective means of assessment as well as an indication of the actual behavioural response to sound.

The HPCSA guidelines recommend physiologic assessment of younger children. Physiologic assessment requires that a child be very still (asleep or sedated) to reduce movement artefact, access to specific electrophysiology equipment, and setting up and appropriate adjusting of recording parameters. The increased age of electrophysiology testing for this sample indicates the number of children who would require sedation and the medical personnel and medical equipment (such as specialised paediatric resuscitation equipment) necessary to ensure safety during sedation.

With electrophysiology testing, 72% of this sample had missing threshold information for 250 Hz and 4000 Hz. Click stimuli (that applies to 28% of this sample) is based on information that activates a greater portion of the cochlear partition and a larger number of neural components (with larger amplitude for wave detection), but has limited frequency specificity [19]. This poses difficulties with overestimating thresholds with a sloping hearing loss. These children have a classification of degree and type of hearing loss based on incomplete information which might lead to inaccuracies. This could have an effect on aural rehabilitation options as well as communication and language development of the child.

Behavioural testing is dependent on appropriate equipment e.g. visual reinforcement materials for VRA, as well as audiologists skilled in conditioning a child to respond to tones and in accurately detecting response to sound. The age of behavioural testing as well as the cultural diversity of the sample shows the need for audiologists able to condition children who might speak a different language, an audiologist to condition the child and an audiologist to conduct the test, in addition to appropriate visual reinforcement equipment. Adherence to clinical guidelines is thus dependent on resources, equipment and personnel available. Behavioural testing frequencies not included as part of the diagnostic battery for this sample are 250 Hz, 4000 Hz and 8000 Hz. This will have an effect on programming of hearing aids for the low and high frequencies, and thus have an effect on the child's access to the complete speech spectrum.

The programing of aids with partial or incomplete testing (behavioural or electrophysiology) means that amplification programming will be affected and benefit from amplification might not be optimal. In this sample, 81% fell into the category of partial and incomplete testing.

6. Conclusion

Diagnostic audiology is the link between identification of hearing loss and provision of amplification and intervention services, so as to ensure appropriate choices in terms of communication methodology, education options and future development of the child. As found in Kanji and Opperman [16], there are gaps in age-appropriate assessment protocols, which will have an effect on accurate diagnosis of paediatric hearing loss. This will have an effect on amplification options, programming of hearing aids, aural rehabilitation, communication modality options and early intervention. The inclusion of all aspects of the recommended guidelines for diagnosis is thus an important aspect for the accurate differential diagnosis of the degree and type of hearing loss.

Reasons for not including all testing components of the HPCSA recommended guidelines should be explored in order to determine if this is due to lack of resources and equipment, or due to audiologists feeling that the tests excluded are not relevant for accurate diagnosis. This will inform the needs for allocation of additional resources and equipment, additional audiology training or a reworking of the HPCSA recommended guidelines.

The HPCSA recommended guidelines are currently based on the JCIH (2000) guidelines for diagnostic testing in a developed world context. There might be a need for development of guidelines in a developed world context, where children are being tested at older ages, and there is less availability of medical personnel and equipment. Guidelines for a South African specific, developing world context might include a decreased need for electrophysiology testing as older children, who are able to be conditioned for behavioural testing, may not require electrophysiology. If analysed from this ' developmental' perspective, the large number of children that had comprehensive testing completed would then be included in the category of recommended diagnostic testing. However, a focus on behavioural testing for older children would present challenges related to staff resources and conditioning of second language English speakers, as well as further training of audiologists to conduct accurate behavioural testing for the paediatric population. A focus on behavioural testing could be a solution to the challenge of sedating older children (together with the extra resources required for this) for electrophysiology testing.

This study has looked at diagnostic audiology data over a period of five years (2006–2011), in three provinces. Studies on the current status of paediatric diagnostic audiology in a national context will provide an indication of the national status quo of paediatric diagnostic audiology, what progress has been made (in the three provinces studied) and factors that are aiding or hindering progress. Development of task teams related specifically to how challenges related to the field of paediatric diagnostic audiology can be addressed will be an initial step towards making improvements in the field of paediatric diagnostic audiology.

Author contributions

This article is part of the first author's PhD write-up, which was funded by the University of the Witwatersrand. The second author is the study supervisor and assisted with study conceptualisation, article write-up and editing.

Competing interests

The authors declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this article.

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Conclusion

This article highlighted the limited adherence to recommended guidelines for paediatric diagnostic audiology testing in three provinces of South Africa. Recommendations from this article include the identified need for developing guidelines for diagnostic testing that might be more suitable for a developing world context. This would possibly reduce the need for the extra resources and cost of electrophysiology testing and a focus on more rigorous training of audiologists to conduct behavioural testing.

However, electrophysiology testing on older children will still need to be conducted on children that cannot be conditioned for behavioural testing. This then will require the use of sedation and, as with guidelines for diagnostic testing, there are guidelines for paediatric sedation. Since paediatric sedation is a necessary component of the paediatric diagnostic testing process for older children, it is important to determine the protocols used for sedation during paediatric diagnostic audiology testing. The next research paper, therefore, focuses on the sedation practice of audiologists when conducting auditory electrophysiology testing.

Article 4

Moodley, S. & Störbeck. C. (2016). Sedation for paediatric auditory electrophysiology in South Africa. *Southern African Journal of Anaesthesia and Analgesia, 1*(1):1–5.

Introduction to Article 4

The diagnostic audiology reports of children undergoing auditory electrophysiology testing were examined to extract sedation information. Since the audiology report is often the only information taken to subsequent appointments for diagnosis or for a second opinion, the researcher felt it was important to analyse the information that was included in the audiology reports. Sedation information that was logged included whether children were sedated or not, medication used for sedation, dosage of medication and whether there was medical monitoring during the sedation process.

Sedation information was available for 61 children, which forms the dataset for the following paper.

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RESEARCH

Sedation for paediatric auditory electrophysiology in South Africa

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Background: The sedation of children in the medical and allied professional fields has been a topic of controversy and debate internationally. Limited information is available on the use of sedation for auditory electrophysiology testing in South Africa.
Objectives: The aim of this study was to determine how sedation information is recorded in electrophysiology audiology reports where diagnostic electrophysiology testing was used, and to obtain baseline information on sedation procedures and medications used during diagnostic electrophysiology testing.
Methods: Audiology reports of 169 children undergoing auditory electrophysiology testing were reviewed for sedation information.
Conclusion: Sedation data is not clearly documented and the use of medical or anaesthetist monitoring during sedation is not routinely included in reports. Sedation medication is varied and does not always include medications listed as safe for use with the paediatric population. This places doubt on procedures and protocols as well as the safety mechanisms in place for auditory diagnostic testing of children in South Africa.

Keywords: auditory electrophysiology, diagnostic audiology, sedation

The sedation of children for diagnostic and therapeutic procedures has been a topic of controversy and debate within the medical world for the last decade[1] with the acknowledgement that paediatric sedation is a challenge encountered across all continents.[2]

Included in the controversial discussions is the increase in demand for paediatric sedation outside the operating room.[3] The variety of medical locations requiring sedation services includes radiology, dentistry, paediatric inpatient services, emergency departments and nuclear medicine.[1] Added to this is the periodic need for sedation with diagnosis in allied medical professions such as optometry, audiology and physiotherapy. In paediatric audiology, sedation is used during diagnostic electrophysiology testing.

Diagnostic electrophysiology testing includes measures such as the Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR). ABR is an electrophysiological far-field recording used for assessment of the integrity of the auditory system and for threshold estimation in young children and difficult-to-test populations, while ASSR systems are programmed to use statistical measures to determine hearing thresholds.[4] Both ABR and ASSR recordings require the child to be very still during recording to reduce movement stimulus artefact. Electrophysiology testing may be conducted under one of three different conditions[5]: (1) during the natural deep sleep for infants (0–6 months); (2) using conscious sedation medication such as chloral hydrate (which requires monitoring of heart rate, respiration, oxygen saturation and blood pressure by a nurse or physician), or the synthetic form of a naturally occurring substance called melatonin, which does not require medical monitoring — the child may be tested in the therapy room or theatre; and (3) using general anaesthesia where there is a drug-induced loss of consciousness, patients are not rousable and cardiorespiratory function may be impaired.[6]

Whether for surgery, diagnostic testing or therapeutic procedures, sedation is also associated with certain possible risks and therefore there are specific guidelines for medical monitoring throughout the sedation process.[5] The risks associated with sedation include the possibility of adverse events such as neurologic injury, airway obstruction and even death.[6] Risks are related to the sedation medication used, dosage administered and the availability of medical personnel for monitoring of the child during and after sedation administration. Yet, there is currently a lack of legislated standards (that are able to be monitored and enforced) for what is effective and safe practice.[7]

South African guidelines for the safe administration of paediatric sedation have been developed, including: drugs recommended, essential equipment, recommendations for monitoring based on the sedation methods used, discharge criteria, and recommended documentation before and after sedation.[10] However, this is a guideline document and is based on recommended practice. The importance of regulated sedation practice is further highlighted as the demand for sedation outside the operating room has increased, together with the need for nurses and paediatric specialists to deliver sedation.[1] The need for monitoring of patients through the sedation procedure and ability to assist with resuscitation (if necessary) is important, as is practitioners' understanding of the pharmacology of the sedative agents and possible adverse effects.[7]

The use of sedation and general anaesthesia for auditory electrophysiology specifically has not been extensively studied. In developed countries ABR testing is conducted as part of diagnostic testing soon after a referral from a newborn hearing screening programme, and thus may be conducted in the 0–6-month age period when the child is able to enter a deep natural sleep. With older children (beyond the age of six to nine months for whom deep sleep is not easily achieved) the need for sedation or general anaesthesia may be increased to reduce the natural movement artefact and thereby get a more accurate ABR

or ASSR recording. In South Africa, it has been found that auditory electrophysiology testing is conducted on older children[9] and there is thus an increased need for the use of sedation. Studies on the use of sedation and anaesthesia for auditory electrophysiology in the paediatric population in South Africa were not found.

Objectives

The aim of this study was twofold: (1) to determine the recording of sedation information in audiology reports where diagnostic electrophysiology testing was used, and (2) to obtain baseline information on sedation medications used and medical monitoring during the sedation process.

Methods

This study forms part of a larger retrospective review of the diagnostic audiology records of 711 children referred to the HI HOPES Early Intervention programme from September 2006 to December 2011.[18] The sampling method was convenience sampling of audiology records that were available from the programme.

Study population

Of the 711 children referred to the programme 532 children (75%) were identified as having sufficiently complete data for research purposes and are included in the larger research study relating to paediatric hearing loss and early intervention.[18] Of these 532 children, 230 children (43%) in the sample had comprehensive diagnostic audiology reports included as part of their data. These diagnostic audiology reports were reviewed and 171 of the 230 children (74%) were identified as having an electrophysiology test completed as part of their diagnostic audiology evaluation. Sedation data information on 171 children undergoing auditory electrophysiology testing thus forms the sample for this study. Geographically, 101 children (59%) were from Gauteng, 50 children (29%) were from KZN and 20 children (12%) were from the Western Cape. Testing occurs in various settings, and in our sample 22 children (13%) had electrophysiology testing in public sector audiology departments, 134 children (78%) were tested in private audiology consulting rooms and 15 children (9%) at university audiology departments. The sample is representative of our national sample (n = 532) records, with Gauteng having the largest number as it is the province in which the early intervention programme was first implemented.

Procedures

The audiology records of the 171 children identified as having electrophysiology testing conducted were accessed. The sedation data of these children was extracted from the general audiological data included in the audiology reports and was logged according to four variables: (1) number of times the child was sedated, (2) sedation medication used, (3) dosage information and (4) medical monitoring of the children during the sedation procedure.

Data analysis

The data were transferred to a Microsoft Excel® (Microsoft Corp, Redmond, WA, USA) spreadsheet for analysis. Data analysis techniques included basic descriptive statistics including average values, standard deviation, frequencies and percentages.

Ethics

All families gave written consent for all data, including paediatric audiology records, to be used for research purposes. Permission for the study of all data and records relating to the early intervention programme was provided by the University of the Witwatersrand Ethical Clearance Board. All identifying information from the paediatric audiology records was removed by the early intervention programme and a coding system for tracking and storage of information for data analysis was used so as to ensure privacy and confidentiality of data.

Table 1: Sedation method and age of sedation

Sedation method	No sedation		Sedation			
	Natural sleep		General anaesthetic		Conscious sedation	
	(n = 7)		(n = 6)		(n = 48)	
	Public Sector	Private Sector	Public Sector	Private Sector	Public Sector	Private Sector
n	5	2	2	4	41	7
Average age (months)	40.8	9.0	48	25.8	40.0	27.7
Standard deviation	33.7	2.8	25.5	16.9	18.6	5.8
Range	9–90	7–11	30–66	15–51	7–87	18–32

Results

The audiology records of the 171 children undergoing diagnostic electrophysiology testing were reviewed for information on the use of sedation for auditory electrophysiology testing. Information related to the use and method of sedation was recorded for 61 (36%) of the sample. For the remaining 110 children (64%) it is not known whether the child was sedated as this information is not included in the audiology reports. Of the 61 children for whom sedation information was provided, seven (11%) children were not sedated and electrophysiology testing was conducted under natural sleep. Six (10%) children had diagnostic electrophysiology testing under general anaesthesia and the remaining 48 (79%) children were sedated using medication for conscious sedation.

The number of children for which each type of sedation method is used as well as the average age of sedation using each method in the public and private sector[1] is given in Table 1.

The data show clearly that conscious sedation is the preferred method of sedation in this sample, with public health making up 85% (41) and private health making up 15% (7) of the 48 children that were sedated using conscious sedation. The private sector showed a greater tendency for general anaesthesia, comprising four of the six children (67%) for whom general anaesthesia was used as a sedation method. Of the 48 children on whom conscious sedation was used, 44 (92%) were sedated once and 4 children (8%) were sedated on two separate occasions for auditory electrophysiology testing. The second sedation was due to the initial sedation not being effective enough to allow for the electrophysiology testing to be completed. For the four children having sedation for a second time, two children had the sedation method changed to general anaesthesia, one child had the sedation dosage increased and for the last child the sedation medication was changed.

The medication and dosage information for each of the 48 children where conscious sedation was used is detailed in Table 2.

Table 2: Medication used for sedation

Conscious sedation			
Sedation medication	**Dosage specified** (n = 19)	**Dosage not specified** (n = 29)	**Total** (n = 48)
Unknown sedative agent			
Medication not stated	–	19 (40%)	19 (40%)
Single sedative agent			
Trimeprazine	12 (25%)	1 (2%)	13 (27%)
Chloral hydrate	3 (6%)	1 (2%)	4 (8%)
Promethazine	3 (6%)	–	3 (6%)
Multiple sedative agents			
Trimeprazine and droperidol	1 (2%)	6 (13%)	7 (15%)
Midazolam and propofol	–	2 (4%)	2 (4%)
Total	19 (40%)	29 (60%)	48 (100%)

There are two different sedation techniques: simple (requires appropriate nil per os status and covers the administration of a single sedative agent) and advanced (encompasses techniques in which multiple sedatives are administered).[2] The South African guidelines for sedation[10] provide a list of recommended sedation medications, which are listed below (before we address the sedation medication used for our sample):

- sedatives in the benzodiazepines category: midazolam (the benzodiazepine receptor agonist);
- anaesthetic agents: ketamine, propofol and 'ketofol' — a combination of propofol and ketamine;
- alpha-agonists: clonidine and dexmedetomidine;
- other (non-categorised) sedative agents: chloral hydrate, trichlorphos, trimeprazine, and droperidol).

The sedative agents used for 45 children (92%) are included in the list of drugs for sedation in South Africa. Promethazine, which was used for sedation of three children (6%), is not included in the list of sedative drugs recommended in the South African Guidelines.[10] Nine (19%) of the children had multiple sedatives administered, of which 8/9 (89%) did not have a dosage specified.

The reports of 4 of the 48 (8%) children indicate medical monitoring by an anaesthetist during the sedation procedure. For the other 44 children (92%) information on anaesthetist or medical monitoring was not provided.

Discussion

Paediatric sedation is a controversial field in which there is considerable debate regarding who should be administering sedation, when sedation should be used, and appropriate sedation medication as well as medical monitoring through the sedation process.[1] The diagnostic audiology records for children who had electrophysiology audiology testing conducted allowed for initial information on sedation within the allied medical profession of audiology to be collected in a South African context. In this discussion we will address three key issues: (1) recording of sedation information in audiology records, (2) sedation medication used and (3) medical supervision during sedation.

Sedation information was available for 61 of 171 children (36%) who had electrophysiology testing conducted. This is evidence of the gaps in recording of sedation information in audiology reports in this data set. Data recording of sedation has been identified as important for gathering baseline information on the safety of anaesthesia, identification of high-risk patients for making informed decisions on patient care, obtaining informed consent from families aware of the anaesthetic-related risks and for the facilitation of research on anaesthetic safety.[11] Access to data records on sedation will allow for planning of future sedation and assess the risk based on previous sedation medication, dosage and any possible adverse effects. This is especially important when it is considered that children may have a number of auditory electrophysiology tests, either to gain complete information or when parents consult a different audiologist for a second opinion.

Paper-based patient records have variations in quality and may result in insufficient information being provided in the referral letter/report as well as the possibility that information may not be provided in time for the primary healthcare providers to be informed of all factors for follow-up care.[12] This is evident in the number of children having conscious sedation medication administered for whom dosage of the medication was not provided (60%) and also for whom the type of medication used was not specified (40%). Insufficient or incomplete information on medication, sedation and dosage used could lead to possible adverse events during the sedation process due to drug combinations and interaction as well as leading to a possibility of a repeat of adverse sedation events in the future. Insufficient or incomplete records also means that there may be inadequate or no information to hand if the patient returns after discharge with a complication potentially related to the sedation.

As per South African paediatric sedation guidelines,[10] trimeprazine and droperidol are not recommended for use in 'outpatient' procedures due to the long duration of action for these drugs.[12] For 27% (n = 13) of this sample trimeprazine was used as a single sedative agent and for a further 15% (n = 7) a combination of trimeprazine and droperidol was used, all of which were done in an 'outpatient' context. These 20 children (42%) in this sample were sedated using medication that is considered to be unsafe for use in an outpatient setting (i.e. trimeprazine and droperidol). In addition, a further 4% (2) were sedated with propofol, which is recommended to be used only by highly experienced sedation practitioners.

The range of sedation medications used in this sample is extensive, especially since the monitoring of the children by medical personnel during the sedation procedure is not clearly documented. Where the sedative agent was specified in the sample, trimeprazine was the most commonly used sedative agent (n = 20; 42%) with chloral hydrate the second most commonly used (n = 4; 8%).

In our search of the national and international literature on sedation, studies on the use of trimeprazine as a sedative agent in the paediatric population were not found. A study on the methods of sedation for ABR testing in the USA found that chloral hydrate in carefully measured doses based on the child's weight is safe and effective for the majority of patients.[13] A study on the effectiveness of chloral hydrate as a sedative agent has shown that it has a low incidence of acute toxicity when administered orally in the short term in recommended doses.[14]

However, it has been noted that when using sedative agents that have longer durations of action (including chloral hydrate, trimeprazine and droperidol), the child should be observed and monitored for longer periods even after recovery and discharge criteria (as indicated in SA paediatric sedation[10] guidelines) used by the audiologist doing the testing have been reached.[7,8,15,16] This is especially important in a South African context where the child might be carried on the parent's back, as there is an increased possibility of airway obstruction due to the possibility of prolonged drug effects.[9] Chloral hydrate, used for four children (8%) in our sample, has recently been reclassified as a Section 21 drug in South Africa. This means that the use of chloral hydrate is regulated and has to be authorised by the Medicines Control Council of South Africa.

The American Academy of Pediatrics[14] recommends that sedation not be administered without the safety net of medical supervision. Medical supervision data are only available for 8% ($n = 4$) of the sample, who were monitored by an anaesthetist. The adherence to basic guidelines for safety of all children in this sample receiving anaesthetic medication cannot be commented on. SASA Guidelines state that a person separate from the operator should monitor the patient.

In advanced sedation, someone other than the operator must be responsible for administration of sedation, monitoring of vital signs and, should complications of sedation arise, rescue of the patient. It is recommended that, in such cases, a medical practitioner performs this role.[10] From the diagnostic audiology records, it is not clear if these guidelines are adhered to.

Globally there is the challenge of neither standardisation of sedation practice, nor guidelines and credentials necessary for sedation of the paediatric population.[1] While South Africa has published a document related to guidelines for procedural sedation and analgesia in the paediatric population specifically,[10] adherence to guidelines is difficult to determine.

Conclusion

This research investigated the use of sedation for auditory electrophysiology testing in a sample of 171 children enrolled in an early intervention programme in South Africa.

The study has shown that, when logged, sedation medication and dosage is not clearly documented and that the use of medical or anaesthetist monitoring during sedation is not routinely included in reports. The lack of data sets on sedation has been identified as a challenge in low-income countries due to inadequate information technology infrastructure as well as limited data due to difficulties with patient follow-up.[11] The drugs used for conscious sedation in this sample are extensive, and include medication not recommended in the South African Guidelines, as well as the use of multiple sedative agents. These factors, together with the lack of information on medical monitoring during the sedation process, raise the question of what quality assurance checks are in place for sedation during diagnostic electrophysiology testing of children in South Africa.

South Africa has developed a document called 'Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2010',[10] an update of which is imminent. This was developed after consultation with paediatricians, paediatric radiologists, paediatric surgeons, emergency medicine specialists, paediatric intensive care specialists, paediatric oncologists and sedation practitioners, after the Western Cape Provincial Coordinating Clinician for Anaesthesia highlighted the importance of providing children with safe sedation and analgesia.

The documented guidelines for sedation[10] have provided South African-specific information on sedation medication as well as procedures to be followed for sedation with the paediatric population. A recent study[11] has identified the challenges of sedation in South Africa, including staff with limited or a lack of anaesthesia training, equipment challenges, difficulties with referral and transport as well as difficulties with medication supply. Internationally, there has been a focus on the core issues of the qualifications and training necessary to administer sedation, with the field of paediatric sedation acknowledged to be one shared between paediatric specialists and not limited to the domain of anaesthesiologists alone.

Current research on sedation for auditory electrophysiology in a South African context is limited to a study on the use of melatonin as a sedative agent in adults undergoing auditory brainstem response testing.[17] The present study has contributed to the understanding of sedative agents used for a small sample of paediatric clients undergoing auditory electrophysiology testing in both the public and private sector in South Africa. However, the research was limited in that the retrospective data were restricted to 532 children enrolled in an early intervention programme in South Africa and include a sample of 171 children for whom electrophysiology audiology reports were made available. This limits the generalisability of results and more extensive research is needed. More research is also needed to better understand the possible adverse effects of sedation, the use of medical personnel involved in sedation and the costs involved with the use of different sedation techniques and sedative agents.

This article has highlighted the inconsistencies in recording of sedation information in electrophysiology audiology reports as well as the variation in the use of sedation medication and practice in a paediatric population undergoing auditory electrophysiology testing. The development of guidelines by the HPCSA Board for Speech and Hearing Professions (relating to actual practice as well as data recording and management of sedation information and monitoring) will be an initial step in ensuring adherence to best practice as well as safety of paediatric clients.

Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

Authors' contributions

This article is a write-up of part of Selvarani Moodley's (University of the Witwatersrand) PhD, of which Professor Claudine Storbeck is the academic supervisor. The data analysis was completed by the first author, with the writing of the article being a collaborative process.

Notes

1. In the private sector sedation medication is generally provided by an anaesthesiologist. In the public sector, sedation medication is prescribed and administered by a doctor in the medical department and the child returns to the audiology department for testing. The availability of staff and resuscitation equipment is not stated in reports.
2. 'Outpatient' refers to a setting in which children attend audiology appointments at a public hospital/clinic or private sector audiology rooms. The use of discharge criteria, period of time before discharge or assessment after the sedation is not indicated in reports.

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Conclusion

This paper highlighted the inherent difficulties with ensuring the safety of paediatric clients when they are sedated for diagnostic auditory electrophysiology testing. It was noted that the challenge with monitoring of adherence to clinical practice guidelines is partly due to deficiencies in data recording and data management. Details of sedation medication, dosage, medical monitoring and possible adverse reactions are not always indicated in reports. The HPCSA board should consider the development of guidelines for sedation (and data recording and management thereof) specific to the field of paediatric diagnostic auditory electrophysiology testing.

Article 5

Moodley, S. & Störbeck. C. (In Review). EHDI Data Management in South Africa. Submitted to *South African Journal of Information Management*

Introduction to Article 5

The previous articles have focused on the analysis of information included in diagnostic audiology reports. This has included the diagnostic audiology tests completed across the three provinces in the public and private healthcare sectors, as well as information on sedation of children for diagnostic audiology testing.

The data analysis procedures and logging of information for analysis indicated that the way in which information is included in reports and data is managed is not standard in terms of format as well as comprehensiveness of information.

Data management is an important component of the EHDI pathway as it involves efficient recording and storage of information aspects of the EHDI process. This enables the efficient transitioning from one step of the EHDI pathway to the next. In addition data recording and data management allows for monitoring and evaluation of processes followed in the screening and diagnosis of paediatric hearing loss. This will allow for the determination of whether guidelines for testing are being followed, and where there is need for improvement.

DATA MANAGEMENT FOR EARLY HEARING DETECTION AND INTERVENTION IN SOUTH AFRICA

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Significance of Work: The processes of screening, diagnosis and intervention need to be prioritised for children with any degree of hearing loss. Data management systems can be used to ensure that these tasks are done accurately and timeously.

Abstract

Introduction: Internationally newborn hearing screening is becoming part of standard neonatal healthcare service guidelines for the implementation of early hearing detection and intervention (EHDI) initiatives, including screening, diagnosis, data management and intervention. Data management includes the processes of data collection and storage thereof, as well as analysis and interpretation of the data in order to guide future planning, implementation and evaluation of EHDI programmes. There have been limited studies on this key process of data management in the South African EHDI context.

Methods: The aim of this study was to determine what data management systems are currently in use in South Africa and whether they allow for cross-disciplinary sharing and evaluation of the EHDI processes employed in screening, diagnosis and intervention of paediatric hearing loss. A survey instrument on the management of EHDI data was developed and sent to all 40 HI HOPES referral agents in both the public and private sectors.

Results: A return rate of 80 % was achieved, with 19 (59%) public sector and 13 (41%) private sector audiologists participating in the study. The data revealed that there was no uniform data management system that was used nationally, and no consistent shared system within the public or private sectors. The majority of respondents (44%) used a paper-based system for data recording, which is a potential barrier in cross referring both in public and private health sectors. Additionally, no institutions were using data management systems that enabled sharing of information with other medical professionals, if extended input were required.

Conclusion: The EHDI pathway is a complex intersection of various health sectors and role-players, with the 'patient' going through various steps before the end result is achieved. For this reason data management and tracking of the pathway from new-born hearing screening is necessary in order to ensure quality care and

outcomes for children identified with a hearing loss. International large scale studies reveal both the importance of and effective implementation of data management system, however to date these have focussed on developed country contexts. The identification of challenges in implementing data managements systems within the South African context will reveal areas of misunderstanding of these systems as well as allow for an understanding of current data management practices, both of which can then be used to impact on this essential aspect of the management of the EHDI pathway.

Introduction

Internationally newborn hearing screening is becoming part of standard neonatal healthcare services within developed countries (including UK , Australia, Canada and some European countries). The importance of early detection of paediatric hearing loss and the benefits of early intervention for these babies has been recognised through extensive international research (Yoshinaga-Itano, Sedey, Coulter, & Mehl 1998:1161-1171; Yoshinaga-Itano 2003:252-266; Yoshinaga-Itano 2013:43). The Joint Committee on Infant Hearing, JCIH 2007:898-921) has clear guidelines for the implementation of early hearing detection and intervention (EHDI) initiatives, including principles and process guidelines for screening, diagnosis, data management and intervention. These guidelines have come to represent the international gold standard as it serves as a reference document for countries internationally, including those that are resource constrained like the low and middle income countries (Olusanya 2015:51-64).

Within the South African context, the Health Professions Council of South Africa (HPCSA) recognised the importance and value of early hearing screening and diagnosis and commissioned the development of a South African position statement on EHDI programmes. This statement was modelled closely on the JCIH (ASHA 2000) position statement and includes principles and guidelines for screening, diagnosis and data management with specific adaptations for the South African EHDI contexts. The HPCSA (2007) EHDI position statement therefore recommends screening by 2 months, diagnosis by 4 months and intervention by 8 months of age as opposed the the JCIH which recommends the 1:3:6 timeline for these 3 phases. In addition to these time-based guidelines the importance of information systems for data management has been outlined in both the JCIH (2007) and HPCSA (2007) EHDI position statements. Data management refers to the processes of data collection and storage, as well as the analysis and interpretation of the data in order

to guide future planning, implementation and evaluation of specific EHDI programmes (JCIH 2007).

Data management (from a medical records perspective) involves the keeping of records and logging of data from appointments as a means of supporting patient care (Mann & Williams, 2003), and are "primarily created to provide an account of diagnosis and care" (Parkes 2004:899). Häyrinen, Saranto and Nykänen (2008:291-304) state that medical data can take one of three formats: 1) a personal health record which is a summary of all health information on an individual and is kept by the individual; 2) an electronic medical record which is an electronic version of paper-based medical records and which is owned by healthcare providers from a single organisation providing medical care; and 3) electronic health records which are healthcare information records containing longitudinal information that has been collected from various sources, the purpose of which is efficient and integrated healthcare. Young and Spencer (2008:648-656) identified a fourth on-line format of data that would allow for the interface and potential linking of database systems for the improved information flow within and between the different components of the EHDI referral process. The key advantage of such an online data management system would be the immediate access and availability of the complete patient healthcare records to authorised healthcare providers at the point of consultation (Mostert-Phipps, Pottas & Korpela 2012:326-331), which would include doctors, audiologists and interventionist among others.

Internationally such an on-line central data management system, allowing for interdisciplinary access to the pathway from screening to diagnostic and follow up appointments, has been shown to be a key component in ensuring the success of a comprehensive hearing screening programme (Finitzo & Grosse 2003:73-78). Within the South African public healthcare context, such a system would be essential to the success of a universal newborn hearing screening programme (UNHS) because of the complexity of our three-tier public health referral system. An on-line data

management system would allow for inter-disciplinary tracking along the referral pathway, where paediatric hearing screening occurs at the primary healthcare facility with referral to a secondary or tertiary healthcare facility if advanced diagnostic testing and confirmation of hearing loss is required. This is then followed by the return to the primary healthcare provider for habilitation and/or intervention. It is therefore clear that, in order to ensure a seamless referral process along the three-tiered health system, on-line data needs to be as up-to date, accurate and complete as possible (Alam Gaffney & Eichwald 2014:220-223).

Since the development of the HPCSA EHDI position statement (2007), which is not a legislated document, some institutions in South Africa have begun implementing screening initiatives. Voluntary screening programmes are offered at private hospitals and routine high-risk screening occurs at certain government hospitals. Pilot studies reported on thus far include a newborn hearing screening programme at one private health care hospital in Gauteng (Swanepoel, Ebrahim, Joseph, & Friedland 2007:881-887), infant hearing screening at an immunisation clinic in Gauteng (Swanepoel, Hugo & Louw 2006:1241-1249), use of nurses as screening personnel in the Western Cape (Friderichs, Swanepoel & Hall 2012:552-559) and screening at Maternity Obstetric Units (MOUs) (de Kock, Swanepoel & Hall 2016:124-131) in the Western Cape. Results from these screening forums indicated that, once hearing was screened and a refer result was obtained, parents did not bring the child for the rescreening appointment. A follow up study was done to gain a South African perspective on why parents were not bringing their children in for rescreening, and the results showed that 24% of caregivers forgot about the appointment with a further 32% believing that the follow-up appointment was not necessary. This loss to follow up of 56% of families highlights the benefit of a quality data management system for the effective tracking of referred infants, and telephonic reminders by dedicated personnel to improve follow-up compliance. Before such a central system could even be considered, this study explored the

current status and practice of data management and it was found that South Africa does not have standard methods for audiology record keeping or data management.

As stated in a recent review of EHDI in South Africa, limited studies were found on data management (Moodley & Storbeck 2015:1-10), despite the fact that such data management systems have been identified internationally as part of the gold standard due to the importance for both patient care and evaluation and quality control (Finitzo & Grosse 2003:73-78).

It is therefore necessary to determine what, if any, data management practices and systems are in use in South Africa and if they allow for cross-disciplinary sharing and evaluation of the EHDI processes employed in screening, diagnosis and intervention of paediatric hearing loss.

The aims of this study were to:

1) identify the data recording and management systems used by South African audiologists in the public and private healthcare sectors
2) determine whether these data management systems allow for sharing of information across healthcare professionals
3) establish the challenges associated with the use of an online or electronic database system in the South African public and private healthcare systems

2. Methods

2.1. Study population

This survey on the practice of data management in 3 provinces of South Africa is part of a larger study, which includes a broader survey on diagnostic audiology practice. The sample for the survey included audiologists who referred children to the HI HOPES early intervention programme from September 2006 to December 2011, and who are part of a larger research project involving this longitudinal dataset on deaf children (n=532) in South Africa (Storbeck & Young 2016: 45). The survey was sent to the 40 referral agents, where 21 were from the public and 19 were from the private health sector. Six surveys were not returned with an additional one

private sector audiologist who chose not to participate and a second who did not fully complete the survey. The response rate for the data management component of the survey was thus 32 of the 40 audiologists, making the response rate 80%. Completed surveys were from 19 public sector audiology departments (59%) and 13 from private sector audiologists (41%). In terms of provincial breakdown, 20 (63%) were from Gauteng, 10 (31%) were from KZN and 2 (6%) were from the Western Cape.

2.2 Procedures

A survey instrument was developed and included questions on diagnostic audiology practices as well as EHDI data management in South Africa. The survey instrument was developed to be quick to administer and provide information on aspects of data management that were identified to be important from the literature i.e. data record systems, sharing of audiology diagnostic information and challenges with the use of database systems. The survey was comprised of six close ended questions in a multiple choice format. Options from which respondents could choose were those identified as common to EHDI data management systems and options specific to a developing county context. Respondents were given the option of providing their own responses as well as including further comments.

After the development of the survey instrument, it was piloted on audiologists who were not referral agents to the programme and were thus not eligible to complete the survey. Pilot respondents included an international as well as South African expert in the field of audiology, as well as two audiologists in the public and private health sectors respectively. The piloting of the questionnaire allowed for checking of the appropriateness of the questionnaire for answering the research questions, as well as detecting any flaws in the questionnaire (Brink, van der Walt and van Rensburg 2006).

Before the survey could be sent to public sector audiology departments, permission was obtained from the government research council for each province (Gauteng,

Kwazulu Natal and Western Cape). Permission was then obtained from each individual hospital medical manager for the audiology department to complete the survey. Once written permission was obtained from the hospital medical managers, the audiology departments were contacted telephonically to inform them of the study and to request completion of the survey. Surveys were emailed to the audiology department at those hospitals that agreed to fill in the survey.

Private audiologists were each contacted telephonically to inform them of the study and to invite them to participate in the survey. If agreed, the survey was emailed directly to the audiologist.

2.3. Data analysis

A data collection sheet was designed specifically for the comprehensive logging of the survey information relating to data management. Data were coded and collated. The coded data were then transferred to an excel spreadsheet for systematic analysis. Data were grouped and analysed according to the variables of private vs. public sector and the province in which the practices were located, in order to determine the variation in data management with respect to these variables.
Data analysis techniques included basic descriptive statistics such as average values, standard deviation, frequencies and percentages.

2.4 Ethics

According to research protocol at the University of the Witwatersrand, an application is made to the University research committee for ethical clearance relating to each research project. Formal ethics approval is required before data collection can begin. The University of the Witwatersrand Ethical Clearance Medical Board provided ethical clearance (Protocol number: M111144) for a comprehensive survey study of audiologists in the public and private sectors who referred deaf and hard of hearing children to the HI HOPES early intervention programme in the five

year period between September 2006 and December 2011. This is part of a larger longitudinal study of EHDI data for children receiving comprehensive home-based intervention in the HI HOPES programme during this time period.

RESULTS

Results will be presented in the format of: 1) the data system used for recording of the audiology information, 2) information included in audiology records, 3) data sharing and 4) challenges audiologists face in the implementation of an electronic/online database system.

1) Data recording systems

Audiologists were asked to indicate what data system they were using for recording of EHDI data in their audiology department /practice. The majority of respondents (44%; n=14) used only a paper based system for recording of data. An additional 27 % (n=9) of respondents use a paper based system in addition to a computer based (Excel or Access) programme to generate reports. 25% (n=8) of public sector audiologists use a computer based programme system only. 2 respondents (6%), both in the private healthcare system (one in the province of Gauteng and one in KZN), used a web-based data tracking system in addition to a computer and paper-based system.

The systems used for recording of data are varied, with both the private and public health systems using both paper based and computer systems for data capture.

2) Information included in audiology records

The next question in the survey focused on the information that is included in data records. Multiple choice options included demographic and medical information as well as the capability of the system to allow for generation of reports, account (billing) information and flag for follow-up appointments.

The analysis of information reported to be included in data systems indicates that the majority of data records include medical information (Table 1). A flag for follow-up appointments is available in 15 (47%) of institutions (ten in the public sector and 6 in the private sector). Respondents in KZN and Gauteng in both the private and public healthcare sectors have data recording systems that can generate and record reports, with account information being recorded more in the private sector (12; 92%) than public sector (4; 21%) institutions.

3) Data sharing

The next question in the survey focused on data sharing amongst professionals within and across hospitals. The Gauteng public sector (70%, n=7), as well as some KZN public sector audiology departments (57%, n=4) use systems that are available to other medical professionals in the hospital, as well as 2 (20%) of audiology departments in Gauteng having systems that are accessible to professionals in other hospitals. There is no sharing of audiology data across hospitals in the private sector, with only two practices (one in Gauteng and one in KZN) having a system that is accessible to other medical professionals within their hospital.

4) Implementation of an electronic/online database system

Audiologists were asked to indicate the difficulties they would face if they were to implement the use of an electronic database system and online database system in their audiology department/practice. A list of challenges was provided, as well as providing an option to list additional challenges. The most common difficulty with implementing the use of an electronic/online database system (Table 2) was the lack of time and limited staff for data entry. A limited budget and frequent electricity cuts were identified as difficulties by a few institutions across the public and private healthcare sectors, with one public sector institution identifying limited electricity points as a difficulty. The public sector identified internet connection as a difficulty

with implementing an online database system, with one public sector institution commenting that there is a shortage of computers in the department.

DISCUSSION

Through hearing screening programmes being implemented in a number of countries (including South Africa), more hearing loss is being identified early. However, a factor that has been identified as a challenge within the EHDI system is the variability in the level of diagnostic follow up services. To ensure quality EHDI programmes and services aligned with evidence-based care, there is a need to continuously monitor access, quality and outcomes of services (Russ, Dougherty & Jagadish 2010:S7-S18).

The monitoring of systems and data are through analysis of details from data records. This allows for identification of factors that will be effective in (as well as prevent effective implementation of) EHDI services across the continuum of screening, diagnosis and intervention.

The majority of respondents using a paper-based system for data recording could pose a difficulty with transfer and access of information when referring between the primary, secondary and tertiary departments of the South African public healthcare system. Mostert-Phipps, Pottas and Korpela (2012:326-331) found that referral between healthcare providers using a paper-based record system results in insufficient information being provided in the referral letter as well as the possibility that information may not be provided in time for the primary healthcare providers (as well as at each step of the EHDI pathway) to be informed of all factors for follow up care. In addition, Shulman and colleagues found that reporting systems relying on handwritten forms were found to be more prone to errors than those using computer-based systems (Shulman, Besculides, Saltzman, Ireys, White & Forsman 2010:S19-S27). In South African audiology, it has been found that paper based audiology records provided by audiologists conducting diagnostic testing, in both

the public and private sectors, are varied in terms of format as well as details included in the report (Moodley 2016:1-7).

In this sample of 32 audiologists, the information they state are included in reports indicates that these audiologists may have difficulty with following up on appointments, as few institutions have a flag for follow up included in their reporting system. This is important as South African research has indicated that following up on appointments for screening is a challenge (Swanepoel, Ebrahim, Joseph & Friedland 2007:881-887; Scheepers, Swanepoel & le Roux 2014:652-658; de Kock, Swanepoel & Hall 2016:124-131). To improve the documented rate of follow-up testing in the USA EHDI programmes, data management systems were amended to include a component for reminding parents of follow-up testing (Williams, Alam and Gaffney, 2016). This has been a recommendation from a South African study on parental reasons for not complying with follow-up testing recommendations and appointments (Scheepers, Swanepoel & le Roux 2014:652-658).

The nature of healthcare provision in the public sector relies on referral from primary to secondary to tertiary healthcare for different steps of the EHDI pathway. This means that children will move between various healthcare providers, at the different levels of healthcare, for provision of services.

No institutions in this sample were using systems that enabled sharing of information with other medical professionals. The Gauteng public sector is most likely to use a system that is compatible with systems used by other medical professionals in the same hospital, indicating the ability for development of a system for data sharing. Data sharing within institutions can be achieved through the use of an electronic system accessible by all healthcare providers, while an online database system is necessary for sharing information with medical professionals at other institutions.

The use of an electronic health care system has been shown to result in more complete and accurate documentation by EHDI healthcare professionals, as well as

being important for health policy planning (Finitzo & Grosse, 2003:73-78; Hutt & Rhodes 2008:87-91) An electronic health record system may assist in avoiding double or unnecessary tests as well as providing data for comparison with earlier tests conducted and a reduction of ineffective treatments (Ueckert, Goerz, Ataian, Tessmann, Prokosh 2003:99-108). A study on the use of electronic records in South African healthcare concluded that there is an increased need for sharing of information on procedures and tests done, across the different levels of healthcare provision (Mostert-Phipps, Pottas & Korpela 2012:326-331), to ensure integrated, quality EHDI services.

Challenges faced in the implementation of an integrated data system in the USA included a lack of funding for: 1) a web-based data system accessible to providers, 2) staff for development of the system and 3) provider training on use of the system (Uhler, Thomson, Cyr, Gabbard & Yoshinaga-Itano 2014:34-43). Challenges identified in the current study include the USA challenges of funding and staff for data entry. However, South Africa also has additional challenges such as provision of electricity and internet connection, that are reflective of a developing country,

Conclusion

This study has looked at EHDI data management systems used by public and private sector audiologists in 3 provinces of South Africa. There was mainly use of a paper-based system, with the majority of records including medical information. While paper-based systems are not easily accessible and could be prone to errors, the inclusion of medical information allows for some holistic evaluation and care. However, systems did not allow sharing of information between different professionals or for following up of appointments. This indicates a lack of integrated care.

An online data system for integrated care and decision support is especially important in South Africa where there is implementation of pilot screening initiatives. Data can be used to gather information on the costs of screening, determining the best screening forums, and the best screening techniques. Especially since screening is conducted at different forums by different personnel, data management and analysis are important for the evaluation of quality of services provided, and monitoring of accuracy and timeliness of services.

South Africa has the advantage of learning from international studies on the importance of data management, and including this as part of EHDI programmes from the beginning. The identification of challenges in implementing data managements systems allows for effective preparation and formulation of ideas for how these challenges can be overcome. From this study, difficulties such as a lack of time and staff for data entry reflect the international challenges of having a shortage of audiologists. Difficulties such as electricity access and internet connection are difficulties that are part of a developing country.

Author contributions

This article is part of SM's PhD study which was funded by the School of Education, University of the Witwatersrand. CS was the study supervisor and assisted with study conceptualisation, drafting and revision of the article.

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Conclusion

This article highlighted the lack of efficient audiology data management and tracking systems to allow for evaluation of EHDI services and for sharing of diagnostic information amongst professionals. Challenges with the implementation of online/electronic data management systems include those that are common to a developed world context (time and staff for data entry), as well as challenges unique to a developing country context (electricity access and internet connection).

Concluding Chapter

The introductory article (Moodley & Störbeck, 2015) provided the motivation for this study. Diagnostic audiology testing information for paediatric clients in South Africa is lacking and, while evidence to support the statement of lack of information on paediatric diagnostic testing is provided, it was decided to provide additional support to this statement by conducting a narrative review of studies in the field of EHDI in South Africa. Moodley & Störbeck (2015) clearly highlighted the lack of and need for studies in the areas of diagnostic audiology and data management in South Africa.

Having established the need for studies in diagnostic practice, the aim of this study was to document the current practice of audiologists in South Africa, with reference to paediatric audiology diagnosis, reporting of testing results, record keeping and data management in a closed sample set in 3 provinces of SA. These were provinces in which an early intervention programme had diagnostic audiology records and reports available for review (from September 2006 to December 2011), and included survey data from public and private sector audiologists who referred children to the HI HOPES early intervention during this period.

The South African focus in newborn screening has been on the logistics of hearing screening, across the private and public healthcare sectors. The public sector focus has been on the forum that is most appropriate and accessible for all children to be afforded the opportunity for early hearing screening. The private sector focus has been on the accessibility of screening services and why parents refuse screening services offered to them.

The screening studies have been informative and provided initial knowledge of the use of nurses as screening personnel, the need for medical professionals to be aware of screening services, and the use of inoculation clinics and maternity obstetric units as screening sites.

Progress has been made in the development of guidelines for diagnosis (HPCSA, 2007) and draft diagnostic guidelines for use with the paediatric population (Swanepoel, 2012). However, studies on actual diagnostic audiology practice, and how they compare

to guidelines, are limited. This study provided initial information on diagnostic practice as well as EHDI data management, across the private and public healthcare sectors in three South African provinces.

There was a variation in services across the healthcare sectors, as well as provinces, for all aspects of diagnostic testing, The finding that partial testing was conducted by all audiologists across the public and private healthcare sectors, with limited compliance to HPCSA EHDI guidelines is concerning, as this will have an impact on the accuracy of diagnostic testing. The ethical need for equity of quality services, regardless of geographic or socioeconomic status, poses a difficulty, with both the public and private healthcare sectors being unlikely to complete all recommended tests for diagnosis of hearing loss.

There was a use of electrophysiology with older children and a need for sedation of these children to complete electrophysiology testing. ABR assessment of infants and young children is an advanced procedure and audiologists performing this procedure should have sufficient, equipment, training and experience in this specialised area (McCreery, 2014). The challenge in South Africa is that ABR assessments are often performed by community service audiologists with limited experience in electrophysiology testing. Paediatric audiology in South Africa is not a specialised field, and testing can be conducted by newly qualified graduates. The use of electrophysiology testing by inexperienced audiologists has the potential to result in errors in diagnosis.

It has been stated that the previous dual qualification of speech therapists and audiologists was necessary to allow for the provision of services to a large number of clients with varied difficulties in the public sector. However, it should be noted that there is a shortage of audiologists in developed countries as well. The recognition of the expertise and experience necessary for accurate diagnostic testing has prompted the increase in the qualification necessary to conduct paediatric diagnostic audiology testing, despite the shortage of audiologists in the USA. Whether an increase in qualification is necessary and feasible for a South African context will need to be determined.

Recommendations

This study has provided comprehensive information on diagnostic practice through a review of audiology records as well as a survey on data management. The following are recommendations that can be made from results obtained:

- South Africa is one of only two countries on the African continent to provide audiology training and comprehensive audiology services to paediatric clients. We have aimed to ensure accuracy and best practice in screening and diagnosis, together with a HPCSA (2007) EHDI position statement that is very similar to the JCIH (2007) international position statement. There is a need to review the guidelines for a developing world context. In terms of diagnostic testing, this should incorporate the inclusion of behavioural information being adequate as the means for assessment of older children. It would also include the development of guidelines for sedation during electrophysiology testing and guidelines for data recording and data management. The impact of following USA standards of requirement of a doctorate for paediatric diagnostic audiology testing on the availability of paediatric diagnostic audiology testing facilities will have to be determined. However, the impact of having newly qualified graduates conducting paediatric diagnostic audiology testing and the impact of the lack of experience and expertise on accuracy will also have to be considered.

- The level of qualification for paediatric diagnostic testing and specifically for use of electrophysiology tests that require specialised skill for administration and interpretation (such as the ABR) should be reviewed. However, since South Africa has a shortage of audiologists, an increase in qualifications to conduct paediatric diagnostic testing might not be feasible. A possible solution could be the development of paediatric diagnostic courses, and mentoring of less experienced graduates by experienced professionals

- Since electrophysiology is used extensively with older children who need to be sedated for accurate testing, there is a need for development of HPCSA guidelines for sedation practice and recording of sedation data.

Limitations of the Study

Limitations of this study include the review of reports made available to the researcher through an early intervention programme. There might be some reports that were overlooked by the programme. Also, the reports provided to the programme might not accurately reflect all diagnostic audiology tests used.

In addition, the sample population for the survey was the referral base of audiologists who provided diagnostic audiology reports to the early intervention programme. This resulted in a small sample size for KZN private audiologists and WC public sector audiologists. WC private sector audiologists were not represented in the record review or the survey.

The overall sample base for both the audiology records and the survey was limited to three provinces and thus cannot be generalised to the population. Studies on audiology services in all provinces of South Africa are needed to gain an accurate picture of diagnostic audiology practice.

Strengths of the study

The strengths of this study include the following:

- This is part of a larger longitudinal study on paediatric hearing loss in South Africa
- The study sample includes audiology records from 3 provinces records as well as a survey of audiology data management in 3 provinces.
- There was an inclusion of both public and private health as well as three provinces, which allowed for a comparison of paediatric diagnostic audiology services across the provinces as well as healthcare sectors.
- There was the inclusion of both international and South African paediatric diagnostic guidelines, allowing for comparison and evaluation of South African paediatric diagnostic audiology to the international arena.

Recommendations of further areas for research

This study provided initial information on paediatric diagnostic audiology in 3 provinces of South Africa. Recommendations for future research are:

- Comprehensive studies of paediatric diagnostic audiology (similar to this one) on the tests employed for diagnosis and how this compares to HPCSA guidelines in all the provinces of South Africa
- Determining the impact of current South African audiology qualifications on paediatric diagnostic accuracy as well as the possible impact of an increasing specialisation on accuracy of diagnostic testing as well as availability of services.
- Development of SA specific guidelines for testing of children referred from early hearing screening as well as for testing of older children.

Conclusion

This study provided a comprehensive overview of paediatric diagnostic audiology in terms of a retrospective record review as well as a survey of data management. This provided initial information in this specialised area as well as highlighting the many challenges South African audiologists face in the provision of paediatric diagnostic audiology services.

Comprehensive studies across all regions of South Africa will provide a holistic picture of the status of paediatric diagnostic audiology services. The need for South African specific professional guidelines for testing, as well as a review of the structure of the qualification necessary to conduct paediatric diagnostic audiology testing, was clearly highlighted. There is much need for further research in this specialised area of paediatric audiology.

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List of Appendices

1. Ethical Clearance
2. Survey questionnaire for article 5

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Miss Selvarani Moodley

CLEARANCE CERTIFICATE	M111144
PROJECT	Paediatric Hearing Loss in South Africa: A Survey of Diagnostic Audiology Procedures in 3 South African Provinces (changed title 25/09/2014)
INVESTIGATORS	Miss Selvarani Moodley
DEPARTMENT	Centre for Deaf Studies/Education
DATE CONSIDERED	25/11/2011
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 13/02/2012

CHAIRPERSON .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr Claudine Storbeck

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be

Questionnaire Number:

Healthcare sector **Public** ☐ **Private** ☐

DATA MANAGEMENT

1) Please indicate the system used for capturing of paediatric patient data:

Excel database system	☐	**Access database system**	☐
OZ database management system	☐	**Web-based data tracking system**	☐
Paper based system	☐	**Other**	☐

If other, describe:

2) Data record includes (colour all applicable) :

Demographic information	☐	**Account information**	☐
Medical information	☐	**Flag for follow-up appointments**	☐
Generating and record of reports	☐	**Other**	☐

If other, describe:

3) Data system is compatible with data record system used by other professionals in hospital?

Yes ☐

No ☐

4) Data system is accessible and available online to other medical professionals in the hospital?

Yes ☐

No ☐

5) Data system is accessible and available online to medical professionals in other hospitals?

☐

Yes

No ☐

6) What would be the difficulties associated with having an electronic database system at your facility. Tick all applicable boxes

Limited electricity points	☐	Frequent electricity cuts	☐
Limited budget	☐	Lack of time for data entry	☐
Limited staff for data entry	☐	Other	☐

If other, describe:

7) What would be the difficulties associated with having an online database system at your facility. Tick all applicable boxes

Limited electricity points	☐	Frequent electricity cuts	☐
Limited budget	☐	Lack of time for data entry	☐
Limited staff for data entry	☐	No/intermittent internet connection	☐
Other	☐		

If other, describe:

8) Any further comments on data management?

THANK YOU FOR YOUR TIME!!!!!!!!!!!