

# EFFICACY OF A COMMUNITY-BASED INFANT HEARING SCREENING PROGRAM UTILIZING EXISTING CLINIC PERSONNEL IN WESTERN CAPE, SOUTH AFRICA

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## **Keywords**

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## **Abbreviations**

IHS: Infant Hearing Screening

UNHS: Universal Newborn Hearing Screening

EHDI: Early Hearing Detection and Intervention

PHC: Primary Health Care

MCH: Maternal and Child Healthcare

ENT: Ear, Nose and Throat

DPOAE: Distortion Product Otoacoustic Emissions

HPCSA: Health Professions Council of South Africa

MEE: middle ear effusion

## **ABSTRACT**

*Objective:* Screening programs at primary health care immunization clinics have been proposed as an alternative to hospital-based programs in South Africa. The objective of this study was to evaluate the first systematic community-based infant hearing screening program in a developing South African community in the Western Cape.

*Methods:* A community-based universal infant hearing screening program initiated at eight primary health care clinics in the Cape Metropolitan area was evaluated over a 19-month research period. During this time 6227 infants that were candidates for screening attended their 6, 10 or 14-week immunization visit at the relevant clinic. Clinic nurses were trained as screening personnel. A two-stage distortion product otoacoustic emissions screening protocol was utilized. The target disorder was uni- or bilateral hearing loss and infants referring the first screen were scheduled for a 4-week follow-up visit at the clinic. Diagnostic audiological and medical evaluations were scheduled at referral hospitals when indicated. The study evaluated the

efficacy of the program based on coverage, referral and follow-up rates and diagnostic outcomes according to guidelines specified by the Health Professions Council of South Africa 2007 Position Statement.

*Results:* Overall coverage rate across the eight clinics was 32.4% with 2018 infants (aged 0-14 weeks) screened. The mean age of the sample at first stage screen was 3.9 weeks of age and 13.5 weeks of age for first hospital visit. Overall first stage screen referral rate was 9.5% with 62 subjects (3%) referred for diagnostic services at hospital level after a follow-up screen. The average follow-up rate for rescreens at clinic level was 85.1% and for initial diagnostic assessments at hospital level it was 91.8%. Prevalence rates were 4.5/1000 with significant hearing loss, including sensorineural (1.5/1000) and conductive (3/1000) losses, and 12.9/1000 for subjects with middle ear effusion.

*Conclusions:* The community-based infant hearing screening program was valuable in attaining high follow-up return rates but reaching sufficient coverage may require dedicated screening personnel as opposed to existing nursing personnel.

## **INTRODUCTION**

A growing body of research demonstrate that infant hearing screening (IHS) is 'preventative' in nature, precluding the adverse consequences of late diagnosis and the burden of permanent hearing loss [1-3]. The investment in early childhood, especially from a developmental perspective such as IHS, has a two-fold effect. Not only does it have an enormous impact on the child's health but it can result in important long term economic returns, which may be significantly higher than investment in formal education [4,5]. Universal newborn hearing screening (UNHS) programs are considered the gold standard in facilitating early detection and intervention for hearing loss and yield the best outcomes in terms of language and speech

development [6,7]. Research evidence has shown it to be practicable, effective, cost-efficient, safe, and facilitative of optimal outcomes for infants with hearing loss [1,4,8].

UNHS programs however, are a privileged reality for babies born in developed countries such as the United States and the UK [9]. In developing countries IHS programs are rare due to socio-economic and health care barriers, limited contextual research evidence, lack of financial and/or human resources and the absence of political will [9]. Governments are often burdened by communicable and fatal diseases, such as HIV/AIDS, tuberculosis and malaria, which easily marginalise infant hearing loss [2]. This has led to a general neglect of hearing loss despite two-thirds of all persons with disabling hearing loss residing in developing countries of which at least 25% is from birth or early childhood onset [10].

Annually more than 800 000 babies are born with or acquire early onset permanent bilateral hearing loss worldwide [10,11]. More than 90% of these reside in developing countries where there is virtually no prospect of early detection [11]. In 2009, the World Health Organization called for a consensus on the best approaches to newborn and IHS with a demonstration of its effectiveness and cost-efficiency to justify its universal use in resource-poor countries [9]. Olusanya (2011) suggests that targeted newborn hearing screening is an option in less developed countries where UNHS is not immediately practicable at any level of healthcare delivery [12]. However prior to embarking on targeted newborn hearing screening or UNHS it is recommended that each country establish context-specific risk factors, their rationale for screening as well as operational issues related to effective implementation. Contextual empirical evidence from pilot studies at community, state or national level, or even non-governmental initiatives, is necessary to demonstrate the importance and feasibility of widespread IHS [9]. These pilot sites can provide a platform for contextual research to promote and guide

improvements in service provision suited to each context and may serve as examples for future program implementation on a wider scale [13]. This is important because Western models of hospital-based IHS for newborns may not be appropriate for the majority of developing countries [11,14,15].

Immunization clinic-based screening programs have been proposed as an alternative to hospital-based programs typical of developed countries for a number of reasons. Firstly, the World Health Organization recommends the co-ordination of Early Hearing Detection and Intervention (EHDI) systems with existing programs such as immunizations or well-child care in community settings to reduce costs [9]. Adopting a horizontal (integrated) as opposed to the traditional vertical (isolated) approach to service delivery may ensure that services are mutually beneficial, cost-efficient and effective [16]. Secondly, a significant proportion of births in most parts of the world occur outside regular hospital facilities making conventional hospital-based UNHS programs of limited value for optimal coverage [9,17,18]. Well-child clinics for routine childhood immunization are reputed for attracting babies regardless of their place of birth for a diverse range of health interventions otherwise not reached by hospital-based programs [16,17]. Thirdly, Olusanya and Okolo (2006) reported that prevailing cultural attitudes play a role in the success of IHS programs [18]. Taking an apparently healthy child to a hospital for any check-up is sometimes viewed as socially and culturally inappropriate in many communities because of the notion that hospitals cater only to the sick. Furthermore, the attitude towards non-life threatening health conditions like infant hearing loss in some communities may be detrimental to the efficacy of a stand-alone IHS program [18].

Emerging evidence from pilot community-based IHS programs has demonstrated the value and feasibility of this platform [15,17,19]. A higher yield of permanent congenital and early-

onset hearing loss was reportedly detected at community level compared to that of the hospital-based screening programs in Nigeria [19]. Screening infants attending routine clinics for immunization potentially captured a significant number of infants with postnatal hearing loss mostly missed by hospital-based UNHS programs [11]. First-stage referral rates, screening cost per baby and cost per child detected with permanent congenital and early-onset hearing loss were also reported to be considerably lower for community-based screening programs in comparison to more traditional hospital-based screening programs [19]. Inclusion of a second-stage screening can significantly reduce the referral rates of an IHS program at community level [17,19]. Coverage rates of babies screened for a community-based IHS program have been reported to be satisfactory relative to the 95% target for UNHS and the average age of screening can be below 6 weeks of age [11,15,17]. A commonly reported challenge for community-based screening programs is a loss of patients to follow-up [2,14,15]. The challenge of high default rates is not however specific to community-based IHS programs and not uncommon in the early stages of hospital-based NHS programs in developed countries [20,21].

In South Africa where less than 10% of newborns are afforded the opportunity to have their hearing screened [22,23] community-based IHS, utilizing immunization visits, may be well suited for delivering these services. More specifically however many babies in South Africa are not born in hospitals and those who are born in public health hospitals are usually discharged within the first twelve hours after birth [15,24]. This leaves limited time to screen newborns and leads to unacceptably high referral rates due to residual vernix and effusion in the ear which confounds screen results [25]. The only study on a community-based immunization clinic IHS program in South Africa demonstrated its potential for effective coverage with acceptable referral rates on a relatively small sample [15]. Community-based IHS programs were subsequently recommended as one of the proposed platforms for IHS in South Africa [13]. The aim of this

study was therefore to evaluate the first systematic community-based IHS program at primary health care (PHC) clinics in a developing South African community in the Western Cape.

## **METHODS**

The national health regulatory board, namely the Health Professions Council of South Africa (HPCSA), has developed a revised and contextually appropriate Position Statement on EHDI programs in South Africa for the year 2007 [13]. This HPCSA Year 2007 Position Statement provides guidelines for clinic-based screening programs in the form of benchmarks and quality indicators, namely a coverage rate of 95% within the first 6 months of screening, a referral rate for audiologic and medical evaluation of less than 5% within the first year of screening, a referral rate of more than 70%, confirmation of hearing loss by 4 months of age and enrollment into an intervention program by 8 months of age [13]. Based on these guidelines from the HPCSA Year 2007 Position Statement, this study evaluated the efficacy of a community-based IHS program in the Western Cape regarding coverage and referral rates at clinic level, follow-up rates at all levels, diagnostic outcomes and a comparison of coverage, referral and follow-up rates across clinics. The institutional review and ethics board at the University of Pretoria and City of Cape Town Health Department approved this study before any data collection commenced.

### ***Research Setting***

The hearing screening program was implemented at eight Maternal and Child Healthcare (MCH) clinics over a 19-month research period, 5 days per week (depending on the clinic), in the Cape Metropolitan area. MCH clinics are part of PHC facilities that serve as immunization, health education and general healthcare centres and are primarily managed by nursing staff [26]. The number of these clinics throughout the Cape Metropolitan area total approximately 100. The eight clinics utilized in the current study were selected according to the following criteria: 1) one community-based MCH PHC clinic per sub-district in the Cape Metropolitan area (Khayelitsha,

Klipfontein, Mitchells Plain, Tygerberg, Northern, Southern, Eastern and Western) 2) PHC clinics with the most 6-week immunization visits 3) clinic with immunization services provided Monday through Friday, 4) clinic closest to secondary or tertiary audiological and medical services or with as many auxiliary medical services as possible i.e. Ear, Nose and Throat (ENT), pediatrics, 5) clinic with trained screening personnel (PHC community nurses – professional, staff and enrolled) 6) clinic with quiet room for testing and secure area to lock equipment away 7) clinic with telephone and fax facilities and photocopy machine 8) clinic with electricity and running water. Based on these criteria the City of Cape Town Health Department identified one community-based PHC clinic per sub district within the metropolitan area. The screening program was introduced at the 8 clinics in 3 phases over the 19-month research period, namely Ravensmead and Langa clinic in phase one (August 2008 – March 2010), Masincedane, Kuyasa and Westridge/Rocklands clinic in phase two (June 2009 – March 2010), Retreat, Wallacedene and Ivan Toms clinic in phase three (September 2009 – March 2010). The screening program was introduced in three phases to carefully monitor the quality of the program, in terms of coverage, referral and follow-up rates. The necessary adjustments were made to the screening program based on feedback from each phase. The total area of Cape Town is 2,479 km<sup>2</sup> and is the second-most populous city in South Africa with a population of 3,4 million people [27,28]. The City Development Index and the Human Development Index, an average of infrastructure, health, education and income indicate that Retreat, Ravensmead and Westridge/Rocklands have higher indices compared to Masincedane, Langa and Kuyasa who have lower indices and considered the poorer areas [28].

### ***Study population***

During the 19-month research period (August 2008 – March 2010), 2018 infants (52.8% female) between the ages of 0 and 14 weeks attending their immunization appointments at the eight PHC clinics were enrolled in the study. 6 subjects included in the study were late for their

immunization appointment and therefore fell slightly outside this range. The oldest subject was 16 weeks of age due to time spent in the neonatal intensive care unit at one of the tertiary hospital facilities. The City Health unpublished report for immunization for the period July 2008 – March 2009 indicated that more than 99% of infants are immunized within the first year of life allowing for sufficient coverage through IHS [29]. The mean age of the sample at first stage screen was 3.9 weeks of age with 89.7% of babies 6 weeks or younger. Even though the scheduled immunization visits are set at 6, 10 and 14 weeks of age, caregivers brought infants at various age intervals thus leading to the spread of infants from birth to 14 weeks and included neonates attending the clinic to obtain formula, missed BCG immunization at the hospital or routine 0-6 week developmental questionnaire. Verbal and written informed consent was obtained from each parent/caregiver by clinic nurses prior to enrolling the infant into the study.

### ***Protocol and methods***

The study employed a two-stage distortion product otoacoustic emissions (DPOAE) screening protocol at clinic level utilizing a DPOAE screener. A two-stage screening protocol was employed to reduce the burden of false positive referrals to tertiary hospital level. The DPOAE screening parameters included evaluation of four frequencies (5, 4, 3, and 2 kHz) using a 65/55 stimulus level (L1/L2). Three of the four frequencies were required to pass (with a  $\geq 6$  dB signal to noise ratio) for an overall pass result. This screening technology was chosen instead of automated auditory brainstem response testing based on recommendations from a pilot research project [15] and the HPCSA Year 2007 Position Statement highlighting the ease of use and lower screening costs for these settings [13,15]. Furthermore, the instruments were chosen as they are fully automated handheld DPOAE devices (Bio-Logic AuDx) and therefore easy to use by non-specialists as they require no interpretation. They are powered by inbuilt rechargeable batteries, which is important considering the occurrence of power failures in the Western Cape.

A bilateral otoacoustic emissions refer criteria was used as criterion for an overall refer. Although unilateral hearing loss impacts developmental and emotional outcomes of children [30] for the sake of cost-effectiveness a bilateral refer criteria may be necessary in resource constrained settings [13, 15]. Infants who referred both ears were scheduled for a follow-up screen within 4 weeks from the initial screen to coincide with their next immunisation visit. If an initial screen could not be conducted due to irritability or restlessness a follow-up screening appointment was also scheduled. The follow-up screening consisted of the same protocol and if a second refer result was obtained a diagnostic audiology and ear-nose and throat specialist evaluation was scheduled at tertiary hospital level. If the follow-up screen at clinic level could not be completed due to irritability or restlessness a second or third follow-up screen was scheduled. Those infants with a unilateral refer result and bilateral pass result with risk factors for hearing loss were given a 6 month follow-up appointment to coincide with their immunization visit and caregivers were counseled regarding speech-language and hearing development and milestones.

Clinic nurses, trained and mentored in IHS before the service commenced, served as screening personnel. Nurses were trained by the program manager and colleague at their relevant clinics and received ongoing support and training from the program manager throughout the course of the screening program. Screening was conducted in a nurse's office or designated room in the clinic where ambient noise levels were adequate for testing. A test form including a brief medical case history, high-risk register, demographic information and screening outcome was completed for every visit to the clinic. A separate form was completed for every visit to the tertiary hospital. The screening protocols at clinic level were based on guidelines from the HPCSA Year 2007 Position Statement on EHDI [13]. Assessment protocols at tertiary level depended on the tertiary hospital's protocol.

### ***Data management and statistical analysis***

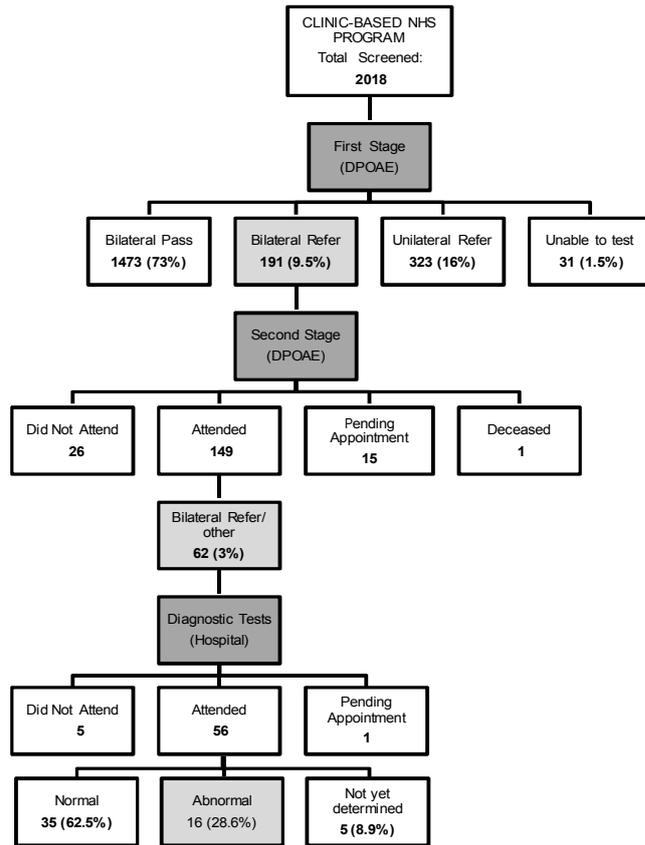
Data was captured in the EHDI SA Oz eSP Database System and included all information from the participant's test form at clinic level and information for those participants who required diagnostic services at tertiary hospital level. The researcher worked with personnel from Oz Systems to contextually modify the original database. All information from the EHDI SA Oz eSP Database System was extracted to MS Excel 2007 and analyzed using statistical package SPSS version 17.0 and 19.0. The type of statistical data analysis utilized was descriptive in nature. Frequency distributions and other descriptive measures such as the mean, median and standard deviation, as well as box plots and histograms were used to describe the results.

### **RESULTS**

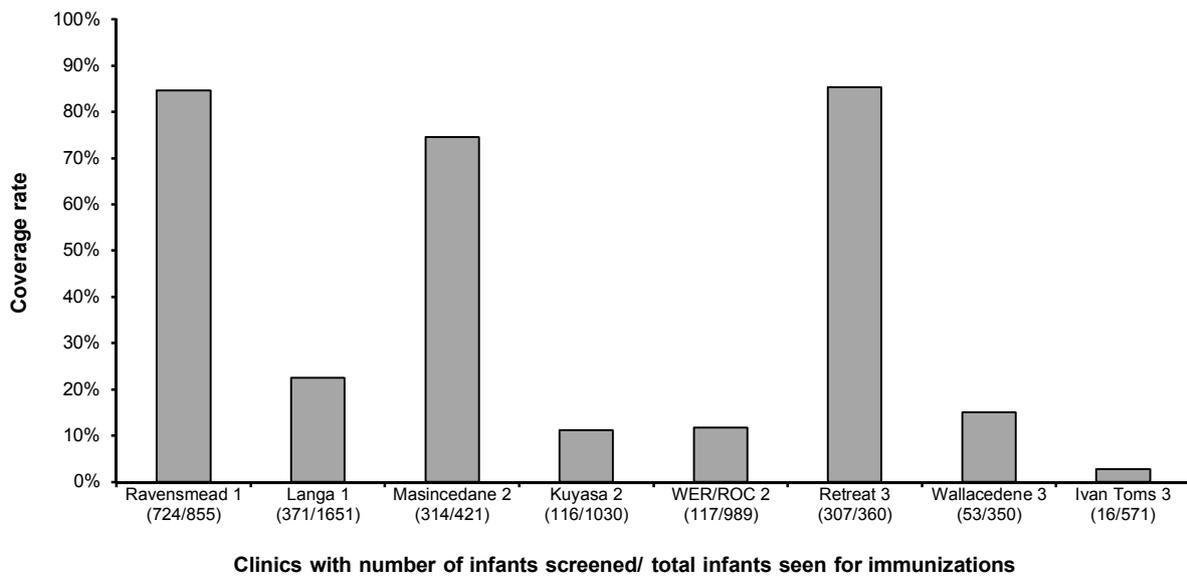
The initial DPOAE screening procedure was performed on 2018 subjects at the 8 PHC clinics. Figure 1 summarizes the outcomes of the screening for all subjects in the sample group (n = 2018). The majority of subjects were successfully screened at the first stage screen. However, due to irritability and restlessness 1.5 % of all subjects (n = 31) required a follow up appointment, of which only 41.4% returned for a second stage rescreen. A rescreen for a third or fourth time was required for 0.5% of all subjects (n = 9) before a reliable referral to tertiary hospital level for diagnostic services was made. The outcome of these rescreens was included in the second stage screen results.

### **Coverage**

Coverage rates, illustrated in figure 2, indicate the number of babies initially screened at the PHC clinic compared to the number of babies who attended their 6, 10 or 14-week immunization visit. As evident from Figure 2, three of the clinics presented with coverage rates between 74.6 to 85.3% but the majority had much poorer coverage. Although 98.5% (n = 1987)



**Fig. 1. Overall outcome of phases in the screening process at primary health care clinics**



**Fig. 2. Screening coverage rates at the primary health care clinics. 1 = clinics in phase 1; 2 = clinics in phase 2; 3 = clinics in phase 3**

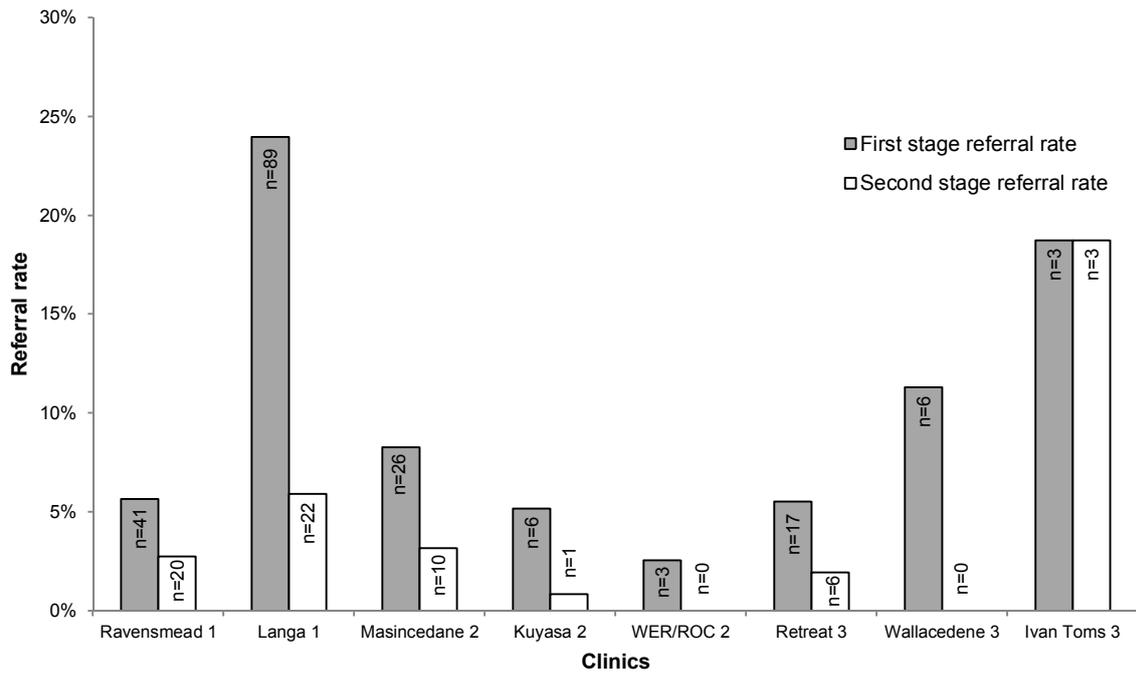
of the total subjects in the sample group were successfully screened at stage one, the overall coverage rate across the 8 clinics was 32.4%.

### **Referral rate**

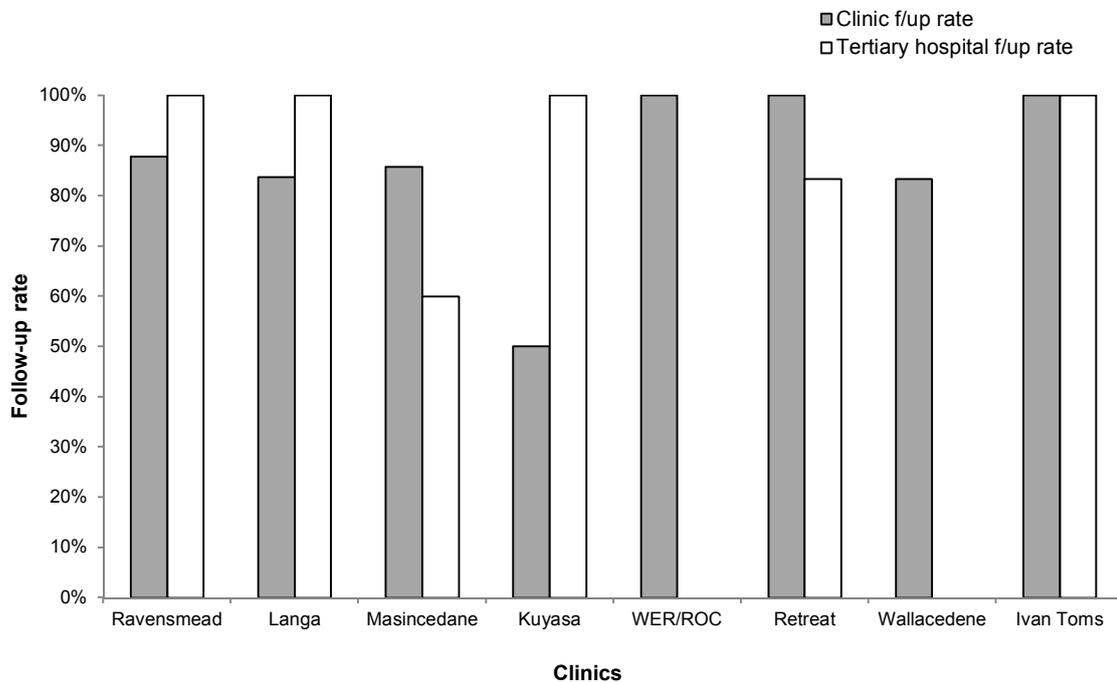
Although the screening protocol specified a bilateral DPOAE screening for all subjects only one ear could be screened with DPOAE in 16% (n = 323) of the sample whilst no measurements could be performed in 1.5% (n = 31) of subjects. Those subjects who could not be tested due to irritability or restlessness were scheduled for a follow-up screening appointment. As evident from Figures 1 and 3, the overall first stage screen referral rate at clinic level was 9.5% (n = 191). The overall second stage screen referral rate for these subjects who were sent to tertiary hospital level dropped to 3% (n = 62). Referral rates varied greatly amongst the clinics from 2.6 to 23.9% at first stage screen and 0 to 18.8% at second stage screen. However in all cases, except for 1 clinic, the second stage screen referral rate dropped below 6%.

### **Follow-up rate**

As evident from Figure 4 the overall follow-up rate at clinic level was 85.1% and the follow-up rate of those subjects attending their initial appointment at tertiary hospital level was 91.8%. Follow-up rates varied amongst the clinics from between 50 to 100% at clinic level and 60 to 100% at tertiary hospital level. However in the majority of cases the follow-up rates at clinic and tertiary hospital level were above 80%. All subjects from Wallacedene and Westridge/Rocklands clinic passed their second stage screen and required no referral and follow-up at tertiary hospital level.



**Fig. 3. Screening referral rates at the primary health care clinics. 1 = clinics in phase 1; 2 = clinics in phase 2; 3 = clinics in phase 3**



**Fig. 4. Follow-up return rates at the primary health care clinics and diagnostic referral hospitals**

### **Mean age of screening and diagnosis**

The mean age at first stage screen was 3.9 weeks (SD 2.3) with 89.7% of babies 6 weeks or younger. Six subjects fell slightly outside the 0 to 14 week range for their first screen. The mean age of the sample at second stage screen was 8.4 weeks of age (SD 3.4) with 1 subject as an outlier at 18 weeks of age. The mean age of the sample at first tertiary hospital visit was 13.5 weeks of age (SD 6.2) with 76.4% of babies 16 weeks or younger. There were however 4 subjects who fell well outside the mean age and were between 27–36 weeks of age at first tertiary hospital visit. The mean number of visits for diagnostic services at tertiary hospital level was 3 visits per subject (SD 2.5) although 3 subjects had between 9 to 15 visits.

### **Diagnostic outcome of subjects**

The diagnostic outcome of subjects (Figure 1) who attended their tertiary hospital appointments (n = 56) were divided into a normal (62.5%), “abnormal” (28.6%) and not yet determined (8.9%) category. Those subjects whose appointments were still pending or who had been seen at tertiary hospital level but had no conclusive diagnostic results yet were classified as ‘not yet determined’ (NYD). The outcome of subjects in the “abnormal” category was ear specific and included temporary/transient conductive or confirmed permanent sensorineural hearing loss as well as unilateral and bilateral hearing loss as evident in Table 1. Some subjects with middle ear effusion (MEE) had not had a diagnostic hearing test at the time of data analysis and were therefore excluded from the fluctuating conductive temporary/transient hearing loss category.

The age at first diagnosis of hearing loss was only calculated for the 3 subjects with confirmed permanent hearing loss and not for those subjects with unconfirmed or temporary/transient hearing loss due to the unreliable fluctuating nature of conductive hearing loss. This was 13.6 weeks for bilateral sensorineural HL, 40.9 weeks for bilateral mixed HL (with

**Table 1. Diagnostic outcome of subjects in the “abnormal” category**

<b>Diagnostic Outcome</b>	<b>Number of subjects (%)</b>	<b>Age at first diagnosis of HL (weeks)*</b>
Normal & NYD	1 (.05%)	
MEE	5 (.25%)	
MEE & NYD	1 (.05%)	
<b>Temporary/transient HL</b>		
Conductive with MEE	4 (.20%)	
Normal & Conductive with MEE	2 (.10%)	
<b>Confirmed permanent HL</b>		
Sensorineural	1 (.05%)	13.6
Mixed with MEE	1 (.05%)	40.9
Normal & Sensorineural	1 (.05%)	41.6

*HL = Hearing Loss, NYD = Not Yet Determined, MEE = Middle Ear Effusion. Diagnostic outcome was ear-specific indicated as a single bilateral outcome or a unilateral combination of different outcomes. \*The age at first diagnosis of hearing loss was only calculated for the 3 subjects with confirmed permanent hearing loss and not for those subjects with unconfirmed or temporary/transient hearing loss due to the unreliable fluctuating nature of conductive hearing loss.*

MEE) and 41.6 weeks for unilateral sensorineural HL. It must however be noted that the mean age at first screen at the clinic was 7 weeks and at first tertiary hospital visit was 11.9 weeks of age for this sample group.

The prevalence rates were 3/1000 (6/2018) for bilateral and unilateral fluctuating conductive hearing loss, and 1.5/1000 (3/2018) for sensorineural hearing loss, including bilateral, mixed and unilateral losses at the time of data analysis. The overall prevalence rate of significant hearing loss, including sensorineural and conductive losses, was 4.5/1000. It must be noted that although 35 subjects that were referred to tertiary hospital level were found to have normal outcomes, 13 subjects were diagnosed with MEE requiring several tertiary hospital level follow-up appointments. Therefore the prevalence rate of MEE for this research sample, including subjects from the normal and “abnormal” outcomes category was 12.9/1000 (26/2018) with 6 subjects requiring grommets at a later stage.

An analysis of the subjects who obtained a bilateral refer result with risk factors for hearing loss (n = 31) and who were referred for diagnostic services at tertiary hospital level was conducted. Results indicated that gestational age less than 40 weeks and post natal infections (HIV positive mother and/or baby) were the most prevalent risk factors amongst the sample at 32% (n = 10) and 23% (n = 7) respectively.

## **DISCUSSION**

The Western Cape has limited primary and secondary Audiology and ENT services in the public health care sector [31]. Through public-private partnerships this research program was made possible and is one of the first to implement and determine the efficacy of a systematic community-based IHS program in South Africa. The outcomes were evaluated against

guidelines in the form of benchmarks and quality indicators for a clinic-based screening program according to those specified by the HPCSA Year 2007 Position Statement on EHDI [13].

## **Coverage**

Although 98.5% of the total subjects in the sample group were successfully screened at stage one, the overall coverage rate across the 8 clinics (32.4%) and coverage at the various clinics did not meet the required benchmark of 95% as stipulated by the HPCSA Year 2007 Position Statement for the year 2007 [13]. The nurses were heavily burdened with a variety of tasks and struggled to effectively combine screening with other regular duties often regarded as more important. This was evident with Kuyasa clinic (11.26%) where the burden of attending to HIV and TB patients accounted for lower coverage rates. Often times they were short staffed at the clinics, such as Ivan Toms clinic (2.8%) that functioned on skeleton staff for over a year due to budget cuts and challenges with post allocations. A high turnover of clinic staff also accounted for lower coverage rates at Langa clinic (22.47%). These factors were the main reasons for poor coverage, as previously reported in other developing countries also with similar challenges [2]. Missed screening opportunities due to incorrect or inconvenient immunization times and shortage of immunization stock were also found to contribute to a lower coverage rate [32]. Some clinics managed to maintain high coverage rates which approximate the 95% benchmark [13]. Those clinics with higher coverage rates in the study had a dedicated day set aside in the week for screening and/or dedicated screening personnel with focused training who took ownership of the program. Retreat clinic combined the hearing screening with an existing newborn program held every Thursday afternoon. This accounted for the highest coverage rate of 85.27% as they had a dedicated day and specific clinic staff to perform the screening. Ravensmead (84.67%) and Masincedane clinic (74.58%) screened three days or more per week but had allocated one member of staff to perform the screening. The screening staff rotated biweekly or monthly to ensure preservation of their screening skill. Furthermore, these clinics

had the lowest number of babies coming to the clinic for immunization which meant they had more time to perform screening. Immunization rates were lowest for Ravensmead, Masincedane and Retreat clinic and highest for Kuyasa, Ivan Toms and Westridge Rocklands clinic. With buy-in and financial support from government, the allocation of dedicated screening personnel could effectively address the shortage of health care workers in resource poor-settings [11].

### **Referral rate**

Referral rates usually decrease over time in well-monitored screening programs especially with the use of a two-stage screening protocol [17,21]. Although the overall first stage screen refer rate of 9.5% at clinic level (n = 191) did not meet the required benchmark of 5% [13], the overall second screen referral rate of 3% to tertiary hospital level (n = 62) was well within this target. These outcomes were similar to earlier community-based UNHS studies performed where first-stage referral rates went from 14.3% to 4.1% in Nigeria and 14% to 3% in South Africa [15,19]. Although the program employed a bilateral refer criteria for first and second stage screen, 5 subjects did not adhere to this criteria but were still referred to tertiary hospital level. This was due to the fact that these subjects displayed significant risk factors for hearing loss or had an existing automated auditory brainstem response appointment at tertiary hospital level.

Referral rates varied greatly between the clinics. This may be attributed to the fact that the screening program was implemented over the course of 19 months in 3 phases. Therefore those clinics introduced in the latter phases of the program did not have the same time and experience in screening compared to the earlier clinics [11]. This was evident for one of the clinics with first and second stage referral rates of 18.8% who was introduced in the last phase of the program. This clinic had the lowest coverage rate due to consistently being short staffed, which meant screening personnel had less opportunity to practice screening and may not have

been as competent [33]. Other factors that could potentially have influenced the referral rates include noisy clinic waiting rooms [34] and infants with MEE resulting in higher false-positive rates [15]. Furthermore, referral rates are usually minimal when a two-stage hearing screening protocol with a combination of otoacoustic emissions and automated auditory brainstem response is utilized [2]. However due to financial reasons, a two-stage DPOAE hearing screening protocol for this study was deemed the most feasible and was recommended by the HPCSA Year 2007 Position Statement on EHDl [2,13]

### **Follow-up rate**

The overall follow-up rate at clinic level (85.1%) and follow-up rate at the tertiary hospital level (91.8%) was well within the required benchmark of 70% [13]. This is contrary to many previous studies where loss of patients to follow-up was reported as one of the most significant challenges [2,14,15]. The dedicated monitoring of the screening program by a screening coordinator may have been partly responsible for the high follow-up return rates [13,32]. The monitoring included telephone call reminders, home visits by community health workers to recall subjects who did not attend their follow-up appointments, training of administrative personnel dealing with clinic folders and visual reminders in the clinic folders for rescreens. The screening personnel's knowledge of the community's language and culture may have also played a role in the high follow-up return rates in his/her ability to address negative or superstitious perceptions of hearing loss [19]. Data management and tracking systems are also critical for long-term sustainability and efficacy of a screening program and the post-neonatal care pathways [5,13,17,35]. Although no national database registry for IHS currently exists in South Africa, the study utilized an electronic internet-based database (EHDl SA Oz eSP Database System) for management and statistical analysis as part of a larger pilot research program in South Africa.

### **Mean age of screening and diagnosis**

The mean age of the sample at first stage screen was 3.9 weeks of age with 89.7% of babies 6 weeks or younger. Six subjects included in the study were late for their immunization appointment and therefore fell slightly outside the 0 to 14 week range for their first screen. The oldest subject was 16 weeks of age due to time spent in the neonatal intensive care at one of the tertiary hospitals. The mean age of the sample at second stage screen was 8.4 weeks of age with 1 subject as an outlier at 18 weeks of age. This was because the subject was 13 weeks of age at the first stage screen. The mean age of the sample at first tertiary hospital visit was 13.5 weeks of age with 76.4% of babies 16 weeks or younger. This is in line with recommendations by the HPCSA Year 2007 Position Statement on EHDl [13] for diagnostic evaluations before 4 months of age for infants from clinic-based screening programs. The 4 month benchmark for screening programs at PHC clinics has been specified to allow sufficient time across three immunization visits (6, 10 & 14 weeks) for rescreens and diagnostic assessments. Four subjects were well outside the mean age however (between 27 to 36 weeks of age) at the first tertiary hospital visit. This was attributed to poor parental compliance regarding clinic and tertiary hospital follow-up appointments as also reported by Olusanya (2009) in a hospital-based UNHS screening program in Nigeria [36]. It was apparent that some of the subjects went to live with family members in rural communities in another province far from the initial screening and diagnostic services in the Cape Metropolitan area.

### **Diagnostic outcome of subjects**

An average of three visits was necessary to the tertiary hospital before a final diagnosis was recorded although 3 subjects had between 9 to 15 visits. The most important reason was due to persistent MEE as diagnosed by ENT Surgeons, which resulted in a delay in ascertaining accurate air conduction hearing thresholds. Furthermore, 2 of the subjects had a disability (cleft palate and Trisome 21), which also resulted in a delay in diagnosis of potential hearing loss due to associated MEE and difficulty in testing. The tertiary hospitals also mostly rely on natural

sleep to test babies' diagnostically, which may contribute to the poor success rate and multiple visits required.

The mean age at first diagnosis of confirmed permanent hearing loss was approximately 32 weeks, with a range of 13.6 to 41.6 weeks of age. Although this is significantly lower than previous findings in the Western Cape of 23 months of age [37], it is higher than the recommended benchmark of 4 months of age for clinic-based screening programs [13]. It must also be noted that the mean age at first screen at the clinic was 7 weeks and at first tertiary hospital visit was 11.9 weeks of age for this sample group. Factors that may have contributed to the delay in diagnosis of hearing loss are poor parental compliance, long hospital waiting lists for diagnostic tests and persistent MEE. Park and colleagues (2005) report that 20% of delayed diagnoses of hearing loss was due to middle ear infections [38].

The prevalence rate of MEE for this research sample was 12.9/1000 (26/2018) with 6 subjects requiring grommets at a later stage. This rate may have been higher if the project had utilized a unilateral refer criteria [39]. It must be noted that although 35 subjects were found to have normal outcomes, 13 subjects had MEE requiring several tertiary hospital level follow-up appointments. Therefore, although not the primary target population, the research project was preventative in identifying and treating MEE that could potentially have led to chronic otitis media with effusion and consequently a hearing loss later in life [40]. Once data analysis was completed it became evident that the subject with bilateral mixed hearing loss was diagnosed with bilateral permanent sensorineural hearing loss once the recurrent MEE dissipated. This highlights the necessity to closely monitor MEE cases since they may mask a sensorineural hearing loss [39].

## Overview and recommendations

Screening coverage and overall referral rate for diagnostic evaluation are two key measures in the effectiveness of UNHS programs [17]. Poor coverage rates at the clinic could have accounted for the low overall prevalence rate of 4.5/1000 compared to outcomes in other developing countries for community-based UNHS programs like Nigeria with a yield of 22.5 per 1000 with permanent congenital and early-onset hearing loss [9,19]. The use of a two-stage DPOAE screening protocol may not have offered the same specificity and sensitivity as the transient-evoked otoacoustic emissions/ automated auditory brainstem response combination utilized by Olusanya et al [19]. Furthermore, other unilateral losses would have been missed for the most part due to the bilateral refer criterion. However due to practical and financial reasons, targeted bilateral hearing loss criterion for this study was deemed the most feasible and was recommended by the HPCSA Year 2007 Position Statement on EHDI [13]. Another factor which could have influenced the low prevalence rates were subjects that defaulted initial and follow-up screening appointments, as well as those with pending appointments and NYD outcomes at the time of data analyses. This is illustrated in the outcomes where all subjects with hearing loss (except one) were screened at phase one clinics.

The importance of a program coordinator monitoring quality and providing on-going support and training was demonstrated by the high follow-up return rates achieved in this pilot investigation. In contrast to this, utilising already burdened clinic nursing staff as screeners may explain the poor coverage rates in this study. Dedicated screening personnel may be necessary to ensure sufficient coverage rates at clinics are achieved. In addition to dedicated screening personnel an alternative platform such as the midwife obstetrics units in the Western Cape may also improve coverage and referral rates. These units are dedicated birthing facilities alternative to domiciliary delivery in Cape Town which offer pre- and post-natal support to mothers [41]. Of particular interest are the 3 and/or 7 day post-natal visits where UNHS could effectively take

place. Coverage rates may increase as midwife obstetric units personnel focus specifically on maternal and infant care and referral rates may be low due to the fact that infants are 3 or 7 days old when screened.

## **CONCLUSION**

The community-based UNHS model in this study was partly effective with confounding variables intrinsic to the model resulting in varied coverage and referral rates and a low yield of permanent congenital and early-onset hearing loss. Findings emphasize the need for dedicated screening personnel in community-based UNHS programs and also for consideration of an alternative community-based platform such as midwife obstetric units which may improve coverage and referral rates. The high follow-up return rate attained in this study demonstrates the value of community-based programs and also emphasize the importance of a dedicated EHDI services coordinator.

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## **Conflict of interest statement**

The authors have no conflict of interests to declare.

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