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HEARING AIDS FOR CHILDREN WITH CONDUCTIVE HEARING LOSS:

OUTCOMES AND CAREGIVER EXPERIENCES

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PLAGIARISM DECLARATION

Full name:	Chéri Pienaar
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Title of dissertation**:**	Hearing aids for children with conductive hearing loss: Outcomes and caregiver experiences

I declare that this dissertation is my own original work. Where secondary material is used, it has been carefully acknowledged and referenced in accordance with university requirements.

I understand what plagiarism is and am aware of university policy and implications in this regard.

Chéri Pienaar **30 September 2021**

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ABSTRACT

Hearing aids (HAs) are considered an alternative to surgical intervention for otitis media (OM). However, it is essential to determine whether they are an effective management option for children with CHL in a low-to-middle-income country (LMIC) such as South Africa, as well as what caregivers' experiences are regarding this form of management. The aim of this study, therefore, was to describe the outcomes and caregiver experiences of children with conductive hearing loss (CHL) fitted with behind-the-ear (BTE) HAs.

This study was carried out in two phases. Phase 1 involved a retrospective review of clinical data from children aged 0-13 years with CHL who were fitted with BTE HAs between January 2017 and March 2020 at Red Cross War Memorial Children's Hospital (RCWMCH). The study sample included 19 children (mean age 88.6 months; 36.9 SD; range 14.0-149.0) with CHL fitted with BTE HAs (11 bilateral and 8 unilateral) and with available outcome data. HA fitting details were obtained for 17 participants and outcomes at the one-month post-hearing aid fitting were documented in terms of daily HA use (data-logging) (n=14/19) and caregiver and teacher reported auditory behaviour obtained through the *Parents' Evaluation of Aural/oral performance of Children* (PEACH) (n=12/19) and the *Teachers' Evaluation of Aural/oral performance of Children* (TEACH) (n=13/19) respectively. Phase 2 involved a telephonic survey with caregivers of phase 1 participants (n=13/19), to explore their perceptions and experiences.

Average HA use was 6.2 h/day (2.6 SD; range 3.8-10.1) for unilateral HA users and 6.5 h/day (2.0 SD; range 4.1-10.3) for bilateral HA users. PEACH results indicated 83.3% of paediatric HA users used their HAs more than 75% of the time at home; with more than half (58.3%) of the paediatric HA users showing typical auditory behaviour after one month of HA use. TEACH results indicated that 92.3% of paediatric HA users used their HAs more than 75% of the time at school. Paediatric HA users performed better in quiet than in noise, with limited sensitivity to loud sounds at home and school. Caregivers who participated in the telephonic survey reported HA use of more than five hours a day for most children (76.9%). All caregivers reported perceived benefit from their children's use of HAs and most caregivers

(76.9%) indicated that their children provided positive feedback regarding wearing their HAs.

Children in this study sample used their BTE HAs for comparable hours reported for children with sensorineural hearing loss (SNHL), but not for the recommended use required for optimal language development (10 h/day). Caregivers were supportive of HA use for CHL, with perceived benefits equivalent to expectations. The challenges experienced by caregivers are similar to those reported in high-income countries regarding stigma and device compliance. Children with CHL demonstrate clear benefit from using BTE HAs.

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KEYWORDS

Hearing Aids

Conductive Hearing Loss

Otitis Media

Paediatric

Outcomes

Hearing Aid Use

Questionnaire

Caregivers

Experiences

Challenges

ABBREVIATIONS

AOM	acute otitis media
BTE	behind-the-ear
CHL	conductive hearing loss
CSOM	chronic suppurative otitis media
ENT	Ear, Nose, and Throat
FM	Frequency Modulation
HA	hearing aid
LMIC	low-to-middle-income country
NICE	National Institute for Health and Care Excellence
OM	otitis media
OME	otitis media with effusion
PEACH	Parent's Evaluation of Aural/oral performance of Children
PHAMI	Parent Hearing Aid Management Inventory
RECD	real-ear-to-coupler difference
RCWMCH	Red Cross War Memorial Children's Hospital
SII	speech intelligibility index
SNHL	sensorineural hearing loss
SSA	Sub-Saharan Africa
TEACH	Teacher's Evaluation of Aural/oral performance of Children
VT	Ventilation tubes

1. INTRODUCTION

1.1. Background

It is estimated that 466 million people globally have a disabling hearing loss, with at least 34 million being children under 15 years old (World Health Organization [WHO], 2021). Hearing loss is the second most prevalent disability affecting at least 15.5 million children globally under the age of five years old (Olusanya et al., 2018). Due to the silent yet non-threatening nature of the disease, hearing loss is often overlooked in low-to-middle-income countries (LMICs) regardless of its highly prevalent nature (Olusanya, Luxon, & Wirz, 2004; Swanepoel, Delport, & Swart, 2007). Sub-Saharan Africa (SSA) has one of the greatest prevalence rates of hearing loss (WHO, 2013). Estimates suggest that the prevalence of hearing loss in children 5 to 14 years of age is 1.9% in SSA, more than double that of high-income countries (0.4%) (Olusanya, Neumann, & Saunders, 2014).

In SSA there are numerous health concerns to address, with hearing loss not prioritised despite the burden that it poses (Adedeji, Tobih, Sogebi, & Daniel, 2015). Likely reasons are the substantial challenges inherent to LMICs, such as poor healthcare infrastructure and access; widespread poverty; unemployment; lack of education regarding when to seek medical care and parental involvement; and a high incidence of infectious diseases such as human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS); and otitis media (OM) and its associated hearing loss (Swanepoel & Störbeck, 2008; WHO, 2016, 2021). Each of these factors significantly influences when a child will be diagnosed with a hearing loss, and when and if intervention will occur (Theunissen & Swanepoel, 2007; Van der Spuy & Pottas, 2008).

Almost 60% of hearing loss in children under the age of 15 years old is preventable (WHO, 2016). Many cases of childhood hearing loss while preventable, are common in LMICs, constituting almost half (48.9%) of all cases (Adedeji et al., 2015). Prenatal and perinatal complications are risk factors for hearing loss in LMICs, with postnatal infections being more prominent (Tharpe & Seewald, 2016). It is well documented that poor socioeconomic factors can lead to an increase in middle ear pathology and the associated preventable

hearing loss, in addition to the restricted access to human resources and ear health care (Tharpe & Seewald, 2016; Vos et al., 2017; WHO, 2021).

1.2. Childhood conductive hearing loss

The most prevalent causes of hearing loss in children are associated with OM (57.1%) and congenital abnormalities (21.1%) (Olusanya et al., 2018). Several pathologies are associated with conductive hearing loss (CHL) and persistent contributors include outer ear malformations, middle ear malformations and genetic syndromes (Joint Committee on Infant Hearing [JCIH], 2019; Tharpe & Seewald, 2016). These contributors tend to occur more frequently in LMICs, adding to the high incidence of CHL in SSA (Kesser, Krook, & Gray, 2013).

Prenatal factors

Prenatal factors can cause outer or middle ear malformations. Outer ear malformations, such as Atresia, occur in about 1 in 6000 births; and are unilateral in 70-90% of cases (Bartel-Friedrich & Wulke, 2007). These malformations can cause a permanent CHL up to 60dBnHL depending on the severity of the barrier (Bartel-Friedrich & Wulke, 2007; Madell, Flexer, Wolfe & Schafer, 2019). Atresia can be bony or membranous, with the barrier being of similar material. Another congenital abnormality resulting in permanent CHL is microtia (an abnormally formed pinna), which is often associated with defects, stenosis, or narrowing of the ear canal (Tharpe & Seewald, 2016; Madell et al., 2019). Microtia is more prevalent in males than females with a high incidence of asymmetry (Tharpe & Seewald, 2016). On the other hand, middle ear malformations affect the structure and size of the middle ear space (Bartel-Friedrich & Wulke, 2007). Common malformations include congenital cholesteatoma (a non-causative cyst occurring in the middle ear cavity), atypical development of the ossicles, and malformations of the oval window (Bartell-Freidrich & Wulke, 2007; Madell et al., 2019).

Some common syndromes associated with outer and middle ear malformations are Treacher Collins syndrome (Marres, 2002), Down syndrome (JCIH, 2019), Townes-Brock syndrome (Powell & Michaelis, 1999), Goldenhar syndrome (Skarżyński, Porowski, & Podskarbi-Fayette, 2009), Cornelia de Lange syndrome (Kim, Kim, Lee, Lee, & Kim, 2008),

and CHARGE syndrome (Blake & Prasad, 2006). These tend to occur more frequently in LMICs, adding to the high incidence of CHL in SSA (Kesser et al., 2013; Rodman & Pine, 2012).

Postnatal factors

The most common and treatable postnatal risk factor of CHL is OM (Tharpe & Seewald, 2016). OM is also the greatest contributor (63.7%) of acquired, temporary hearing loss in children under the age of five years old (Haile et al., 2021; Monasta et al., 2012). Globally more than 98.7 million people have hearing loss secondary to acute OM (AOM) and chronic suppurative otitis media (CSOM) (Institute for Health Metrics and Evaluation, 2020). At least 80% of all children will have an episode of acute otitis media (AOM) before three years of age, with an incidence of at least 43% in SSA (Biagio, Swanepoel, Laurent, & Lundberg, 2014; Schilder et al., 2016). The global incidence of CSOM is 4.8% and it accounts for more than half of the global burden of hearing loss (Baigio et al., 2014; Monasta et al., 2012; WHO, 2004). SSA has the second-highest prevalence rate of CSOM (Monasta et al., 2012) with HIV-positive children being more prone and severely affected than immunocompetent children (Miziara, Weber, Araujo-Filho, & Neto, 2007).

Causes of OM and its implications are multifaceted, with several risk factors noted: person-specific (age, gender, allergy, immune competence, craniofacial abnormalities) as well as environmental (day-care, tobacco smoke exposure, breastfeeding, socioeconomic status) (Biagio et al., 2014; Casselbrant & Mandel, 2003; Monasta et al., 2012; Morris & Leach, 2009). There is also growing evidence suggesting a genetic predisposition to OM (Rye, Blackwell, & Jamieson, 2012). OM can be characterised by the presence or absence of an effusion in the middle ear cavity, the nature of the effusion, as well as the duration of the effusion (Madell et al., 2019). Otitis media with effusion (OME) is the most common term for the disorder with the effusion described by its nature: serous, suppurative, mucosal, or sanguineous (Madell et al., 2019). Alternatively, an adhesive form of OM can occur and is described as a significant retraction of the tympanic membrane into the middle ear cavity (Madell et al., 2019). Chronic OM is often associated with acquired mild to moderate CHL, and if untreated can lead to permanent sensorineural hearing loss (SNHL) (Monasta et al., 2012; WHO, 2021). A study in a low-income South African community found that CHL was

the most common type of hearing loss in the paediatric population (12.2%), specifically in first-year entry school children (Hussein, Swanepoel, Mahomed-Asmail, & De Jager, 2018). CSOM is the most severe form of OM and is typically identified by an infection of the middle ear cavity, mastoid air cells, perforation of the tympanic membrane, as well as otorrhoea (WHO, 2004). The effects of OM and its impact on a population differs greatly between LMICs and high-income countries; with regions like India and SSA accounting for the greatest number of deaths due to OM complications (Biagio et al., 2014; WHO, 2004).

Previously it was estimated that South Africa had a childhood OM prevalence rate of between 3.8% and 12% (Halama, Voogt, Musgrave, & van der Merwe, 1987; Prescott & Kibel, 1991). However, these studies only focused on school-age children rather than younger preschool children who are more likely to get OM (Biagio et al., 2014; Casselbrant & Mandel, 2003). It was recently found that OME was the most common pathology in South African children aged 2-5 years (23.9%) with AOM only found in 3% of children younger than 2 years old (Biagio et al., 2014). Additionally, CSOM was found to occur more frequently in children aged 6-15 years old, with a notable prevalence of 9.3% (Biagio et al., 2014; WHO, 2004). OME can resolve naturally or require medical or surgical treatment. During this period, the CHL fluctuates depending on the severity of the fluid build-up in the middle ear cavity (Madell et al., 2019). While the prevalence of OM decreases with age, its impact on hearing has long-lasting effects (Monasta et al., 2012).

1.3. Implications of childhood conductive hearing loss

Childhood CHL can influence many spheres of childhood development, including hearing, language, communication, social and emotional outcomes. The inability to communicate effectively can negatively impact a child's quality of life and lead to feelings of loneliness, isolation, embarrassment, and frustration (WHO, 2021). In LMICs, children with hearing loss rarely receive any schooling, with some even being at an increased risk of violence (Mulwafu, Kuper, & Ensink, 2016; WHO, 2021).

The development of spoken language is proportionate to hearing ability (National Research Council, 2005; WHO, 2021). If not addressed timeously, hearing loss may not only have implications for language development, but also cognitive development, academics, as well as the development of relationships (Engdahl, Idstad & Skirbekk, 2019; Hall, 2017; Hussein

et al., 2018; Wilson, Tucci, Merson, & Donoghue, 2017). The onset of hearing loss also needs to be taken into account, particulary in children. Children who experience permanent, congenital CHL have been found to show similar performance academically to individuals with SNHL, and also experience behavioural challenges (van Hövell Tot Westerflier, van Heteren, Breugem, Smit, & Stegeman, 2018).

Congenital CHL that is not addressed timeously directly impacts speech, language and academic development (JCIH, 2019). Children with congenital hearing loss, who have a pure-tone average greater than 40dBnHL, experience behavioural problems later in life with a profound effect seen with their academic performance (Vohr et al., 2012). This subsequently leads to an increased number of grade failures and the need for educational support (Davis, Reeve, & Hind, 2001; Vohr et al., 2012; WHO, 2021). Additionally, they have difficulty with phonological processing and reading (Wake et al., 2006). Therefore, early intervention through amplification is critical to minimise the adverse effects of permanent CHL in children (WHO, 2021; Wolfe & Smith, 2016).

Commonly children with congenital CHL that is genetic in origin, experience not only hearing defecits but also cognitive difficulties; further increasing their speech and language struggles (Kesser et al., 2013; Tharpe & Seewald, 2016). The difficulties experienced by individuals such as those with permanent CHL, are exacerbated by increased healthcare costs and low income which are common in LMICs (WHO, 2021).

Children who develop post-lingual hearing loss are often impacted by the hearing loss in terms of the quality of speech production, as well as cognitive and literacy skills (Haile et al., 2021; Hussein et al., 2018; Wilson et al., 2017). Children with acquired, temporary CHL (like a transient episode of OM) experience changes in hearing but only for a limited duration and with a treatable solution (Tharpe & Seewald, 2016; WHO, 2021). Temporary CHL is typically noted when children reach school going age as they start to struggle in the classroom environment (Hussein et al., 2018). Acquired hearing loss as a result of OM has been found to increase difficulties in speech perception and reading, delayed reaction to auditory input, pronunciation difficulties and attention difficulties (Rosenfeld et al., 2016; Smit, Burgers, de Veye, Stegeman, & Breugem, 2021). In addition, temporary CHL has been

associated with poor task orientation skills and difficulties with independent class work (Roberts, Rosenfeld, & Zeisel, 2004; Rosenfeld et al., 2016).

It is evident that the impact of permanent CHL is far reaching, directly altering a child's developmental trajectory when compared to acquired, temporary CHL. However, both these groups of children with CHL require timeous and critical hearing intervention in order to limit the impact of their hearing loss (JCIH, 2019).

1.4. Hearing technology for children with conductive hearing loss

Children with hearing loss require auditory support through assistance of acoustic input using amplification (Bagatto, Moodie, Seewald, & Bartlett, 2011). The American Academy of Audiology Paediatric Amplification Protocol (AAA) (2013) and the National Institute for Health and Care Excellence's (NICE) *Guideline on Otitis Media with effusion in under 12's* (2008) support the use of appropriate hearing technology in combination with evidence-based HA fitting protocols for children with CHL (Bagatto et al., 2011). Two separate studies in children with unilateral atresia and congenital, permanent CHL (older than 5 and 6 years respectively), indicated no grade failure when they utilised hearing technology such as frequency modulation (FM) systems and hearing devices (Kesser et al., 2013; Smit et al., 2021). Various modes of acoustic amplification are available for CHL and are generally determined according to the severity and duration of hearing loss.

Hearing aids

Children who have been diagnosed with CHL, starting from a mild degree of hearing loss, should where anatomically possible, be fitted with behind-the-ear (BTE) HAs (AAA, 2013; Bagatto et al., 2011; JCIH, 2019). It is recommended that children with documented longstanding OM and an accompanying three frequency pure-tone average (the average of hearing sensitivity at 500, 1000 and 2000 Hz) of 25-30 dB HL or worse in the better ear, should be strongly considered for surgical intervention (Gan, Overton, Benton, & Daniel, 2017; NICE, 2008).

While surgery is considered first-line treatment, the NICE (2008) has recommended the use of HAs for OME that has not resolved within three months, or as an alternative to ventilation tube (VT) insertion. Additionally, the use of HAs has been recommended while

awaiting surgery, to limit the negative effects of temporary CHL on a child's academic performance (NICE, 2008). The use of HAs during this time will assist by optimising their listening and learning environments (Austeng et al., 2013; NICE, 2008; Roberts et al., 2004; Rosenfeld et al., 2016).

Bone conduction hearing devices

Treatment of permanent, congenital CHL associated with structural abnormalities, such as atresia or microtia, is not possible through conventional BTE HAs due to the limitation of available ear structures (AAA, 2013; Tharpe & Seewald, 2016). Therefore, amplification options for these populations with permanent CHL are limited to a bone conduction hearing device (BCHD) (Evans & Kazahaya, 2007). BCHDs are beneficial amplification options for children with permanent CHL as they route sounds directly to the cochlea through transmission of vibrations from a sound processor to the mastoid, bypassing any barriers in the external or middle ear (Westerkull, 2018).

BCHDs have adapted over the years and now include both non-surgical and surgical devices (transcutaneous and percutaneous) (Mejia et al., 2015; Wolfe, 2020). The most common non-surgical options are either the softband or adhesive BCHDs (Mejia et al., 2015; Neumann, Thomas, Voelter, & Dazert, 2019). They are usually recommended for children under the age of five years old, those who are awaiting implantation, or children whose candidacy for implantation is still under review (Liu, Livingstone, & Yonker, 2017; Madell et al., 2019). These non-surgical BCHD options are more cost effective as they do not require surgery in order to be utelised, making them an acceptable option in LMICs (Liu et al., 2017; Neumann et al., 2019). While these options are more financially acceptable, access to these devices in the South African public sector are restricted by the Government State Tender Board. This is where various HA companies apply each year to make their amplification devices available to the public sector (Department of Health, 2006).

Percutaneous BCHDs are surgically attached through the implantion of a titanium fixture (and become osseointegrated) and transcutaneous BCHDs are when the titanium fixture implanted into the skull is affixed to a magnetic plate that rests on the skull (Wolfe, 2020). Either of these options are typically considered for the management of permanent CHL (Mejia et al., 2015). Research has shown that percutaneous implants have better

audiological outcomes when compared to non-surgical options such as a softband for older children and adults (Liu et al., 2017; Wolfe, 2020). This advantage has been attributed to the fact that the processor on the implanted abutment has the ability to directly stimulate the inner ear and maximise gain by eliminating transcutaneous attenuation, a disadvantage experienced by BCHDs utelising a softband (Liu et al., 2017). However, the costs of percutaneous devices are high, especially when considering the surgical procedures involved (Hagr, 2007), limiting access in LMICs (McMahon, Nieman, Thorne, Emmett, & Bhutta, 2021).

1.5. Hearing technology outcomes in children with conductive hearing loss

Children with CHL fitted with BCHDs showed significantly improved functional hearing gain as well as improvements in speech perception in both quiet and noise (Neumann et al., 2019). However, differences were noted between users with bilateral CHL versus unilateral CHL. Children with bilateral CHL who are fitted with BCHDs showed a greater improvement in both localisation and speech recognition; additionally, they reported being satisfied with their amplification choice (Priwin, Jönsson, Hultcrantz, & Granström, 2007). Furthermore, users with permanent CHL showed an increase in hearing gain of between 30-35dBnHL (de Wolf, Hendrix, Cremers, & Snik, 2011; Lustig et al., 2001). Up to 80% of bilateral CHL amplification users felt that their BCHD was an improvement, especially when it came to learning (Priwin et al., 2007). This supports the use of hearing technology for the educational use of learners with CHL.

On the other hand, the benefits of amplification for children with unilateral CHL is more varied, with sporadic device usage (Priwin et al., 2007). While users with unilateral CHL did show some improvement in their speech recognition in noise, none had improvements in localisation (Priwin et al., 2007). However, individual reviews of children with unilateral CHL who struggle with their speech, language, and academic skills; showed an improvement in their quality of life once they were fitted with amplification (Lieu, 2013). De Wolf et al. (2011) therefore advised that due to the varied results for unilateral CHL amplification users, the decision to fit amplification in this population should be made on a case-by-case basis. Additionally, a trial period is suggested for at least two weeks to allow the use of the device within an educational setting (Bagatto & Tharpe, 2014; de Wolf et al., 2011).

Studies on the use of BTE HAs in children with acquired, temporary CHL are limited, the majority of which are dated (Flanagan et al., 1996; Jardine et al., 1999) and have a small sample size (Gan et al., 2017). A recent study indicated that at least a third of paediatric ENT patients who had OME were referred to a hearing health professional for temporary HA fitting; with up to 50% having received this intervention while the remainder had their CHL resolved by the time of assessment (Gan et al., 2017). Of those who received the intervention, it was reported that 95% used their HAs, however, usage varied (Gan et al., 2017). Other small-scale studies by Flanagan et al. (1996) and Jardine et al. (1999) found that more than two-thirds of children fitted with HAs used them regularly. There is limited data available on the outcomes of children with CHL fitted with BTE HAs, with available literature using small sample size studies and focusing on high-income countries (Cai & McPherson, 2017; Gan et al., 2017).

With healthcare systems emphasising evidence-based practice, decisions made will need to be in the best interest of children; requiring audiologists to assimilate clinical experience with external evidence obtained through research to continue improving service delivery for the paediatric population (Abrams, McArdle, & Chisolm, 2005).

1.6. Family-centred care for paediatric hearing aid users and their families

The selection of hearing technology is only one aspect of the management of childhood hearing loss (JCIH, 2019). An integral aspect of managing childhood hearing loss is a family-centred approach where families are not only the primary stakeholders in the decision-making process but also primarily responsible for the implementation of HA use and management (Bagatto & Tharpe, 2014; Muñoz et al., 2015).

Buy-in and support are essential when trying to achieve the best outcomes during the intervention process (JCIH, 2019). Caregivers understanding of how hearing loss can impact their child's development, the intervention required, as well as how to manage hearing loss as part of a daily routine, are all critical for well-managed hearing technology and achieving improvements in language development (Muñoz et al., 2015). To better support families and improve hearing outcomes, an understanding of caregiver experiences during the amplification process is needed (Muñoz et al., 2015).

A study by Muñoz et al. (2015) found that at least 50% of parents felt that the behaviour of their children made HA use a challenge; with a third reporting that alternative caregiver education of the HAs made consistent usage a challenge. Some additional concerns noted were the stigma associated with HA use (Jardine et al., 1999); and that consistent motivation and monitoring were needed from caregivers to sustain HA usage (Muñoz et al., 2015). Walker et al. (2013) reported that maternal education, the severity of hearing loss and the age of the child were predictors for HA usage. Muñoz et al. (2015) added that parent challenges, perception of benefit, and the task of daily HA maintenance all influenced HA outcomes.

Hearing loss can lead to increased stress levels for many caregivers of children with hearing loss (Lederberg & Golbach, 2002). While some studies investigated caregiver experiences of children with hearing loss fitted with HAs, these have been limited to caregivers of school-aged children and children with permanent SNHL (Lederberg & Golbach, 2002; Meinsen-Derr, Lim, Choo, Buyniski, & Wiley, 2008). Still, the data from these studies suggest that caregiver experiences, challenges, and perceived benefits of HAs can impact the outcomes of HA use (Lederberg & Golbach, 2002; Meinsen-Derr et al., 2008). There is a dearth of data on caregiver experiences of children with CHL fitted with HAs, with current data focusing on reasons for poor HA use only (Gan et al., 2017).

1.7. Problem statement and rationale

LMICs have higher rates of acquired, temporary CHL and less access to advanced treatments like Ear, Nose and Throat (ENT) surgical skills (Kaspar et al., 2018; Mulwafu, Ensink, Kuper, & Fagan, 2017). When available, specialist services are distributed inequitably and standardised treatment options for children who would normally have surgery as the first line of treatment are limited (Mulwafu et al., 2017). This then leads to children with acquired, temporary CHL being referred to hearing health professionals where they are fitted with hearing technology to minimise the period and impact of hearing loss (Gan et al., 2017).

Globally, available guidelines for the management of paediatric amplification in children with CHL are not age-specific, with most available data used to develop guidelines for children older than five years of age (AAA, 2013; Bagatto et al., 2011). To date several

studies on CHL have maintained focus on amplification by BCHDs (de Wolf et al., 2011; Neumann et al., 2019; Priwin et al., 2007); however, this is not always feasible for temporary changes in hearing or, in LMICs where these devices are costly and not freely available (McMahon et al., 2021).

Substantial evidence exists about the impact of SNHL on a child's quality of life, the family's quality of life, as well as the child's outcomes with their HAs. However, there is limited research on the outcomes of children with CHL who use BTE HAs, with current literature having limited sample sizes and focusing on high-income countries (Gan et al., 2017; Stewart, Coker, Jenkins, Manolidis, & Bautista, 2000). While the evidence is available that supports the use of HAs in CHL management (Gan et al., 2017; Stewart et al., 2000), there is a lack of data focusing on the experiences of the family (Muñoz et al., 2015).

Continued research into the management and outcomes of children with CHL is necessary for evidence-based service delivery and improved family-centred care. With ENT specialists increasingly referring children for HAs as a management option for OM (Gan et al., 2017) in LMICs, it is necessary to determine whether this is an effective treatment option for temporary childhood CHL, as well as how caregiver perceptions and experiences can influence this. To do this, the question that should be asked is: *What are the HA outcomes and caregiver experiences for children with CHL who are fitted with BTE HAs?*

2. METHODOLOGY

2.1. Research aim

This study aimed to describe HA outcomes and caregiver experiences of children with CHL that were fitted with BTE HAs.

2.2. Research design

This study was carried out in two phases. Phase one used a retrospective descriptive research design to describe and explain the characteristics and HA outcomes of paediatric HA users with CHL (Leedy & Ormrod, 2020). This phase collected quantitative data and was retrospective as the information obtained had been collected as part of ongoing audiological management at Red Cross War Memorial Children's Hospital (RCWMCH) (Leedy & Ormrod, 2020).

Phase two of this study was conducted using cross-sectional data in the form of a telephonic caregiver survey. A survey design was used to obtain a large amount of information from several individuals in a cost-effective manner (Manchaiah, Beukes, & Roeser, 2021). Survey data were used to supplement and enhance the previously collected retrospective data. In this phase, quantitative data were collected, as well as qualitative data that were obtained through several open-ended questions included in the survey (Leedy & Ormrod, 2020; Manchaiah et al., 2021). Qualitative data allows for a more comprehensive understanding of a topic (Leedy & Ormrod, 2020), which in this survey was caregiver experiences for children with CHL.

2.3. Research context

RCWMCH was built in 1956 in Cape Town and is the first stand-alone tertiary institution in SSA dedicated entirely to child health care - caring for children from birth to 13 years of age. Children from across South Africa and the African continent are referred to the hospital with approximately 250 000 to 300 000 seen annually (The Children's Hospital Trust, 2018).

The City of Cape Town has an estimated population of just under four million people, with the distribution of females (51.1%) being higher than males (48.9%) (South African National Census, 2012). The population comprises Black Africans (38.6%), Coloured (42.4%), Caucasian (15.7%) and Asian (1.4%) racial groups (Statistics South Africa, 2016). Approximately 25% of the population are children under the age of 14 years old (South African National Census, 2012).

The RCWMCH Department of Audiology assesses and assists in the rehabilitation of hearing for approximately 200 children every month. As a tertiary institution, referrals are received from various district, secondary and primary level facilities (Kuschke, Swanepoel, le Roux & Strauss, 2020). The hospital serves mostly families who do not have access to private medical care and receive care from the public health sector (The Children's Hospital Trust, 2018). Children with CHL are predominantly referred from the medical out-patients department (MOPD) or the ENT department (Kuschke et al., 2020).

An initial hearing assessment is conducted to determine whether a hearing loss is present. Should a CHL be diagnosed in a child, an ENT consultation takes place to determine which method of management will be followed. Management methods include either watchful waiting, medical management, surgical management or monitoring of hearing sensitivity until eligible for surgical management. A repeat hearing assessment takes place three months later to determine whether the hearing loss has resolved. Should there be no improvement or surgery is delayed due to chronological age, a joint session with all stakeholders takes place to discuss the recommendation of HAs. A review of school performance is also included when determining candidacy. If the family consent, ear mould impressions are taken and a HA fitting date is scheduled.

The RCWMCH Department of Audiology follows the guidelines for clinical practice as outlined in the AAA Clinical Practice Guidelines on Paediatric Amplification (2013) when carrying out HA fittings. All HA fittings performed within the department are verified electro-acoustically using the Desired Sensation Level (DSL) version 5.0 paediatric fitting formula to provide a standardised and individual fitting process.

To measure the response of the HA to a variety of input levels, the real-ear-to-coupler difference (RECD) is measured. RECD is the sound pressure level (SPL) difference between

the 2cc coupler as used in HA specifications, and the actual measurement obtained specific to an individual's ear canal (Bagatto & Tharpe, 2014; King, 2010). The smaller the ear, the greater the SPL; therefore, RECD measures are critical when fitting paediatric amplification; to prevent over-amplification (AAA, 2013; Bagatto & Tharpe, 2014; King, 2010). Should this not be possible, often due to increased cerumen in the ear canal or poor patient co-operation, age-appropriate RECDs are provided in the verification software (King, 2010). This also yields an aided Speech Intelligibility Index (SII) which indicates whether the fitted amplification is providing sufficient access to speech sounds, in comparison to when the patient is unaided (Bagatto & Tharpe, 2014).

To determine HA use (data-logging), the average hours worn per day are determined by checking the automatic data logging on the HA. Additionally, the department utilises outcome measure tools in line with international evidence-based guidelines (AAA, 2013), namely the *Parent's Evaluation of Aural/Oral Performance of Children* (PEACH) and the *Teacher's Evaluation of Aural/Oral Performance of Children* (TEACH).

These data (HA use and functional outcomes questionnaires) are captured for children fitted with amplification at the first follow-up at one month post fitting and reviewed at the one-month follow-up appointment to determine whether any audiological management changes are needed. Additional information is obtained, where possible, through aided audiograms. All HA fitting and outcome data are recorded in the children's hospital folders.

2.4. Ethical considerations

To conduct research ethically, it is essential to protect the rights and the well-being of the participants involved (Leedy & Ormrod, 2020; World Medical Association, 2013). This study observed guidelines relevant to research in the South African context (Health Professions Council of South Africa, 2008) as well as those outlined by the University of Pretoria's research code of ethics (University of Pretoria, 2018). Initially, before data collection could commence, ethical clearance was obtained from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria (Appendix A); the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town (Appendix B); as well as the Research Review Committee at RCWMCH, Cape Town (Appendix C). Prior to phase two of data collection, an addendum proposal was submitted in order to include a

telephonic caregiver survey within the study design. This addendum proposal was submitted and subsequently accepted for ethical clearance by the Research Ethics Committee of the Faculty of Humanities, University of Pretoria (Appendix D) and the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town (Appendix E); in addition to the original ethical clearance. The ethical principles and their application are explained below.

Permission

An information letter detailing the study outline and what information would be required from the department was sent to the Head of the Department of Audiology at RCWMCH (Appendix F). The Head of the Department of Audiology permitted in writing (Appendix G) access to departmental records.

Informed consent

Participants for phase one of this study were identified through the departmental electronic database, and their HA and outcomes data were obtained retrospectively from both departmental and hospital records. Routinely, caregivers of children seen at the RCWMCH Department of Audiology were required to sign a consent slip (Appendix H) that stated they permitted their child's hospital folder information to be used for research purposes.

Phase two required caregiver consent for participation. A verbal consent form (Appendix I) was created to provide and outline the procedure, risks, and benefits of participation by caregivers. The information provided was concise and easy to understand, with the study title and participants rights clearly described (Leedy & Ormrod, 2020). Before undertaking the telephone survey (Appendix J), each prospective participant had to give verbal consent to participate in this research study. This was recorded by the interviewer before commencement.

Confidentiality and privacy

A critical research requirement is to protect the confidentiality and privacy of all research participants by omitting all identifiable information from the data (Leedy & Ormrod, 2020). In phase one of the study, each participant was allocated an alphanumeric code, and all

corresponding documentation for that participant utilised that unique code to ensure confidentiality. In phase two, caregiver participants were informed that their identity would be strictly confidential, with their information only known to the researcher analysing the data. Only the interviewer conducting the survey and researcher was aware of the participant's identity. Each participant was allocated an alphanumeric code that corresponded to the relevant phase one participant, and any characteristic data was omitted to ensure privacy. Confidentiality and the right to privacy were confirmed in both the Department of Audiology research consent slip (Appendix H) and the telephone survey verbal consent form (Appendix I).

Protection from harm

A primary concern in health research is the respect for participant dignity, wellbeing, and safety (World Medical Association, 2013); with minimal risks not outweighing those in normal daily life (Leedy & Ormrod, 2020). As the research data were collected through a retrospective data review and telephonic survey; there was no physical contact or testing that would expose research participants to any harm, both physically and mentally.

Benefits

All participants were informed that there were no direct benefits for them by consenting to participate in this study, rather that the results obtained through this research may provide evidence to improve the management of children with CHL.

Release of findings

Caregiver participants were informed that the results obtained in this study may be published in scientific journals (Appendix I). To ensure this research is available to the broader scientific community, a research article was compiled, submitted and accepted for publication (Appendix K). Additionally, a research dissertation was compiled and will be made available both online and in hard copy at the University of Pretoria library.

Data storage

All data pertaining to this study will be stored electronically at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for at least fifteen years.

Additionally, the research datasets will be uploaded onto Figshare, the University of Pretoria's Research Data Repository.

Plagiarism

This research report reflects the researcher's work. All secondary material utilised throughout this report was accurately cited and referenced according to the University of Pretoria's guidelines. A declaration of originality has been signed by the researcher (please refer to page iv of this dissertation for the plagiarism declaration).

2.5. Research participants

This study was conducted in two phases, each of which had its own set of participants: paediatric HA users (phase 1) and their caregivers (phase 2). The target paediatric population for this study were children under the age of 14 years old who had been diagnosed with CHL and fitted with BTE HAs. Paediatric participants were recruited from RCWMCH Department of Audiology. The caregivers of paediatric participants were identified and recruited to participate in a telephonic survey.

Paediatric hearing aid user participant selection criteria

Children (0-13 years old) diagnosed with CHL that occurred for longer than three months, were considered participants for this study. Paediatric HA user participants were selected according to a purposive-convenience sampling method; allowing the researcher to select participants based on their type of hearing loss and amplification management; while looking to obtain information that is generalisable and demonstrative of the population from which these participants were found (Leedy & Ormrod, 2020). A total of 19 paediatric HA users were identified to have met the inclusion criteria in phase one of this study.

The following criteria were required for the inclusion of paediatric HA users:

- Participants had to be younger than 14 years old since RCWMCH only provides services for children from birth up to 13 years of age.
- Participants must have been diagnosed with a CHL, regardless of aetiology or laterality of hearing loss (unilateral or bilateral CHL).

The definition of CHL utilised at RCWMCH Department of Audiology is adapted from Schlauch and Nelson (2015):

A difference of 15 dB HL or more between air conduction (AC) and bone conduction (BC) thresholds, with BC thresholds being less than 20dBHL; at all thresholds between 500Hz to 4000Hz.

- Participants must have been fitted with BTE HAs (either unilaterally or bilaterally) and received HA follow-up management at RCWMCH Department of Audiology.
- Participants must have had data available for at least one functional outcome questionnaire (PEACH or TEACH) utilised by the RCWMCH Department of Audiology, to establish functional outcomes.
- Participants must have had a minimum one-month duration of HA use to ensure fair and accurate reporting of HA outcomes data.

Caregiver participant selection criteria

Caregiver participants were selected according to a purposive-convenience sampling method as they were identified based on their relationship to the identified paediatric HA participants (Leedy & Ormrod, 2020). On identification, caregivers were contacted telephonically regarding their willingness to take part in a telephonic survey. A total of 13 caregivers consented to a telephone survey in phase two of this study.

The following criteria were required for the inclusion of caregiver participants:

- Verbal consent following the purpose of the study as outlined in the telephonic survey participant consent form (Appendix I).
- Completion of the caregiver telephonic survey (Appendix J) exploring caregivers' feelings and habits towards their child's HA use; the challenges they experienced during the HA use period; and their thoughts and feelings during the HA usage period.

2.6. Data collection equipment and materials

RCWMCH Department of Audiology electronic database

Routinely, identifying information, type and degree of hearing loss, risk factors for hearing loss, age of diagnosis of hearing loss, and type of amplification are captured by the Department of Audiology in a Microsoft Excel spreadsheet. This is saved on a password protected computer within a locked office. Access to this data is limited to four departmental audiologists trained to record data uniformly, ensuring reliable and consistent data capturing. This database was utilised to retrospectively identify participants with CHL and fitted with BTE HAs for phase one of this study.

RCWMCH clinical records

In phase one of this study, some data not routinely included in the electronic database were captured retrospectively from clinical records in patient hospital files. This data collection included demographic information, family income, HA fitting information (RECD and aided SII values), daily HA use (data logging), and HA functional outcome measures (PEACH or TEACH).

Parent's Evaluation of Aural/Oral Performance of Children

The PEACH is a measure of everyday functional auditory and communication performance (Cupples et al., 2017; Marnane & Ching, 2015) and can be used to identify situations that could negatively impact a child's regular amplification use (Marnane & Ching, 2015). The PEACH requires caregivers to observe and rate both their child's listening and communication skills in quiet and noisy real-life situations (Ching & Hill, 2007; Ching, Dillon, Leigh, & Cupples, 2018); and was designed for use for children of all ages (Ching & Hill, 2007). However, due to the nature of the questions, it was determined that the likely age range is for children older than two years old (Marnane & Ching, 2015).

Caregiver responses are coded according to a five-point scale with response values of 0 = `Never or 0% of the time', 1 = `Seldom or 25% of the time', 2 = `Sometimes or 50% of the time', 3 = `Often or 75% of the time', 4 = `Always or greater than 75% of the time' (Ching & Hill, 2007). The questionnaire consists of 13 items: one regarding the child's HA use and

listening comfort respectively; the remaining 11 items gather information about the child's auditory behaviour and awareness to environmental sounds in quiet (five questions) and noisy (six questions) real-life situations (Ching & Hill, 2007; Cupples et al., 2017). A performance score is then calculated for quiet, noisy, and overall environments using the summed values of the 11 items, as rated by the caregiver. These are expressed as a percentage, with a higher percentage indicating better listening outcomes (Ching & Hill, 2007; Wong et al., 2018). The total percentage score for each subset can be plotted with auditory behaviour determined as `typical performance', `possible review indicated', or `further review indicated' (Bagatto et al., 2011). This can be carried out by the audiologist or other health care professionals (Ching et al., 2018).

Several studies in high-income countries have looked at the use of the PEACH to evaluate HA benefit for the paediatric population, as routine clinical practice (Ching et al., 2018). These studies compared a few questionnaires regularly used to assess hearing or listening difficulties in children. The PEACH scored highly as it: obtained real-life examples of the impact of hearing loss (Cupples et al., 2018; Emerson, 2015; Gan et al., 2017); and was easy and quick to complete (Ching et al., 2018; Cupples et al., 2018; Gan et al., 2017) – making it useful in a clinical setting (Cupples et al., 2018). Additionally, Gan et al. (2017) found that the PEACH was relevant to use in the monitoring of children with OM as it was functional, added to the audiological information, and accounted for fluctuations in hearing loss.

The Learning from the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study (Ching et al., 2018) indicates that the PEACH can be used to monitor the language development of children with hearing loss. This correlation allows the PEACH to be used in populations where standardised tools are not able to be administered, and where language barriers are a limitation (Ching et al., 2018; Emerson, 2015).

Reliability and validity of the PEACH indicate good test-retest reliability (0.93) and good internal consistency (0.88) (Ching & Hill, 2007; Gan et al., 2017). This was emphasised by a large amount of normative data: 90 parents of normal-hearing children and 90 parents of children with hearing loss (Ching & Hill, 2007).

Teacher's Evaluation of Aural/Oral Performance of Children

The TEACH is a measure of everyday functional auditory and communication performance (Cupples et al., 2017; Marnane & Ching, 2015) at a school level (Emerson, 2015). Like the PEACH, it can be used to identify situations that could negatively impact a child's regular amplification use (Marnane & Ching, 2015). The TEACH requires teachers to observe and rate both the child's listening and communication skills in quiet and noisy situations (Ching & Hill, 2007).

Similarly, the TEACH responses are coded according to the same five-point scale as the PEACH, with response values of 0 = `Never or 0% of the time', 1 = `Seldom or 25% of the time', 2 = `Sometimes or 50% of the time', 3 = `Often or 75% of the time', 4 = `Always or greater than 75% of the time' (Ching & Hill, 2007). The questionnaire consists of 11 items: one regarding the child's HA use and listening comfort respectively; the remaining 9 items gather information about the child's auditory behaviour and awareness to environmental sounds in quiet (five questions) and noisy (four questions) real-life situations (Ching & Hill, 2007; Emerson, 2015). A performance score is then calculated for quiet, noisy, and overall environments using the summed values of the 9 items, as rated by the teacher. These are expressed as a percentage, with a higher percentage indicating better listening outcomes (Ching & Hill, 2007; Emerson, 2015).

The TEACH, while not independently studied, is derived from the PEACH; sharing its clinical relevance (Ching & Hill, 2007; Emerson, 2015). Emerson (2015) compared data obtained from the PEACH and TEACH in a sample of hearing-impaired learners from India; with results showing a correlation ($p < 0.01$) in both quiet and overall noise conditions – indicating agreement between caregivers and teachers. A strong correlation between the TEACH and PEACH scores have been previously noted when compared for a population of children with SNHL (Ching, Hill, & Dillon, 2008). Additionally, the TEACH has been recommended by the AAA (2013) as part of their paediatric amplification guidelines.

Telephonic survey

Phase two of this study considered caregiver perceptions and experiences which were obtained using a telephonic survey developed specifically for this research study (Appendix

I). Survey data were used to enhance and supplement the available retrospective descriptive and functional outcome data from phase one.

The telephonic survey was designed for this study after reviewing numerous published articles, protocols, and questionnaires within the field of early childhood intervention and hearing loss (Bagatto et al., 2011; Mathers, Smith, & Concha, 2008; Muñoz et al., 2015; Swanepoel & Storbeck, 2008; van der Spuy & Pottas, 2008), and paediatric CHL (AAA, 2013; Biagio et al., 2014; Kaspar et al., 2018; NICE, 2018; Olusanya, 2008; Tharpe & Seewald, 2016). The study aim was used as a framework, as well as the incorporation of a variety of resources. Specific focus was placed on the *Parent Hearing Aid Management Inventory* (PHAMI), which was specifically developed to better understand caregiver access to information and their experiences with their child's HA management through four domains (Muñoz et al., 2015). Two domains of the PHAMI were used for phase two of this study, namely caregiver expectations and HA use challenges. Internal consistency has been confirmed for the PHAMI (Muñoz et al., 2015).

The telephonic survey obtained caregiver information regarding their child's HA use; thoughts and feelings regarding management and use of HAs; and HA management challenges encountered. The survey was designed for use in English, but in some cases where isiXhosa speaking caregivers struggled to understand the question, the interviewer would then translate accordingly into isiXhosa. The survey consisted of five sections and a total of 36 items were included: 30 close-ended questions and six open-ended questions. A Likert scale (1 = strongly disagree to 5 = strongly agree) was used in the two sections that contained the two domains from the PHAMI. A section with open-ended questions regarding expectations and challenges was included to attain a better understanding of the specific challenges that caregivers of children with CHL fitted with HAs encounter.

The questions looked to obtain caregiver opinions on the HAs, not limited to predetermined responses, and whether they met their expectations. By utilising a larger number of close-ended questions, it allowed caregiver participants to complete the survey in a more timeous manner while simultaneously allowing the researcher to obtain an increased amount of information; participants also tend to understand close-ended questions better (Neuman,

2014). An additional benefit of close-ended questions is that they yield more consistent responses and allow for easier analysis of data (Manchaiah et al., 2021; Neuman, 2014).

The inclusion of a smaller number of open-ended questions allowed for a more effective manner of identifying expectations and challenges that caregiver's perceived (Neuman, 2014). It was important to limit the number of open-ended questions as the survey was telephonic and therefore time was considered when having to answer the survey. Additionally, statistical analysis for open-ended questions can be more challenging (Leedy & Ormrod, 2020; Manchaiah et al., 2021).

Pilot study of the telephonic survey

As this survey was newly developed for this study and adapted from previous surveys, a pilot study was first conducted. The pilot study was used to establish any possible weaknesses within the survey questions and correct them accordingly (Leedy & Ormrod, 2020). This guarantees the precision of the research as well as the accuracy of information obtained (Neuman, 2014).

The objective of this pilot study was to ascertain if the survey was created in a manner that was coherent and adequately addressed the necessary problems relevant to the study aim (van Teijlingen & Hundley, 2002). Additionally, the pilot study was utilised to simplify and adapt the wording of the questions in the survey, given the study population. Two caregivers of paediatric HA users with CHL, who met the inclusion criteria, participated in this pilot study.

In addition, feedback from hearing health professionals working with caregivers and children in hearing healthcare was obtained to safeguard face validity. The professionals who participated in the pilot study consisted of three audiologists with experience in both the research and clinical settings. All professionals had experience with both CHL, as well as paediatric amplification.

All pilot study participants were given a copy of the verbal consent letter (Appendix I) and survey (Appendix J), with the purpose and procedure of the study outlined, including areas requiring their input: content, question suitability, structure, and length. Participants were requested to provide feedback as soon as possible. The hearing health professionals all

provided feedback in the electronic written format while the two caregiver participants provided feedback verbally over the telephone. From this feedback, the survey was then reviewed and adapted to be more suitable for this study.

A summary of the feedback provided from the pilot study, based on the areas of review and the changes made, is provided in Table 1.

Table 1. Telephonic survey pilot study findings

Elements considered	Comments	Modifications
Question structure, order and length	• Section C, question 4: "I am/was concerned about how I will manage how my child feels about wearing the hearing aids" *Lengthy question. Try to simplify.*	The question was simplified to: "I am/was concerned about how I will/would deal with my child's feelings about their hearing aids"
	• Section C, question 1: "I accept/accepted my child's hearing loss" *Consider question order. If starting with question 5, the survey may flow easier.*	Originally question 5, and is now question 1 of Section C.
Question content	• Section E, question 3: "Did you feel that the hearing aids did what you expected them to?" *May be useful to establish what the parental expectation was before this question.*	A question was inserted before this one to establish parental expectation: "What did you expect from the hearing aids when your child started using them?"
Intelligibility	• Section B, question 1a: "If "Yes", what motivates you and your child to continue using their hearing aids?" *Rephrase for clarity.*	Question adapted to: "Why is it important to you and your child to wear the hearing aids?"
	• Section C, question 5: "I think my child is benefiting/was benefiting from using hearing aids" *Re-phrase for clarity purposes.*	The question changed to: "I think the hearing aids help/helped my child"
	• Section C, question 8: "I feel/felt frustrated with the daily management of the hearing aids" *Consider rephrasing daily management as it is quite a broad term.*	The question changed to: "I feel/felt quite frustrated with handling the hearing aids every day"

	• Section C, question 13: "The fact that the hearing aids are/were supposed to be temporary helps/helped manage them" *Clarify who it helped manage, the parent or child.*	The question changed to: "The fact that the hearing aids are/were supposed to be temporary helps/helped me to manage them"
	• Section D, question 7: "The audiologist's lack of response when I have questions" *Clarify the type of interaction.*	The question changed to: "The audiologists lack of response to my questions during the appointment"
	• Section D, question 12: "My insecurities with the appearance of my child's hearing aids" *Consider rephrasing to omit ''insecurities' as it implies it is the parent's fault that they feel this way.*	Question adapted to: "My concern with the appearance of my child's hearing aids"
	• Section D, question 16: "My feelings of frustration with trying to keep the hearing aids on" *Rephrase for clarity purposes.*	The question changed to: "Difficulty keeping the hearing aids on"
	• Section E, question 1: "In your opinion, what are/were the benefits of hearing aids for your child (how does/did your child benefit from his/her hearing aids?)" *Consider rephrasing for more clarity.*	The question changed to: "In your opinion, how did the hearings help your child?"
	• Section E, question 2: "In your opinion, what is/was the greatest challenge associated with your child using hearing aids?" *Consider rephrasing.*	Question amended to: "In your opinion what do/did you find most challenging about your child's hearing aid use?
Relevance of questions	• Section D, questions 9 and 10: "Frequent ear infection, i.e. leaking ear" "Frequent ear pain" *Consider merging into one question.*	None. Questions refer to separate descriptors that can take place in isolation from one another.

2.7. Data collection procedures

Following all necessary ethical approvals, and permission from the Head of the Department of Audiology (Appendix G) to access data of paediatric HA users, phase one of this study commenced. The Department of Audiology's electronic database and clinical records were reviewed retrospectively for the period January 2017 until March 2020.

Paediatric HA users were identified according to the inclusion criteria outline in section 2.5 and 19 participants were identified. Data collected retrospectively for these participants included demographic information, family income, age of diagnosis of hearing loss, age at the fitting of HAs, HA fitting information (RECD and aided SII scores for average sounds) (n=17/19), average daily HA use (in hours) at the one-month follow-up (data-logging) (n= 14/19), and HA functional outcome measures [PEACH (n=12/19) and TEACH (n=13/19) questionnaires] at one-month post HA fitting. This information was then captured in a Microsoft Excel spreadsheet with each paediatric HA participant allocated a unique alphanumeric code.

Following retrospective data collection, phase two of this study commenced. Caregivers of the identified paediatric HA participants were identified as outlined in section 2.5 and contacted telephonically regarding their possible participation in a research study. A verbal consent letter (Appendix I) that explained the research study and provided information on the telephonic survey was discussed with each caregiver. Survey data collection only took place once verbal consent was obtained and recorded by the interviewer. Caregiver participants were then required to telephonically complete the survey questions as read to them by the interviewer. Each telephonic survey took approximately 15-20 minutes. All survey information was recorded manually by the interviewer on a hard copy of the survey (Appendix J). These responses were later captured electronically by the researcher in a Microsoft Excel spreadsheet with an alphanumeric code to maintain confidentiality (Leedy & Ormrod, 2020). Caregiver's who consented to the survey were allocated the same unique alphanumeric code as the corresponding paediatric HA participant to merge the survey data with the retrospectively obtained data.

2.8. Data processing and analysis

Descriptive statistics

All data were captured and prepared in Microsoft Excel (Microsoft Corp, Redmond, WA). The data were imported into the Statistic Package for the Social Sciences Version 27 (IBM SPSS v27.0, Armonk, NY) for analysis. Phase one of this study consisted of quantitative data that were described as measures of central tendency and measures of variability. In addition, the internal consistency of the two Likert scale sub-sections of the telephonic survey was determined using Cronbach's Alpha. As outlined in section 2.6, both the functional auditory performance questionnaires (PEACH and TEACH) were scored according to their design for the three relevant domains (Ching & Hill, 2007, Ching et al., 2008).

For ease of analysis, some of the ratings of the Likert scale sub-sections used in the telephonic survey (phase two) were combined: "strongly disagree" and "disagree" were combined as a "disagree", and "strongly agree" and "agree" were combined as an "agree" response. These results were then displayed in table format.

Thematic analysis of open-ended questions from the telephonic survey

A thematic analysis was conducted for answers to open-ended questions from the telephonic survey used in phase two of this study. The questions inquired about the benefits and challenges of HA use, expectations of HAs, as well as the paediatric HA users' feelings towards using HAs. All qualitative data recorded were analysed using thematic content analysis. The responses obtained from the open-ended questions were categorised, coded, and subsequently grouped into central themes to identify trends amongst responses (Leedy & Ormrod, 2020). These themes were then summarised with examples in table format according to perceived benefits, challenges, expectations, and child's feelings towards HA use.

2.9. Reliability and validity

Reliability looks at the consistency of a measurement tool to provide the same results when carried out in the same situation, on separate occasions; whereas validity is defined as the degree to which a concept is accurately measured (Heale & Twycross, 2015; Leedy &

Ormrod, 2020). Both reliability and validity were used in this study design. Firstly, the PEACH and TEACH questionnaires were valid and accurate sources of obtaining functional outcome information, with good test-retest reliability (0.93) and internal consistency (0.88) confirmed (Ching & Hill, 2007). Additionally, the questionnaires were validated on both normal-hearing children and children with hearing loss. Likewise, by calculating the internal consistency of the telephonic survey sections it indicated that caregiver responses were measured in the same way and would allow for a fair comparison of responses (Leedy & Ormrod, 2020).

To avoid compromising the construct validity of the research study, the caregiver survey only contained questions specific to the research study's aim. Any possible biased, misleading, or ambiguous questions were either adapted or removed from the survey. This was achieved by conducting a pilot study to allow for the adaption of the questions before data collection commenced (Leedy & Ormrod, 2020). To ensure that the telephonic survey measured what it was intended to (Leedy & Ormrod, 2020), published articles and audiological protocols were reviewed before developing the questions to ensure that content validity was achieved. Additionally, face validity of the survey was established through the execution of a pilot study to determine whether the question content, structure, the order and length of the questions, relevance of the questions, and the clarity of the questions met the objectives of the research study (Leedy & Ormrod, 2020). The results of the pilot study allowed for the revision of the questions before data collection. By using the caregiver survey, the reliability and validity of the study have been enhanced as participants would have provided meticulously thought-out responses (Leedy & Ormrod, 2020).

3. CHILDREN WITH CONDUCTIVE HEARING LOSS FITTED WITH HEARING AIDS: OUTCOMES AND CAREGIVER EXPERIENCES, SOUTH AFRICA

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Proof of acceptance: Appendix K

3.1. Abstract

Introduction: Hearing aids (HAs) are a frequent management option for children with conductive hearing loss (CHL) and it is necessary to determine outcomes efficacy. Limited information regarding caregiver perceptions and experiences are available to examine outcomes in this population.

Objectives: To describe hearing aid outcomes and caregiver experiences for children with CHL who wear behind-the-ear (BTE) HAs.

Methods: Retrospective review of clinical data from 19 children between 0-13 years with CHL who were fitted with BTE HAs between January 2017 and March 2020. HA outcomes were documented at one month post-fitting via average daily use (n=14/19) caregiver (n=12/19) and teacher (n=13/19) reports obtained through the *Parents' Evaluation of Aural/oral performance of Children* (PEACH) and the *Teachers' Evaluation of Aural/oral performance of Children* (TEACH) respectively. Telephonic surveys were conducted with 13 caregivers to explore their experiences. Qualitative data from open-ended questions were analysed thematically.

Results: Average HA use was 6.5 h/day (2.0 SD; range 4.1-10.3) for bilateral HA users. Questionnaire results indicated that most (83.3% and 92.3%) children used their HAs more than 75% of the time. Participants performed better in quiet with limited sensitivity to loud sounds at home and school. Reported challenges included stigma and device compliance.

Conclusions: Children with CHL used their HAs for comparable hours (5-8 hours/day) reported for children with sensorineural hearing loss (SNHL), but less than the recommended 10 h/day required for adequate language development. Caregivers reported benefits equivalent to expectations, with challenges like those reported in high-income countries.

Keywords: paediatrics; hearing aids; conductive hearing loss; outcome measures; caregivers

3.2. Introduction

It is estimated that 466 million people globally have a disabling hearing loss, with at least 34 million being children under 15 years old (WHO, 2021). Hearing loss is the second most prevalent disability affecting at least 15.5 million children globally under the age of five years (Olusanya et al., 2018). Sub-Saharan Africa (SSA) has one of the greatest prevalence rates of hearing loss (WHO, 2013). Estimates suggest that the prevalence of hearing loss in children 5 to 14 years of age is 1.9% in SSA, more than double that of high-income countries (0.4%) (Olusanya et al., 2014).

More than 60% of hearing loss in children under the age of 15 years old is preventable (WHO, 2016). Many cases of childhood hearing loss while preventable, are common in low-to-middle-income countries (LMICs), constituting almost half (48.9%) of all cases (Adedeji et al., 2015). Prenatal and perinatal complications are risk factors for hearing loss in LMICs, with postnatal infections being more prominent (Tharpe & Seewald, 2016). It is well documented that poor socioeconomic factors can lead to an increase in middle ear pathology and the associated preventable hearing loss, in addition to the restricted access to human resources and ear health care (Tharpe & Seewald, 2016; Vos et al., 2017; WHO, 2021).

The most prevalent causes of childhood hearing loss are associated with otitis media (OM) (57.1%) and congenital abnormalities (21.1%) (Olusanya et al., 2018). Several pathologies are associated with conductive hearing loss (CHL) and persistent contributors include outer ear malformations (atresia or microtia), middle ear malformations (cholesteatoma or ossicle malformation) and genetic syndromes (Treacher Collins, Down syndrome, Goldenhar

syndrome, Cornelia de Lange syndrome and CHARGE syndrome) (JCIH, 2019; Tharpe & Seewald, 2016). These contributors tend to occur more frequently in LMICs, adding to the high incidence of CHL in SSA (Kesser et al., 2013). The most common and treatable cause of CHL is OM (Tharpe & Seewald, 2016). OM is also the greatest contributor (63.7%) of hearing loss in children under the age of five years (Haile et al., 2021; Monasta et al., 2012). Chronic OM is often associated with mild to moderate CHL, and if untreated can lead to permanent sensorineural hearing loss (SNHL) (WHO, 2021; Monasta et al., 2012).

Globally more than 98.7 million people have hearing loss secondary to acute OM and chronic suppurative otitis media (CSOM) (Hussein et al., 2018; Institute for Health Metrics and Evaluation, 2021). At least 80% of all children will have an episode of acute otitis media (AOM) before three years of age, with an incidence of at least 43% in SSA (Biagio et al., 2014; Daly et al., 2010; Schilder et al., 2016). The global incidence of CSOM is 4.8% and it accounts for more than half of the global burden of hearing loss (Biagio et al., 2014; Monasta et al., 2012; WHO, 2004). SSA has the second-highest prevalence rate of CSOM (Monasta et al., 2012) with HIV-positive children being more prone and severely affected than immunocompetent children (Miziara et al., 2007).

Previously it was estimated that South Africa had a childhood OM prevalence rate of between 3.8% and 12% (Halama et al., 1987; Prescott & Kibel, 1991). However, these studies only focused on school-age children rather than younger preschool children who are more likely to acquire OM (Biagio et al., 2014; Casselbrant & Mandel, 2003). It was recently found that otitis media with effusion (OME) was the most common pathology in South African children aged 2-5 years (23.9%) with AOM only found in 3% of children younger than 2 years old (Biagio et al., 2014). Additionally, CSOM was found to occur more frequently in children aged 6-15 years, with a notable prevalence of 9.3% (Biagio et al., 2014; WHO, 2004). While the prevalence of OM decreases with age, its impact on hearing has long-lasting effects (Monasta et al., 2012).

The development of spoken language is proportionate to hearing ability (National Research Council, 2005). If not addressed timeously, hearing loss may not only have implications for language development, but also cognitive development, academic performance, as well as socio-emotional development (Engdahl et al., 2019; Hall, 2017). Children who develop post-

lingual hearing loss are also impacted by hearing loss, often in terms of the quality of speech production, and cognitive and literacy skills (Haile et al., 2021; Hussein et al., 2018; Wilson et al., 2017). CHL, both temporary and permanent, has been found to increase difficulties in speech perception and reading, delayed reaction to auditory input, vocabulary limitations and attention difficulties (Bellussi et al., 2005; Rosenfeld et al., 2016; Smit et al., 2021). In addition, it is associated with poor task orientation skills and difficulties with independent classwork (Roberts et al., 2004; Rosenfeld et al., 2016; Smit et al., 2021). Two separate studies in children with unilateral atresia and congenital, permanent CHL (older than 5 and 6 years respectively), indicated no grade failure when they used hearing technology such as FM systems and amplification devices (Kesser et al., 2013; Smit et al., 2021). The NICE (2008) has recommended the use of hearing aids (HAs) for OME that has not resolved within three months or as an alternative to ventilation tube (VT) insertion (NICE, 2008). Additionally, the use of HAs has been recommended while awaiting surgery, to limit the negative effects of acquired, temporary hearing loss on a child's academic performance (NICE, 2008). The use of HAs during this time will assist by optimising the child's listening and learning environments (Austeng et al., 2013; NICE, 2008). In children with a genetic predisposition to CHL, such as Down syndrome, behind-the-ear (BTE) HAs have already been recommended as the standard of care (Austeng et al., 2013; NICE, 2008).

While HAs are an option to manage CHL, they are only effective if used by the child (Gan et al., 2017). Previous reports confirmed that at least two-thirds of children with acquired, temporary CHL due to OM who were fitted with BTE HAs made use of them (Flanagan et al., 1996; Jardine et al., 1999). A more recent study indicated that at least a third of paediatric Ear, Nose and Throat (ENT) patients with OME were referred to a hearing health professional for temporary HA fitting; with up to 50% receiving this intervention while the remainder had their CHL resolved by the time of assessment (Gan et al., 2017). Of those who received the intervention, it was reported that 95% used their HAs, however, usage was varied (Gan et al., 2017). There is limited data available on the outcomes of children with CHL fitted with BTE HAs, with available studies using small sample sizes and focusing mostly on high-income countries (Cai & McPherson, 2017; Gan et al., 2017). Research into the management and outcomes of children with CHL is necessary to support evidence-based service delivery and improved family-centred care.

Understanding caregiver experiences is also important for hearing health professionals when providing family-centred care (Muñoz et al., 2015). While some studies have investigated caregiver experiences of children with hearing loss who were fitted with HAs, these have been limited to caregivers of school-aged children and children with permanent SNHL (Lederberg & Golbach, 2002; Meinzen-Derr et al., 2008). However, the data from these studies suggest that caregiver experiences, challenges, and perceived benefits of HAs can impact outcomes in terms of HA use (Lederberg & Golbach, 2002; Meinzen-Derr et al., 2008; Muñoz et al, 2015). There is a dearth of data on caregiver experiences of children with CHL fitted with HAs, with currently available data focusing on reasons for poor HA use only (Gan et al., 2017).

As a common management option for OM, it is necessary to determine whether HAs are an effective and utilised treatment for childhood CHL, as well as what caregiver perceptions and experiences are regarding perceived outcomes. This study, therefore, describes HA outcomes and caregiver experiences for children with CHL fitted with BTE HAs.

3.3. Method

This study was approved by the University of Pretoria Human Research Ethics Committee (HUM064/0519), the University of Cape Town Human Research Ethics Committee (176/2019), and the Red Cross War Memorial Children's Hospital (RCWMCH) Ethics Committee (RCC202).

Study population

RCWMCH is the first stand-alone tertiary institution in SSA dedicated entirely to child health care. The department of audiology provides specialised diagnostic and intervention services for children from birth to 13 years of age from the public health sector. A retrospective review of clinical data from children aged 0-13 years diagnosed with unilateral or bilateral CHL, who were fitted with BTE HAs between January 2017 and March 2020, was conducted. A cross-sectional prospective caregiver telephonic survey was conducted between July 2020 and December 2020.

The definition for CHL used by RCWMCH is adapted from Schlauch and Nelson (2015) and constitutes a difference of 15dBHL between air conduction and bone conduction thresholds,

with bone conduction thresholds better than 20dBHL; at all thresholds between 500Hz to 4000Hz. When CHL is diagnosed, an ENT consultation takes place to determine which method of management will be followed: watchful waiting, medical management in terms of prescription medication, scheduling of surgical management or monitoring of hearing until eligible for surgical management. Each child then receives a follow-up hearing assessment in three months to determine whether the selected management option was successful. If there is no improvement in hearing thresholds, no active otorrhoea or the child is awaiting surgical treatment until they are old enough; the hearing health professional in consultation with the child and caregiver discuss the benefits of using HAs. Academic performance is also taken into consideration for decision-making, and a report from the class teacher is required to determine if the hearing loss has an impact on school performance. Should the child and caregiver consent, ear mould impressions are taken, and an appointment for HA fitting is scheduled.

Children (0-13 years old) diagnosed with CHL (unilateral or bilateral) and fitted with BTE HAs (unilaterally or bilaterally) for at least one month and with data available for at least one functional outcome measure (Parents' Evaluation of Aural/oral performance of Children (PEACH) or Teachers' Evaluation of Aural/oral performance of Children (TEACH)) were considered as eligible participants for this study. Caregivers were later identified through their relationship with the paediatric HA users and contacted regarding their willingness and availability to participate in a telephonic survey.

Data collection materials and procedures

Retrospective record review

Patient data are routinely captured by the department of audiology on an electronic database. This database was utilised to retrospectively identify participants with CHL and fitted with BTE HAs between January 2017 and March 2020. Some data not included in the electronic database were captured from clinical records. Data collected included demographic information, family income, age of diagnosis of hearing loss, age at the fitting of HAs, HA fitting information (real-ear-to-coupler difference (RECD) and aided speech intelligibility index (SII) scores for average sounds), average daily hearing aid HA use (in

hours) at the one-month follow-up (data-logging), and HA functional outcome measures (PEACH and TEACH questionnaires).

The PEACH (designed for children > 2 years) (Ching & Hill, 2007) and TEACH (designed for school-aged children) (Ching et al., 2008) questionnaires were routinely issued to caregivers and teachers in hard copy at the initial HA fitting, and they were asked to complete the questionnaires the day before the first follow-up appointment (scheduled for one-month after HA fitting). Thus, PEACH and TEACH outcomes were obtained one month after HA fitting. These questionnaires were used in their original English format. Both questionnaires were scored, and results were recorded by the hearing health professional at the follow-up appointment. The PEACH and TEACH questionnaires measure everyday functional and auditory communication performance at home and school respectively (Ching & Hill, 2007; Ching et al., 2008; Emerson, 2015; Marnane & Ching, 2015). Listening performance is rated in a variety of communication situations in quiet and noisy environments (Ching & Hill, 2007). Several studies have recommended the PEACH and TEACH questionnaires to evaluate paediatric HA use as they obtain real-life examples of the impact of hearing loss (Cupples et al., 2018; Emerson, 2015; Gan et al., 2017) and are quick and easy to complete (Cupples et al., 2018). These questionnaires are not only used for SNHL, but also for monitoring children with OM, as they account for fluctuations in hearing loss (Gan et al., 2017). Additionally, the questionnaires were validated on both normal-hearing children and children with hearing loss. Good test-retest reliability (0.93) and internal consistency (0.88) were confirmed (Ching & Hill, 2007).

The PEACH and TEACH questionnaires rate listening behaviour according to a five-point rating scale from 0 (`Never') to 4 (`Always'). The PEACH consists of 13 items: two regarding the child's HA usage and loudness comfort; the remaining 11 items gather information about the child's auditory behaviour and awareness to environmental sounds in quiet (five questions) and noisy (six questions) situations (Ching & Hill, 2007). The TEACH consists of 11 items: two regarding the child's hearing aid usage and loudness comfort; the remaining 9 items gather information about the child's auditory behaviour and awareness to environmental sounds in quiet (five questions) and noisy (four questions) situations (Ching et al., 2008). In both questionnaires, a percentage score is calculated for quiet, noisy, and overall. The total percentage score for each subset is plotted and auditory behaviour with

HAs are then determined as `typical performance', `possible review indicated', or `further review indicated' (Ching & Hill, 2007; Ching et al., 2008).

Prospective telephonic caregiver survey

Data on caregiver perceptions and experiences were collected using a telephonic survey (Appendix J). Survey data were used to enhance and supplement the retrospective descriptive and functional outcome data. Specific sections of the *Parent Hearing Aid Management Inventory* (PHAMI) were used in the survey with minor adaptions (Muñoz et al., 2015). The PHAMI was specifically developed to better understand caregiver access to information and their experiences with their child's HA management through four domains (Muñoz et al., 2015). Two domains of the PHAMI were used and adapted for this study, namely "feelings and habits" and "hearing aid use". Internal consistency has been confirmed for the PHAMI (Muñoz et al., 2015).

The telephonic survey obtained caregiver information regarding their child's HA use; thoughts and feelings regarding management and use of HAs; and HA use challenges encountered. The survey was designed for use in English, but in some cases where isiXhosa speaking caregivers struggled to understand the question, the interviewer would then translate accordingly into isiXhosa. The survey consisted of five sections and a total of 36 items were included: 30 close-ended questions and six open-ended questions. A Likert scale (1 = strongly disagree to 5 = strongly agree) was used in the two sections that contained the two domains from the PHAMI. A section with open-ended questions regarding expectations and challenges was included to attain a better understanding of the specific challenges that caregivers of children with CHL fitted with HAs encounter. Caregivers were contacted telephonically, and the verbal consent form was read to them to determine their participation in the survey. On confirmation of consent, the survey was carried out by the interviewer and took between 15-20 minutes. All survey information was captured manually in hard copy by the interviewer and was later recorded electronically for analysis.

Data analysis

All data were captured on an excel spreadsheet, using Microsoft Excel 2018 (Microsoft Corp, Redmond, WA). The data were analysed using SPSS 27 (Version 27.0.IBM Corp., Armonk,

NY). Quantitative data analyses consisted of descriptive statistics in terms of measures of central tendency and measures of variability; with the internal consistency of the two Likert scale survey sections calculated by Cronbach's Alpha. In both the PEACH and TEACH questionnaires, percentage scores were calculated for the quiet, noisy, and overall domains. A thematic analysis was conducted for the qualitative data obtained from the open-ended questions from the telephonic survey. This qualitative data was categorised, coded, and subsequently grouped according to central themes.

3.4. Results

A total of 3333 children were diagnosed with hearing loss at RCWMCH between January 2017 and March 2020, of which 2135 (64.1%) children were diagnosed with CHL. During this period, 43 children with CHL were fitted with BTE HAs (unilaterally or bilaterally). Of this group, 19 children were included in this study since they were fitted with BTE HAs for at least one month and had data available for at least one functional outcome measure. The mean age at diagnosis of CHL for this sample was 77.6 months (36.0 SD; range 12.0-144.0) with a mean age at the one-month HA follow-up of 88.6 months (36.9 SD; range 14.0-149.0).

Hearing aid fitting and use

The mean age at HA fitting was 87.6 months (36.9 SD; range 13.0-148.0) with a mean delay from diagnosis to HA fitting of 10.1 months (12.0 SD; range 0.0-39.0). Eleven paediatric HA users (57.9%) were fitted bilaterally, while eight (42.1%) were fitted unilaterally (n=19). Most children (84.2%, n=16/19) presented with some form of OM, and the degree of hearing loss was either mild (47.4%, n=9/19) or moderate (52.6%, n=10/19). Table 2 describes the sample population.

HA fitting details were available for 17 of the 19 (89.5%) participants at initial HA fitting. RECD was measured for 3 children (17.6%) and specific age-predicted RECD values were used for 14 children (82.4%) (n=17). Aided SII values for average speech input at initial fitting were reviewed for this study. As paediatric HA users were fitted either unilaterally or bilaterally, aided SII percentages for the ear with the higher percentage value was utilised for bilateral HA users. Across the sample (n=17) the aided SII value was 86.4% on average

(6.1 SD; range 78.0-100.0). The aided SII values for average speech input (65 dB SPL) were plotted by the severity of hearing loss (pure tone average in dB HL) using the Aided SII Normative Values Worksheet (Bagatto et al., 2011). HA users in this study sample with available data (n=17) had SII values for average speech input representative of typical audibility for the severity of their hearing loss (Bagatto et al., 2011).

HA use was tracked through data logging at the one-month follow-up appointment for the 14 paediatric HA users whose HAs had data logging functionality. Data logging for bilateral HA users was determined by selecting the recorded logging of the better ear. The average hours per day that HAs were used was similar for unilateral (6.2 h/day, 2.6 SD; range 3.8-10.1; n=5) and bilateral HA users (6.5 h/day, 2.0 SD; range 4.1-10.3; n=9).

Table 2. Demographic characteristics of paediatric hearing aid users and their caregivers

Paediatric hearing aid users (n=19)	***n (%)***	***Caregivers (n=13)***	***n (%)***
Gender		Respondent for caregiver survey	
Male	10 (52.6)	Father	1 (7.7)
Female	9 (47.4)	Mother	10 (76.9)
Home language		Other	2 (15.4)
Afrikaans	6 (31.6)	Caregiver home language	
English	6 (31.6)	Afrikaans	4 (30.8)
isiXhosa	7 (36.8)	English	3 (23.1)
Language of instruction		isiXhosa	6 (46.2)
Afrikaans	2 (10.5)	Interview language	
English	11 (57.9)	Afrikaans	0 (0)
isiXhosa	6 (31.6)	English	9 (69.2)
Educational setting		isiXhosa	4 (30.8)
Mainstream school	15 (78.9)		
Special needs school (mainstream curriculum)	1 (5.3)		
Special needs school (alternative curriculum)	2 (5.3)		
Too young for school	1 (5.3)		
Family income			
H0 (formally unemployed)	8 (42.1)		
H1 (0 USD – 400.62 USD per month*)	8 (42.1)		
H2 (400.62 USD – 1430.84 USD per month*)	3 (15.8)		
H3 (>1430.84 USD per month*)	0 (0.0)		
Comorbidities			
Microtia	1 (5.3)		
Congenital ptosis	1 (5.3)		
Foetal alcohol syndrome	1 (5.3)		
Down syndrome	2 (10.5)		
Neonatal jaundice	1 (5.3)		
Premature birth	1 (5.3)		
OM	16 (84.2)		
Types of OM (n=16)			
AOM	2 (12.5)		
Chronic OM	7 (43.8)		
CSOM	5 (31.3)		
OME	2 (12.5)		
Degree of CHL**			
Mild (16-40dBHL)	9 (47.4)		
Moderate (41-60dBHL)	10 (52.6)		

** Exchange rate of 1 USD = R14.56 (South African rand/ZAR)*
***Degree of hearing loss according to Clark (1981)*

Caregiver and teacher reported outcomes and experiences

PEACH and TEACH ratings

PEACH questionnaires were completed by caregivers and returned for 12 paediatric HA users at the one-month follow-up appointment. Caregiver reports indicated that most paediatric HA users (83.3%, n=10/12) used their HAs often or always, and seldom or never complained of sensitivity to loud sounds. Figure 1 indicates caregiver reported ratings of HA use and loudness discomfort for 12 paediatric HA users. Mean PEACH scores were similar in

both Quiet (74.5%) and Noise (72.1%), indicating typical performance in those environments when aided (Table 3). Based on PEACH scores, more than half of the participants (58.3%, n=7/12) showed typical performance overall (Figure 2).

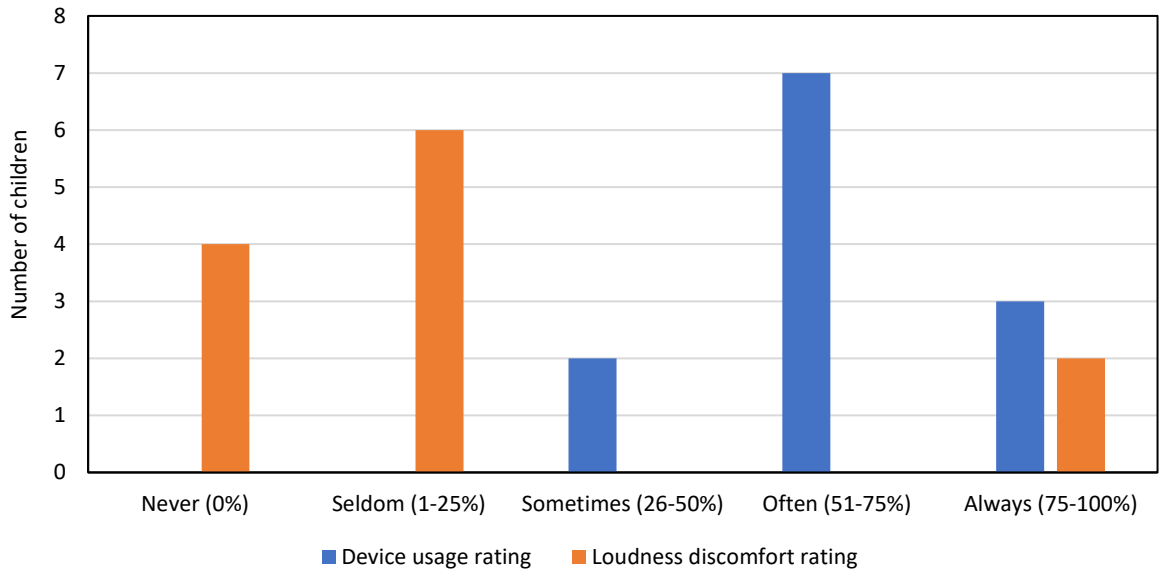


Figure 1. Caregiver-reported ratings of children's hearing aid use and loudness discomfort level (n=12)

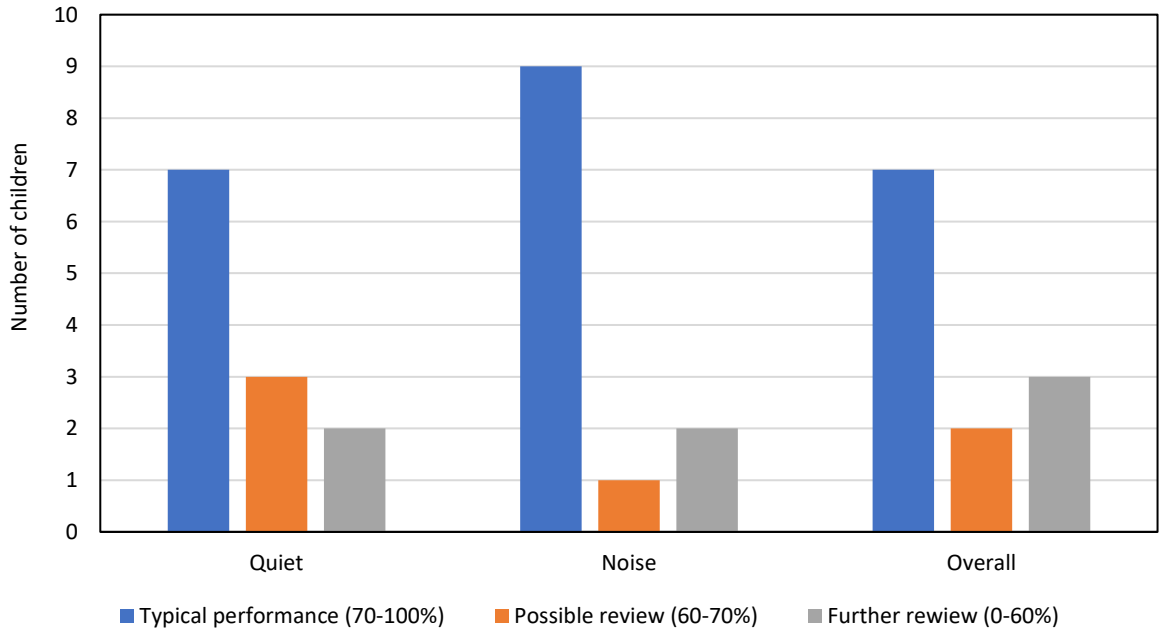


Figure 2. PEACH percentage score represented as auditory behaviour for quiet, noise and overall (n=12)

TEACH questionnaires were completed by involved teachers and returned for 13 paediatric HA users at the one-month follow-up appointment. Teacher reports indicated that almost all paediatric HA users (92.3%, n=12/13) used their HAs often or always, and seldom or never (84.6%, n=11/13) showed sensitivity to loud sounds. Figure 3 indicates teacher reported ratings of HA use and loudness discomfort for 13 paediatric hearing aid users. Mean TEACH percentage scores were higher in Quiet (78.1%) than in Noise (72.0%) (Table 3).

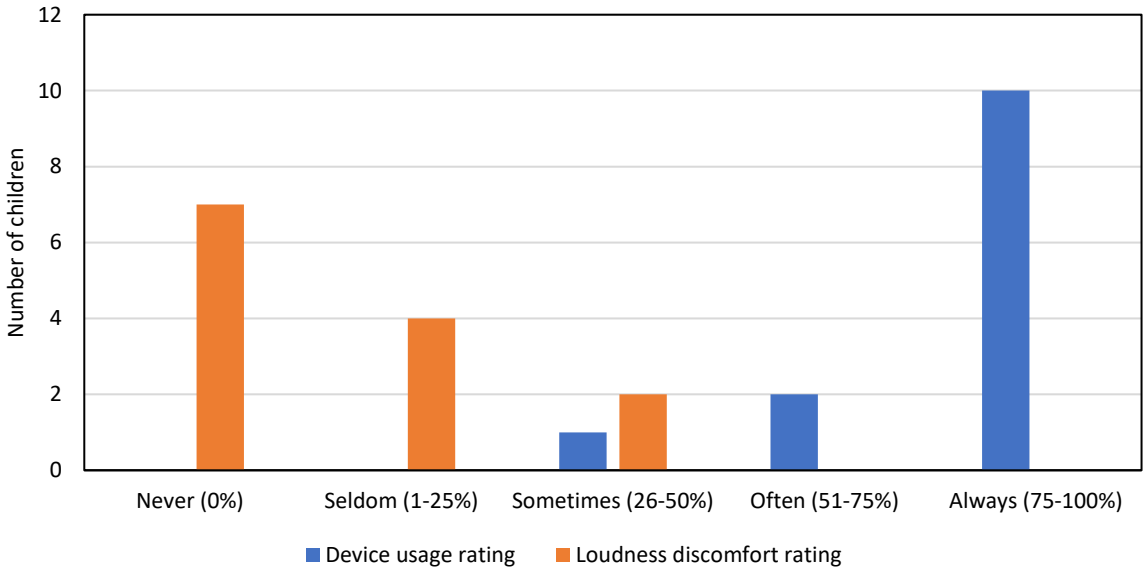


Figure 3. Teacher-reported ratings of children's hearing aid use and loudness discomfort level (n=13)

Table 3. Mean PEACH and TEACH percentage (%) scores for quiet, noise, overall

	M (SD)	*Range*
PEACH (n=12)		
Quiet	74.5 (19.7)	30.0 – 100.0
Noise	72.1 (17.4)	45.0 – 100.0
Overall	73.4 (18.3)	36.0 – 100.0
TEACH (n=13)		
Quiet	78.1 (22.1)	30.0 – 100.0
Noise	72.0 (31.5)	6.3 – 100.0
Overall	75.4 (26.1)	19.4 – 100.0

Prospective caregiver survey

Only 13 (68%) of the 19 caregivers consented to a telephone survey (four caregivers could not be reached and two declined). At the time of the telephone survey, six children (46.2%) were still active HA users, while seven children (53.8%) did not use their HAs anymore (n=13). Caregiver reasons for their children no longer using their HAs was largely due to improved hearing (57.1%, n=4/7), with the remaining 42.9% reporting otorrhoea (n=1/7), bullying (n=1/7) or patient discomfort (n=1/7). The average duration of HA use for the active HA users at the time of the telephonic survey was 43.6 months (41.8 SD; range 2.0-156.0), while the average duration of HA use for those who did not use HAs anymore was 14.4 months (13.1 SD; range 2.0-37.0).

Caregivers were asked to report on typical daily HA use for their children (those whose children were no longer actively using their HAs were asked to report this in retrospect). Most caregivers (69.2%, n=9/13) reported HA use between 5-10 hours a day, with almost a quarter (23.1%, n=3/13) reported HA use for less than 5 hours a day, and only one caregiver reported HA use for all waking hours.

The sub-sections that utilised Likert Scale questions (feelings and habits and challenges related to HA use) were checked for internal consistency and were found to have a Cronbach α value of 0.11 and 0.88, respectively. This indicates that the section related to challenges showed good consistency, and was similar to previous findings (Cronbach's α = 0.82) of the PHAMI (Muñoz et al., 2015). Questions related to feelings and habits showed poorer consistency but could not be compared to previous PHAMI findings as the consistency was not reported in the original study for this section (Muñoz et al., 2015). Possible reasons for poor internal consistency could be related to the subjectiveness of the questions and the fact that they do not follow a specific theme.

When reviewing caregiver feelings and habits (Table 4), all caregivers (100.0%, n=13/13) felt that the HAs help/helped their child; with more than three-quarters of caregivers (76.9%, n=10/13) reporting that they could confidently tell when their child's HAs were not working correctly. Almost all caregivers reported that they checked their children's HAs every day (92.3%, n=12/13).

Table 4. Caregiver feelings and habits towards hearing aids (n=13)[¥]

	Disagree* n (%)	Unsure n (%)	Agree* n (%)
I accept/accepted my child's hearing loss	2 (15.4)	2 (15.4)	9 (69.2)
I am/was concerned with the appearance of my child's hearing aids	5 (38.5)	0 (0.0)	8 (61.5)
I am/was concerned about what others think**	5 (38.5)	3 (23.1)	5 (38.5)
I am/was concerned about how I will/would deal with my child's feelings about their hearing aids	3 (23.1)	2 (15.4)	8 (61.5)
I think the hearing aids help/helped my child	0 (0.0)	0 (0.0)	13 (100.0)
My child does not/did not need hearing aids	8 (61.5)	1 (7.7)	4 (30.8)
I think occasional hearing aid use is/was enough for my child to learn	4 (30.8)	1 (7.7)	8 (61.5)
I feel/felt quite frustrated with handling the hearing aids every day	7 (53.8)	0 (0.0)	6 (46.2)
I feel/felt confused about how to keep the hearing aids on my child	8 (61.5)	0 (0.0)	5 (38.5)
I feel/felt confident I can tell when my child's hearing aids are not working correctly	0 (0.0)	3 (23.1)	10 (76.9)
I check/checked my child's hearing aids every day	1 (7.7)	0 (0.0)	12 (92.3)
Talking with other parents helps/helped me manage the hearing aids**	4 (30.8)	4 (30.8)	5 (38.5)
The fact that the hearing aids are/were supposed to be temporary helps/helped me to manage them	3 (23.1)	2 (15.4)	8 (61.5)

[¥]Adapted from Muñoz et al. (2015).
** Ratings of "strongly disagree" and "disagree" were combined as a "disagree" response and ratings for "strongly agree" and "agree" were combined as an "agree" response.*
*** Due to rounding, percentages may not precisely reflect the absolute figures.*

When asked about how their child's HA use is/was affected by various challenges (Table 5), caregivers reported difficulty with frequent ear infections (61.5%, n=8/13), frequent ear pain (53.8%, n=7/13), maintaining use during activities (53.8%, n=7/13), and frequent feedback (46.2%, n=6/13). However, most caregivers reported that they did not have difficulty getting into a set routine (76.9%, n=10/13) and coping with the demands of managing the HAs (76.9%, n=10/13). When reviewing audiological management as a possible challenge, most caregivers felt there was not a long wait time to get an appointment with the hearing health professional (84.6%, n=11/13) and almost all caregivers felt that the hearing health professional was able to answer their questions during an appointment (92.3%, n=12/13). Additionally, most caregivers (84.6%, n=11/13) reported they did not run out of batteries before their next appointment.

Table 5. Caregiver challenges experienced impacting hearing aid use (n=13)[¥]

	Disagree* n (%)	Not Sure n (%)	Agree* n (%)
Distractions and needs of other children in the home	8 (61.5)	0 (0.0)	5 (38.5)
Activities (e.g., playing outside, riding in the car)	5 (38.5)	1 (7.7)	7 (53.8)
My child's behaviour**	6 (46.2)	2 (15.4)	5 (38.5)
Difficulty getting a set routine	10 (76.9)	0 (0.0)	3 (23.1)
Long wait time to get an appointment with the hearing health professional	11 (84.6)	0 (0.0)	2 (15.4)
Other caregiver's ability to manage hearing aids	11 (84.6)	2 (15.4)	0 (0.0)
The hearing health professional's lack of response to my questions during the appointment	12 (92.3)	0 (0.0)	1 (7.7)
Difficulty coping with the demands of managing hearing aids	10 (76.9)	0 (0.0)	3 (23.1)
Frequent ear infection, i.e., leaking ears	4 (30.8)	1 (7.7)	8 (61.5)
Frequent ear pain	6 (46.2)	0 (0.0)	7 (53.8)
Frequent feedback (whistling/squealing) from the hearing aids	7 (53.8)	0 (0.0)	6 (46.2)
My concern with the appearance of my child's hearing aids	9 (69.2)	1 (7.7)	3 (23.1)
Running out of batteries before my next appointment	11 (84.6)	0 (0.0)	2 (15.4)
The hearing aids not working correctly	11 (84.6)	1 (7.7)	1 (7.7)
My child's reaction to sounds when wearing the hearing aids	8 (61.5)	0 (0.0)	5 (38.5)
Difficulty keeping the hearing aids on	9 (69.2)	1 (7.7)	3 (23.1)

[¥]Adapted from Muñoz et al. (2015).
** Ratings of "strongly disagree" and "disagree" were combined as a "disagree" response and ratings for "strongly agree" and "agree" were combined as an "agree" response.*
*** Due to rounding, percentages may not precisely reflect the absolute figures*

Answers to open-ended questions from the telephone survey were captured from 13 caregivers. The questions inquired about the benefits and challenges of HA use, expectations of HAs, as well as the paediatric HA users' feelings towards using HAs. Four themes and six sub-themes were extracted following qualitative inductive thematic analysis. These are summarized with examples in Table 6 in terms of perceived benefits, challenges, expectations, and child feelings.

Table 6. Thematic analysis of open-ended questions of the caregiver telephone survey (caregiver perceptions and experiences) (n=13)

Themes	Sub-themes	Examples/ illustrative quotes
Benefits	Improved hearing and communication	*"He has improved speech, communication and learning"* *"Hears better at school… she understands us better"* *"Don't have to shout anymore. Can talk softer now"* *"Struggles to communicate when hearing aids are not on"* *"She stopped looking at my mouth when I talk"*
	Improved behaviour	*"She is more pleasant person"* *"She copes better at school"* *"Improved her behaviour at school; she used to become frustrated and was very short-tempered"*
Challenges	Stigma/bullying	*"She was bullied a lot at school"* *"She is seeing she is different and doesn't like to wear them"* *"Other children made fun of him"*
	Device compliance	*"Difficulty keeping them in his ears, especially on the playground"* *"He didn't want to wear it… he took them out all the time"* *"I forget to put the hearing aids on over the weekend"* *"Teacher was always complaining that the hearing aid is making a noise"*
Expectations		*"That he would learn at school"* *"Help him hear better and do better at school"* *"Help her hear better as she speaks loudly"*
Child's feelings towards hearing aid use	Acceptance	*"He loved them!"* *"No problems. She reminds me in the morning"* *"He loves them … asks for them"* *"Feels normal"* *"Most of the time she doesn't mind wearing them and often fetches them for me"* *"She did not have a problem because it helped her"* *"She loved them so much she even wanted them back when she no longer needed them"*
	Dislike	*"She does not like them at all and does not want to wear them"* *"He did not really like them, but he knew they help him"*

3.5. Discussion

HA use for all children with CHL in this study showed consistent daily use within the first-month post-fitting. Additionally, caregiver reported outcomes indicated typical auditory performance with HAs for more than half of the children (53.8%) at one month post-fitting. Survey responses indicated that all caregivers supported the use of HAs and noted an improvement in hearing from the time of HA fitting. Based on the positive auditory performance and the fact that most of the sample (84.2%) presented with some form of

OM, the benefit of BTE HAs was confirmed for this population of children with temporary CHL.

The average age of diagnosis of CHL in this sample was 6.5 years, which is the age of entry to formal schooling in South Africa. The average age at HA fitting was just over seven years. A recent South African study investigating predictors of hearing technology use in children under the age of 11 years at an early intervention centre in the Western Cape (with various types of hearing loss), noted lower means for both the age of diagnosis (2.5 years) and HA fitting (2.8 years) (Booysen, le Roux, Masenge, & Swanepoel, 2021). Delays in diagnosis of CHL and subsequent HA fitting are expected considering that 84.2% of the sample had an acquired hearing loss. Additionally, the delay between diagnosis and HA fitting of almost one year (10.1 months) in this study sample could be attributed to long waiting periods for an ENT appointment, as well as recommended periods of watchful waiting (Mulwafu et al., 2017; NICE, 2008).

The average daily HA use (6.2-6.5 hours for unilateral and bilateral fittings respectively) and caregiver reported use was comparable to the 5-8 h/day previously reported for children with SNHL (Muñoz et al., 2015). However, HA use in this study was lower than the 9.4 hours per day recently reported by another South African study (Booysen et al., 2021) on children with various types of hearing loss (including CHL), as well as the 10 hours per day required for adequate language development (Tomblin et al., 2015). To the authors' knowledge, no recommended guidelines exist regarding HA use in children with CHL specifically. The fact that almost half of the children (47.4%) in this study had a mild degree of hearing loss and 42.1% were fitted unilaterally may have contributed to slightly lower usage since the severity of hearing loss is usually proportionate to HA use (Booysen et al., 2021; Marnane & Ching, 2015). Paediatric HA users in this study likely used their HAs predominantly in certain listening and learning environments with many probably having decreased usage over weekends and during holidays (Flanagan et al., 1996; Jardine et al., 1999). The fact that more than two thirds (68.8%) of paediatric HAs users with OM had less severe forms (AOM, COM, OME) may explain why more than half (53.8%) only used their HAs for just over one year. The nature of CSOM, the number of children diagnosed with CSOM (31.3%), as well as the long waiting period to access appropriate surgical management (Mulwafu et al., 2017;

WHO, 2021) are possible reasons why 46.2% of paediatric HA users wore their devices for approximately four years (43.6 months).

Caregiver reported outcomes according to the PEACH indicated that more than half (58.3%) of the paediatric HA users in this study had typical auditory performance overall at one month post-fitting. The overall PEACH score of 73.8% is slightly lower than a study on children with unilateral SNHL (84%) and slightly higher than a study on children with bilateral SNHL (68.26%) (Johansson, Asp, & Berninger, 2020; Karimi, Esmaili, Fatahi, & Bagheban, 2017). The remaining HA users (41.7%) required possible (16.7%) or further (25%) review based on PEACH scores. Since almost one third (31.3%) of this study sample had CSOM, the benefit of HAs during periods of otorrhoea may have been limited. Additionally, the fact that all children in this study had either a mild (47.4%) or a moderate (52.6%) degree of hearing loss could have further influenced the auditory performance in some cases. PEACH and TEACH scores indicated that the auditory behaviour of paediatric HA users in this study was better in quiet than noise and supports the positive correlation between these two questionnaires previously found by Ching et al. (2008). High noise levels are known to have an impact on listening and learning, both at home and school (Roberts et al., 2004; Rosenfeld et al., 2016). To overcome this, an increased signal to noise ratio is required, which can be supported by HAs or assistive listening devices like FM systems.

Results from the telephone survey showed that all caregivers felt that the HAs helped their child, which is in agreement with another study on HA benefit in children with CHL (Jardine et al., 1999). Survey results indicated that caregivers observed an improvement in their child's hearing when using HAs, and that HAs should therefore be considered by both ENT specialists and hearing health professionals in the management of CHL. In contrast, Sjoblad et al. (2001) found that almost two-thirds of caregivers of children with SNHL questioned the benefit received from HAs initially, but this perception improved with time. The differences experienced by caregivers of these two groups of children could be related to the limited development of speech and language skills of children with SNHL, as well as the impact that severity of SNHL has on these skills (Sjoblad et al., 2001). Regardless of reported benefit, several caregivers in this study were still concerned about what the HAs looked like (61.5%), and more than a quarter (38.5%) were concerned about what others would think. These stigma concerns are in line with several studies on children with CHL and SNHL, which

noted that caregivers felt that HA aesthetics and thoughts of others were a concern (Cupples et al., 2018; Gan et al., 2017; Jardine et al., 1999; Muñoz et al., 2015; Sjoblad et al., 2001). This suggests that the caregivers in this study's concerns regarding their child's HAs are comparable to those in high-income countries. Furthermore, its highlights the importance of how hearing health professionals impart information to caregivers and support them to achieve effective HA management and outcomes (Muñoz et al., 2015).

Qualitative analyses of caregivers' reported expectations were in line with the benefits reported (improved hearing, communication, and behaviour). Caregiver reported challenges included stigma and device compliance with bullying specifically by school peers and buy-in from teachers being a barrier to HA use. Several studies on children with both CHL and SNHL fitted with HAs have noted caregiver challenges and concern regarding stigma and bullying by school peers (Cupples et al., 2018; Gan et al., 2017; Moeller, Hoover, Peterson, & Stelmachowicz, 2009; Muñoz et al., 2015; Sjoblad et al., 2001; Walker et al., 2013). This may partly explain why the majority (61.5%) of caregivers felt that only occasional HA use was enough for their child to learn, in addition to the large number of children with CHL due to OM (84.2%). In this study only a few caregivers reported daily HA tasks as challenges to HA use; with three caregivers reporting difficulty coping with the demands of managing HAs and one caregiver reported running out of batteries. Surprisingly, only 38.5% of caregivers reported their child's behaviour as a challenge limiting HA use, which is much less than the 50% reported by Muñoz et al. (2015). Based on the open-ended questions most caregivers (76.9%) reported positive paediatric HA user feedback regarding wearing their HAs. There were however some (23.1%) children who were not as amenable to wearing their HAs, with one reporting that it was due to bullying at school. This feedback highlights the importance of counselling caregivers and the child, as well as liaising with teachers to address and alleviate stigma and bullying at school (Muñoz et al., 2015).

While previous studies on paediatric HA users focused on predictors of HA use (Booysen et al., 2021; Marnane & Ching, 2015), this study focused on the outcomes of a unique population – children with CHL that use BTE HAs. Due to the small sample size and variable age range (14.0-149.0 months) of paediatric HA users in this study, possible associations between independent variables and outcome variables could not be evaluated. The discrepancy in daily HA use between children with CHL and more permanent types of

hearing loss could be because daily HA use was reported at a single point in time (one-month post-fitting follow-up), whereas other studies reported longitudinal data with multiple data points over time. Additionally, in comparison to children with CHL, the permanence and degree of SNHL can also account for the increase in daily HA use seen for children with SNHL. Despite a limited sample size, this study provides contextual information regarding HA use for CHL allowing a better understanding of caregiver experiences during the period of HA use. Further studies with a larger sample size could investigate HA outcomes of children with CHL prospectively, considering multiple data points for outcomes as well as possible predictors of HA use for this unique population.

3.6. Conclusion

Children with CHL on average used their HAs for approximately six hours a day. Caregivers reported typical auditory performance for more than half of the children in this sample, confirming HA benefit. Children experienced minimal listening discomfort at home and school after one month of HA use. All caregivers supported the use of HAs for CHL, with clear reports of expectations meeting benefits. The challenges experienced by caregivers (stigma and compliance) are reflective of their counterparts in high-income countries and those of children with SNHL. While this study population is limited, caregivers of children with CHL see more auditory benefit at the initial follow-up than their SNHL counterparts. As the majority of paediatric HA users in this study presented with some form of OM, study results suggest that the fitting of BTE HAs is a viable management option to limit periods of hearing loss, and should be a common recommendation by ENT specialists and hearing health professionals for children with CHL in LMICs.

4. DISCUSSION AND CONCLUSION

This study aimed to investigate and describe the HA outcomes and caregiver experiences for children with CHL who are fitted with BTE HAs. Exploring HA outcomes for this population provides valuable insight regarding audiological management of this population and helps guide whether this form of amplification should be considered more frequently (Gan et al., 2017). This study described characteristics and HA outcomes of children with CHL in an LMIC, whose predominant cause of CHL was due to OM.

The current study was the first to explore HA outcomes in children with CHL in the South African context, as well as provide insight into caregiver experiences for this population. As such, this study indicated that children with CHL who were fitted with BTE HAs demonstrated similar usage as children with SNHL (Muñoz et al., 2015). In addition, this study was one of the first of its kind conducted in an LMIC and included the first caregiver perspective data for children with CHL.

4.1. Summary of results

Hearing aid use

This study investigated the HA outcomes of 19 diverse children with CHL under the age of 13 years, who were fitted with BTE HAs. Average daily HA use for these children (6.2 and 6.5 h/day for unilateral and bilateral HA users respectively) was comparable to the 5-8 h/day previously reported for children with SNHL (Muñoz et al., 2015), but was noticeably less than the 9.4 h/day of another South African cohort of children with various types of hearing loss (Booysen et al., 2021). HA use in this study was lower than the 10 h/day deemed necessary for optimal language development (Tomblin et al., 2015), however, according to the researcher's knowledge, no current research exists regarding recommended HA use in children with CHL specifically.

With the severity of hearing loss being previously linked to HA use (Booysen et al., 2021; Cupples et al., 2018), the lower than recommended HA use in this study can be attributed to the fact that more than a third of children were only fitted unilaterally (42.1%), and almost

half (47.4%) had only a mild degree of hearing loss. Furthermore, children with CHL have been known to have limited periods of HA use (Flanagan et al., 1996; Jardine et al., 1999). It is therefore plausible that this sample was no different and that paediatric HA users only used their HAs when they were at school (Gan et al., 2017; Jardine et al., 1999). When looking at the duration of HA use, the study participants were separated into two groups: previous HA users (53.8%) and active HA users (46.2%). Previous HA users made up more than half of the sample and used their HAs for just over one year (14.4 months); this could be related to the fact that more than two thirds (68.8%) of HA users had less severe forms of OM. Active users on average had their HAs for three times longer (43.6 months) than previous users. Likely reasons for this include that almost a third (31.3%) of HA users had CSOM, which by nature makes HA use challenging during periods of otorrhoea (Madell et al., 2019); as well as the long waiting periods to access appropriate ENT management (Mulwafu et al., 2017; WHO, 2021).

Caregiver and teacher functional outcome questionnaires

As part of HA outcomes, this study investigated functional auditory performance recorded by caregivers and teachers using the PEACH and TEACH questionnaires. PEACH reported scores indicated that more than half (58.3%) of the paediatric HA users in this study had typical auditory performance overall at the one-month post-fitting follow-up. HA users in this study obtained an average overall PEACH score of 73.8%, which is higher than the 68.3% average overall PEACH score for children with bilateral SNHL (McCreary & Walker, 2017) but notably lower than the 84% for children with unilateral SNHL (Johansson et al., 2020). Plausible explanations for these differences in average PEACH scores are the severity of hearing loss explored by SNHL studies, as well as the fluctuating nature of CHL. However, since this study grouped unilateral and bilateral users, a fair comparison to the SNHL population is not possible in this small sample.

Not all HA users (41.7%) had typical auditory performance. A small number of paediatric HA users required possible review (16.7%), while a quarter (25%) required further review. With almost a third (31.3%) of the study sample having been diagnosed with CSOM and likely experiencing periods of otorrhoea, this could have limited HA benefit for some participants. Furthermore, the degree of hearing loss of this sample alone (mild (47.4%) and moderate

(52.6%)) could have affected auditory performance. The results of this study support the correlation between the PEACH and TEACH questionnaires previously found by Ching et al., (2008); with both indicating better auditory performance for paediatric HA users in quiet. With listening and learning both affected by increased noise levels (Roberts et al., 2004; Rosenfeld et al., 2016), an increased signal to noise ratio provided by HAs is required; and subsequently supports the use of BTE HAs in children with CHL, particularly when temporary.

Caregiver perspectives and experiences

Survey data found that all caregivers experienced improvements in hearing when their children used HAs, which supports previous findings of BTE HAs benefiting children with CHL (Jardine et al., 1999). This noticeable improvement in hearing with BTE HAs therefore reaffirmed the need for ENT specialists and hearing health professionals to consider these devices as a more frequent management option for children with acquired, temporary CHL. Not surprisingly, these results contradicted those of caregivers of children with SNHL who initially questioned HA benefit (Sjoblad et al. 2001). The difference in experiences by these caregivers is likely related to the limited development of speech and language skills of children with SNHL, as well as the impact that the severity of SNHL has on these skills (Sjoblad et al., 2001).

Concerns reported by caregivers in this study are in line with previous reports on children with both CHL and SNHL (Cupples et al., 2018; Gan et al., 2017; Jardine et al., 1999; Muñoz et al., 2015; Sjoblad et al., 2001). In particular, more than half (61.5%) of caregivers were concerned over HA aesthetics and at least a third (38.5%) about the opinions of others. Considering these findings, the caregivers of this study presented comparable concerns to those in high-income countries and those of children with SNHL.

In addition to quantitative questions, the survey included five open-ended questions that allowed for qualitative analysis to explore caregiver experiences. The predominant challenges that caregivers identified were device compliance due to stigma and bullying by school peers; with reports of poor buy-in from teachers adding to the challenges of HA use. Numerous studies investigating HA use in children with CHL and SNHL have reported challenges relating to stigma and bullying (Cupples et al., 2018; Gan et al., 2017; Moeller et

al., 2009; Muñoz et al., 2015; Sjoblad et al., 2001; Walker et al., 2013). These challenges could have contributed to the fact that almost two thirds (61.5%) of caregivers felt that occasional HA use was sufficient for learning; in addition to the fact that most paediatric HA users (84.2%) had CHL due to OM. However, regardless of these challenges caregivers reported benefits of improved hearing, communication, and behaviour as being in line with their expectations of HA use. Surprisingly, very few caregivers reported daily HA tasks as challenges to HA use. Only a third of caregivers reported child behaviour as a barrier to HA use, which is much less than the 50% of caregivers of children with SNHL (Muñoz et al., 2015).

When caregivers were asked how their children felt about using HAs, most caregivers (76.9%) indicated a positive response. As expected, there were some reports (23.1%) of children not wanting to use the HAs, with one caregiver specifically saying it was due to bullying at school. These findings highlight the need for counselling of both paediatric HA users and their caregivers (Muñoz et al., 2015), but also the liaison with teachers to help alleviate the stigma and bullying at schools.

4.2. Clinical implications

The clinical implications for this study are discussed below.

Implications for audiologists

With the average HA use in this study compared to previous reports on children with SNHL (Muñoz et al., 2015), the indication is that children with CHL in this study used their HAs consistently, albeit for limited periods (Gan et al., 2017; Jardine et al., 1999). For children with CHL who use HAs, audiologists should consider an adjusted expectation in terms of daily HA use as it will allow for more focused intervention that targets specific hearing situations like those taking place at school. This is supported by the fact that HA use during all waking hours for children with hearing loss is not feasible when compared to normal hearing children (Booysen et al., 2021; McCreary & Walker, 2017) and therefore the audiologist's expectations need to be adapted. The average duration of HA use in this study is almost equivalent to the amount of time spent in the classroom. Taking this into consideration, the audiologist could rather emphasise the type of listening environments

where the HAs are worn to ensure that they are used where they will have the greatest impact. By taking this approach it may encourage better HA compliance by children as they know that they will only need to wear their HAs for limited periods.

Previously children with temporary CHL hearing loss due to OM were predominantly considered for medical or surgical management options (Mulwafu et al., 2017; Simon et al., 2018). The audiologist's role in managing CHL has primarily been to regularly assess and monitor hearing thresholds (Dougherty & Kesser, 2015; Simon et al., 2018). However, this study highlights the significant role that audiologists have in the management of temporary childhood CHL. The audiologist's role includes not only the audiological assessment of children but also how they could assist in minimizing the impact of temporary hearing loss in childhood through the fitting of BTE HAs. Subsequently, this research supports audiological management of CHL with BTE HAs for children, more specifically children with temporary CHL as a result of OM. Additionally, the outcomes reported by the PEACH and TEACH questionnaires at only one-month post-fitting emphasise the perceived benefit of HAs in this study population and help solidify the fitting of BTE HAs as a third option to manage temporary CHL rather than a last resort or solely for the management of congenital CHL (AAA, 2013; Dougherty & Kesser, 2015; Simon et al., 2018).

There are limited studies available on children with CHL fitted with BTE HAs, as well as their functional outcomes using the PEACH and TEACH questionnaires. By incorporating functional auditory performance questionnaires such as these completed by caregivers and teachers, at specific intervals in the intervention process, it could support a more comprehensive and continuous collection of outcomes data to track changes in HA outcomes over time.

On the other hand, the cost-effectiveness of temporary HAs versus surgery could be investigated to determine what is most feasible in LMICs. While high-income countries have the resources, LMICs must consider the financial implications of these options for the patient and the health care system. Gillard & Harris (2020) recently investigated a cost comparison for the management of otosclerosis. Their study compared the cost of stapedectomy surgery to the fitting of HAs as management options and found that surgery was most cost-effective (Gillard & Harris, 2020). While this study was conducted in a high-

come country looking and the management of adults, it does provide insight into the cost considerations when determining patient management. With limited resources and the high incidence of OM and acquired, temporary CHL in LMICs, the results of cost comparison for management of children with temporary CHL could yield valuable information to determine context-specific management as well as assist policy makers when considering the allocation of funding.

With limited data on caregiver experiences of children with CHL fitted with BTE HAs, and even less in LMICs; the results from this study provide a valuable and unique perspective on the management of childhood CHL. The overwhelming acceptance for the use of HAs by caregivers and minimal difficulty regarding the management of the physical device indicates a positive response by caregivers to this form of management. Furthermore, it highlights that even in areas where resources are limited, caregivers can see the benefit and subsequently support the fitting of HAs to manage CHL.

The caregiver experiences reported in this study have provided South African audiologists with direction on where they could better foster relations in the management of school-going children with CHL. Understanding a teachers' knowledge base and their experiences of children with CHL is essential to ensure this group of children can maintain mainstream schooling (McCormick Richburg & Goldberg, 2005). Blair et al. (1999) found that almost a quarter of teachers in both mainstream primary schools and high schools were unaware that their students had hearing loss, and half did not understand the type, severity, and impact of hearing loss. This highlights the importance of educating teachers about hearing loss, as well as its impact on speech and language development and academic performance.

In addition, this study was also able to reflect that caregivers struggle with stigma and bullying. Audiologists need to consider the education of teachers in terms of the importance of consistent HA use in the classroom, as well as how to manage the stigma and bullying experienced by HA users. If equipped with the correct information and support from audiologists, teachers have a crucial role to place in reducing these challenges. Audiologists could also consider school outreach visits to assist HA users and teachers in educating peers on the reasons for HA use.

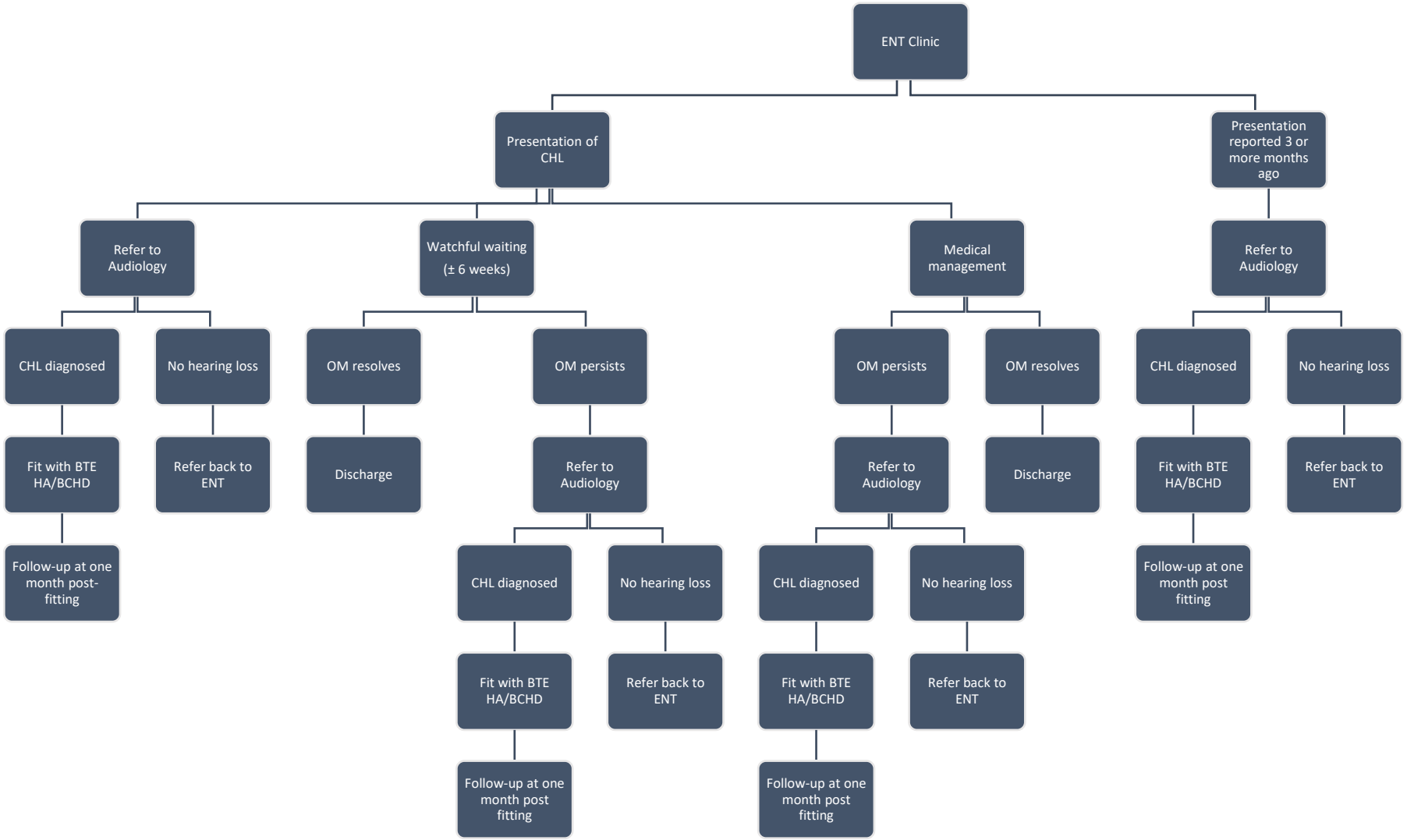
Implications for ENT specialists

The acceptance of HAs by caregivers in this study as well as the positive outcomes reported for the children with CHL supports that more children with temporary CHL should be referred by ENTs for fitting with BTE HAs. Study results also highlight that referral for HA fitting could be considered as a first-line 'treatment' when indicated. With limited ENT resources and service delivery constraints in SSA, waiting times for management of OM can lead to long periods of temporary CHL that negatively impact childhood development and schooling. Therefore, by referring to an audiologist for BTE HA fitting, ENT services could take place less frequently for this population, specifically if there are contraindications to surgery or waiting lists.

ENT specialists often consider VT insertion as the primary treatment option for OM and do not regularly recommend HAs as a management option for children with OM (Gkiousias et al., 2016; NICE, 2008). However, some caregivers have reported traumatic surgical experiences and the short-lived effects of VT insertion as reasons why they would have preferred the option of HAs (Gkiousias et al., 2016). With the positive uptake of HAs from caregivers in this study and the limited ENT resources in LMICs (Mulwafu et al., 2017), ENT specialists could be referring children with temporary CHL for HA fitting more frequently, rather than waiting for surgery dates or OM resolution. Additionally, caregivers could be given an alternative to surgery, especially in very young children.

Overall, this study demonstrated the effective use of BTE HAs for children with CHL, particulary temporary CHL. This implies that BTE HAs are a viable management option to limit periods of hearing loss in children with temporary CHL and could be recommended more frequently by ENT specialists and audiologists. Based on the findings in this study, a new management pathway for children with temporary CHL due to OM is proposed and outlined in Figure 4. This pathway recommends BTE HAs as a third management option, as well as when other treatment considerations are unsuccessful.

Figure 4. Proposed pathway for the management of CHL in children



4.3. Critical evaluation

To develop critical thinking and uphold the academic veracity of a study, a critical evaluation is necessary to determine its strengths and limitations (Leedy & Ormrod, 2020).

Strengths of the study

The strengths identified for this study are outlined below.

- While the data used in phase 1 of this study were captured retrospectively, it was initially actively recorded for paediatric HA users as part of routine clinical practice at RCWMCH. The use of retrospective data eliminates the risk of recall bias by participants (Lee & Hotopf, 2012).

- A strength of the current study is that it was the first study to look at HA outcomes for children with CHL in an LMIC. This is critical considering that CHL is prominent in LMICs (Adedeji et al., 2015; Kesser et al., 2013). Current literature about children with CHL who use HAs originated in high-income countries such as the United Kingdom (Flanagan et al., 1996; Gan et al., 2017; Jardine et al., 1999). The results from these studies while valuable, are difficult to generalise to an LMIC such as South Africa. As almost half (48.9%) of preventable childhood hearing loss occurs in LMICs (Adedeji et al., 2015), the current study could be more applicable in similar contexts.

- The results of the current study contribute to the limited existing literature on children with CHL who are fitted with BTE HAs (Flanagan et al., 1996; Gan et al., 2017; Jardine et al., 1999). Additionally, this study made use of the PEACH and TEACH questionnaires which considered functional auditory performance while using HAs as a measure of outcome and did not solely rely on HA use. Previous studies that used the PEACH and TEACH (Ching & Hill, 2007; Ching et al., 2008; Cupples et al., 2018; Johansson et al., 2020; Karimi et al., 2017; Marnane & Ching, 2015) focused only on children with SNHL and often those with severe to profound degrees of hearing (Emerson, 2015; Karimi et al., 2017). The use of these questionnaires allowed for auditory performance comparisons between children with CHL and SNHL. Lastly, this study also noted similar findings when comparing results of the PEACH and TEACH which supports those noted by Ching et al. (2008).

- The findings in this study indicated similar HA use for bilateral and unilateral HA users (6.5 and 6.2 h/day). The management of unilateral hearing loss varies, with the type and degree of hearing loss determining the intervention (Krishnan & Hyfte, 2016). Available literature predominantly focuses on children with unilateral SNHL and the impact on their quality of life (Bagatto et al., 2019; Krishnan & Hyfte, 2016; Snapp & Ausili, 2020; Vila & Lieu, 2015). To the researcher's knowledge, the management of unilateral CHL and its impact on quality of life has not been reviewed for children with CHL. While not an aim of the study, it was beneficial to note such similarities in HA use for both unilateral and bilateral HA users and suggests that the implications of unilateral hearing loss are not only significant for children with SNHL.

- Lastly, this study was the first of its kind to consider caregiver experiences of HA use for children with CHL in an LMIC. Study samples of previous literature on caregiver experiences originated from high-income countries and focused on children with SNHL (Lederberg & Golbach, 2002; Meinsen-Derr et al., 2008; Muñoz et al., 2015; Sjoblad et al., 2001; Walker et al., 2013). While the results from previous studies are useful, they are not necessarily comparable to LMICs where resources are significantly constrained. Therefore, the experiences of caregivers in this study are more relatable in an LMIC context. Interestingly though, the main challenges noted by caregivers in this study were similar to those of high-income countries, suggesting that regardless of resources and caregiver education, external influences can create barriers to HA use, i.e., stigma and bullying.

Limitations of the study

An integral part of critically evaluating a study is notifying the readers of weaknesses in the study design and results (Leedy & Ormrod, 2020). The limitations of this study are discussed below.

- The retrospective nature of this study implied that available data was limited. Retrospective data is not usually collected with research in mind; thus, findings are often limited and cannot always fully answer a research question (Euser, Zoccali, Jager, & Dekker, 2009). Retrospective studies are also considered an inferior method of study compared to experimental studies (Leedy & Ormrod, 2020; Manchaiah et al., 2021).

- The lack of randomisation in this study meant that only participants that met specific criteria could be included in the study sample (Leedy & Ormrod, 2020), limiting the generalisability of the findings beyond the study site. However, in this study where a specific intervention was investigated, it was beneficial to use this method of sampling as the data obtained was specific to the research aim (Andrade, 2021; Etikan, Musa, & Alkassim, 2016).

- PEACH and TEACH data were originally collected as part of routine clinical management and therefore not anonymous in that context. It is then probable that the data collected by these questionnaires could have been biased as caregivers and teachers may have over-estimated performance to meet clinician expectations (Manchaiah et al., 2021). The degree of bias typically differs between stakeholders (Lee & Hotopf, 2012; Leedy & Ormrod, 2020), however, the similarities between the two questionnaires could suggest that caregivers and teachers were honest in their responses. This is supported by the findings by Ching et al. (2008) who also obtained similar outcomes between the PEACH and TEACH questionnaires.

- Because of the limited sample size of this study, results obtained could not be generalised and were subsequently descriptive in nature. No possible associations could be made between independent variables and outcome variables, preventing analysis that could provide insight into factors affecting HA outcomes for this population (Leedy & Ormrod, 2020). Regardless, the data obtained in this study does contribute to research in the field of CHL and paves the way for future research that could consider the factors impacting HA outcomes for children with CHL.

- The outcome measure of HA use (data logging) in this study, was limited due to it being captured at only a single interval. This is useful when investigating outcomes at a single point in time (Leedy & Ormrod, 2020), but does limit comparison to other longitudinal studies (Booysen et al., 2021; Flanagan et al., 1996; Jardine et al., 1999). Additionally, an investigation of HA use at a single point in time does not consider factors such as active OM, running out of batteries or caregiver challenges with managing the physical HA devices (Booysen et al., 2021; Kesser et al., 2013). With the varying duration of HA use for children with CHL, comparison within the study sample would likely need to be

grouped. However, as this was the first study of its kind in South Africa, it does indicate the need for future studies to consider multiple HA use intervals for children with CHL.

- The caregiver telephonic survey responses in this study were predominantly from mothers. While a larger variation in survey participants could allow for differing experiences (Muñoz et al., 2015), this was not possible as details of caregivers according to hospital records were predominantly mothers who routinely brought their children to appointments at RCWMCH. While no differences between the type of caregivers were reported previously in high-income countries (Muñoz et al., 2015), this likely differs when compared to LMICs as some households consist of single parents and culture influences the presence of various caregivers in a child's daily life.

- The PEACH and TEACH questionnaires, as well as the telephonic survey in this study, were used in English format. While caregivers were asked if they were competent in English, some may have overestimated their competency and understanding, making responses in English limited and leading to a loss of valuable caregiver insight. During phase 2 of data collection (caregiver telephonic survey), this was partially overcome when an interviewer who could translate contents to isiXhosa was available. While this was done informally, and a separate translated survey was not created, most caregivers responded in English and the results obtained provided valuable insight into the experiences of this unique population.

- Phase 2 of data collection for this study utilised a telephone survey. While telephone surveys and interviews are considered more cost-effective and less timely, they have been found to have a lower response rate when compared to other forms of interviews (Leedy & Ormrod, 2020). Telephone surveys also prevent the interviewer from gauging any non-verbal cues and building a rapport with the interviewee (Leedy & Ormrod, 2020; Manchaiah et al., 2021). While caregivers had to consent to participate in the survey, often individuals are not solely focused on the questions being answered, which could influence their responses (Leedy & Ormrod, 2020). While the limitations of this manner of research are noted, phase two of this study took place during the COVID-19 pandemic and national state of disaster. Therefore, alternative methods of data collection could not have been considered.

4.4. Future research

Conducting research not only answers questions but also creates additional questions for investigation brought about by interesting findings or gaps in the findings (Manchaiah et al., 2021). The current study was no different with the researcher suggesting additional recommendations for investigation relevant to children with CHL.

- A future prospective longitudinal study describing HA outcomes for children with CHL fitted with BTE HAs should be carried out. Longitudinal studies allow for better comparison between participants and would allow for the measuring of outcomes at various intervals over time (Leedy & Ormrod, 2020). Additionally, this could assist in determining factors that influence HA outcomes in children with CHL. The benefit of a prospective study will allow for more precise planning regarding specific outcome measures to be utilised, specific data to be collected, as well as the intervals at which such data should be collected (Leedy & Ormrod, 2020; Manchaiah et al., 2021). This will allow a better understanding of HA use by children with CHL over time (Booysen et al., 2021) and a more critical comparison of HA use to existing studies (Booysen et al., 2021; Flanagan et al., 1996; Gan et al., 2017; Jardine et al., 1999).

- This study focused on CHL in paediatric HA users. Future research in this area should be more specific with participants grouped according to type (permanent versus temporary CHL) and onset of CHL. Doing so will allow for the comparison in outcomes for the two groups as the impact of acquired, permanent CHL is significantly different to that of acquired, temporary CHL (JCIH, 2019; WHO, 2021).

- Future research should constitute a larger sample size. This would increase the generalisability of the research results as well as their statistical significance (Manchaiah et al., 2021) in an area of paediatric audiology with limited evidence, especially in LMICs. Furthermore, it would enhance the existing body of evidence for children with CHL which currently consists of studies with small sample sizes.

- This study grouped unilateral and bilateral HA users due to the limited number of participants available. In future, a comparison of HA outcomes between these groups of HA users would add to the limited literature on management of childhood unilateral

CHL, as well as whether intervention is warranted for this specific group of children with CHL (Bagatto et al., 2019; Krishnan & Hyfte, 2016; Snapp & Ausili, 2020; Vila & Lieu, 2015). Additionally, a comparison of HA outcomes between unilateral and bilateral HA users would provide unique insight into the auditory performance of these HA users with CHL.

- As paediatric HA outcome data for this study was limited to the one-month post-fitting interval, no consecutive PEACH data was available for paediatric HA users that did not fall within the range of `typical auditory' performance. Future longitudinal research should track these paediatric HA user's performances over time. This will assist in determining whether auditory performance improves over time, or if alternative management should be considered.

- To provide a more comprehensive review on auditory performance for paediatric HA user's with CHL, the use of more diverse and sensitive behavioural measures should be considered. While the PEACH and TEACH are useful measures, they are not a direct comprehensive measure of auditory performance. Therefore, future research in this field should include more specific behavioural measures such as sound localisation tests and speech recognition in noise tests (Hogan, 2007). These assessments help with direct comparison to auditory skills prior to amplification and during amplification; it has also been noted that these assessments are better accepted by families as they can see the difference between unaided and aided assessment results (Hogan, 2007).

- Caregiver experiences were newly investigated in children with CHL for this study. While support and benefit were noted by most caregivers, the challenges reported were beyond the control of the family. Therefore, future research could investigate the development of an intervention program that includes and support teachers, schools and learners throughout the HA fitting and management process. Just as schools have parent evenings every term, a similar set-up could be considered between audiologists, teachers, and the caregivers of children with CHL. Recently, Muñoz (2021) piloted a remote education programme for caregivers to determine if remote education and support could improve HA outcomes. The results of this pilot study indicated that this additional support had a 97% adherence rate by caregivers (Muñoz, 2021). Incorporating

this type of remote programme in an LMIC context and adapting it to include areas relevant for teachers could assist in reducing external challenges for all parties involved when managing children with CHL. Additionally, a convenient and simple communication system can be set up between audiologists and teachers to enable swift communication, especially when there are concerns (McCormick Richburg & Goldberg, 2005). Research into this symbiotic management of paediatric HA users would aid in determining ways to minimise the challenges of stigma and bullying.

4.5. Conclusion

Children with CHL benefit from using BTE HAs. On average, children with CHL used their HAs for comparable hours of the day (5-8 hours) reported for children with SNHL, but less than the 10 h/day recommended for adequate language development. Auditory performance as reported by caregivers was typical for more than half of the children in this sample, confirming HA benefit at the one-month post-fitting appointment. Caregivers were supportive of HA use for CHL, with visible benefits equivalent to expectations. The challenges experienced by caregivers are like those reported in high-income countries regarding stigma and device compliance. In this study the majority of paediatric HA users had a type of OM as the cause of their hearing loss, suggesting that the fitting of BTE HAs are a viable management option to limit periods of hearing loss, and should be considered more regularly by ENT specialists and audiologist for children with acquired, temporary CHL.

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APPENDICES

Appendix A: Ethical clearance (HUM064/0519) from the Research Ethics Committee of The Faculty of Humanities, University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Humanities 100
1919 - 2019
Research Ethics Committee

6 August 2019

Dear Miss C Pienaar

Project Title:	Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape
Researcher:	Miss C Pienaar
Supervisor:	Dr TE le Roux
Department:	Speech Language Path and Aud
Reference number:	10247824 (HUM064/0519)
Degree:	Masters

I have pleasure in informing you that the above application was **approved** by the Research Ethics Committee on 25 July 2019. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely

Prof Maxi Schoeman
Deputy Dean: Postgraduate and Research Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: PGHumanities@up.ac.za

Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Research Ethics Committee Members: Prof MME Schoeman (Deputy Dean); Prof KL Harris; Mr A Biggs; Dr L Blokland; Dr K Bouwer; Dr A-M de Boer; Ms A dos Santos; Dr R Fasselt; Ms KT Govinder Andrew; Dr E Johnson; Dr W Kelleher; Mr A Mohamed; Dr C Puttergill; Dr D Reyburn; Dr M Soer; Prof E Taillard; Prof V Thebe; Ms B Tsebe; Ms D Mokalobe

Appendix B: Ethical clearance (HREC176/2019) from the Human Research Ethics Committee of The Faculty of Health Science, University of Cape Town

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

16 July 2019

HREC REF: 176/2019

Dr T Le Roux
Speech-Language-Pathology and Audiology
University of Pretoria

Dear Dr Le Roux

PROJECT TITLE: OUTCOMES OF CHILDREN WITH CONDUCTIVE HEARING LOSS THAT ARE FITTED WITH HEARING AIDS IN THE WESTERN CAPE, SOUTH AFRICA (MASTERS CANDIDATE: MS C PIENAAR)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until 30 July 2020.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Cheri Pienaar will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

Appendix C: Ethical clearance (RCC202) from the Red Cross War Memorial Children's Hospital Ethics Committee

Western Cape Government
Health

DR AN PARBHOO
Manager: Medical Services
Red Cross War Memorial Children's Hospital
Email: Anita.Parbhoo@westerncape.gov.za
Tel: +27 21 658 5430 Fax: +27 21 658 5006/5166

31 July 2019

Ms C Pienaar
Audiology Department

Dear Ms Pienaar,

RESEARCH: RXH: RCC 202

PROJECT TITLE: Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape

It is a pleasure to inform you that the hospital Research Review Committee has approved your application to conduct above-mentioned study in the Audiology Department at Red Cross War Memorial Children's Hospital.

Yours sincerely,

DR AN PARBHOO
MANAGER: MEDICAL SERVICES

www.westerncape.gov.za

Appendix D: Addendum ethical clearance from the Research Ethics Committee of The Faculty of Humanities, University of Pretoria

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Humanities 100
1919 - 2019

27 February 2020

Dear Ms Pienaar

Project:	**Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape, South Africa**
Researcher:	**C Pienaar**
Supervisor:	**Dr TE le Roux**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**10247824 (HUM064/0519) (Amendment to protocol)**

Thank you for the application to amend the existing protocol that was approved by the Committee on 25 July 2019.

I have pleasure in informing you that the amendment was **approved** the Research Ethics Committee at an *ad hoc* meeting held on 27 February 2020. Further data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the initial proposal. Should your actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely

Prof Innocent Pikirayi
Deputy Dean: Postgraduate Studies and Research Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: PGHumanities@up.ac.za

cc: Dr TE le Roux (Supervisor) and Prof J van der Linde (HoD)

Appendix E: Addendum ethical clearance from the Human Research Ethics Committee of The Faculty of Health Sciences, University of Cape Town

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: HREC-ENQUIRIES@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

18 June 2020

HREC/REF:176/2019

Dr T le Roux
Department of Speech-Language Pathology and Audiology
Humanities, University of Pretoria
Email: TALITA.LEROUX@UP.AC.ZA
Student: cpienaar94@gmail.com

Dear Dr le Roux

Project Title: OUTCOMES OF CHILDREN WITH CONDUCTIVE HEARING LOSS THAT ARE FITTED WITH HEARING AIDS IN THE WESTERN CAPE, SOUTH AFRICA (MASTERS CANDIDATE: MS C PIENAAR)

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee (HREC).

The Ethics Committee has **granted approval** for the amendment to increase the sample size and to supplement the date.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Hrec/ref:176/2019sa

Appendix F: Letter to Head of Department of Audiology at RCWMCH requesting permission to conduct research

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

ATTENTION: Head of Department of Audiology
Red Cross War Memorial Children's Hospital (RCWMCH)

Dear Ms. Kuschke,

RE: Permission to conduct a research study on children with conductive hearing loss fitted with hearing aids at RCWMCH

I am a Master's degree student from the Department of Speech-Language Pathology and Audiology at the University of Pretoria. As partial fulfilment for my degree, I have chosen to conduct research in the field of paediatric amplification. The aim of my study is to retrospectively describe the hearing aid outcomes of children with conductive hearing loss in Cape Town, Western Cape.

Title: *Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape, South Africa*

Primary researcher: Cheri Pienaar
Supervisors: Dr Talita le Roux & Professor De Wet Swanepoel

Design & procedure: A retrospective cohort design will be employed for this study. Hearing aid outcomes, along with demographic information, are routinely captured within the Department of Audiology for all hearing aid patients, as per the departmental protocol. For the purpose of this study, only outcome data recorded at the initial follow-up (approximately 4-6 weeks post fitting) will be utilized. Three outcomes measures have been utilized to capture amplification outcomes, namely the use of the *Parents' Evaluation of Aural/Oral Performance of Children* (PEACH) (Ching & Hill, 2007), Teacher's Evaluation of

Room 4-1.7, Level 4, Building
University of Pretoria, Private Bag X20
Hatfield 0028, South Africa
Tel +27 (0)12 420 1234
Fax +27 (0)12 420 5678
Email name.surname@up.ac.za
www.up.ac.za

Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

Aural/Oral Performance of Children (TEACH) (Ching & Hill, 2007) and the LittlEARS® Auditory Questionnaire (Coninx et al., 2009).

Inclusion criteria: Participants should be younger than 14 years old and should have been diagnosed with a bilateral conductive hearing loss, regardless of aetiology. Participants included must have been fitted with conventional behind-the-ear hearing aids in both ears and receive regular follow-up sessions at RCWMCH Department of Audiology. Participants must have been fitted with hearing aids for at least 1 month, with data available for one of the above mentioned outcome measures. Due to the nature of the questionnaires, only participant whose parents were proficient in English (and were able to complete the tools in English) were included.

Confidentiality: Data obtained will be handled with strict confidentiality and identifying information of participants will not be disclosed. Participants will be assigned an alphanumeric code which will be used for data processing causing the participant identity to be unknown, even to the researcher, which will ensure confidentiality and anonymity. Data will be presented anonymously for the purpose of data-analysis and all participants will be guaranteed anonymity at all times.

Informed consent: Due to the fact that this study will follow a retrospective research design, no direct participation will be required from the paediatric hearing aid patients. Approval for ethical clearance from the RCWMCH Ethics Committee is pending. Data will be provided in a non-identifiable format so as to protect participants' privacy and confidentiality throughout the study.

Risk: There are no associated risks for participation in this study.

Findings: The results of this research study will be published in accredited journals and a research report will be made available to the site on completion.

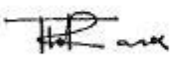
Data storage: Once completed, all data pertaining to this research study will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for a minimum of 15 years.

Faculty of Humanities
Department of Speech-Language Pathology and Audiology
Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

Participation agreement: You are requested to grant permission for de-identified data from a selection of the paediatric hearing aid patients from the Audiology Department of RCWMCH to be provided to the involved researchers. The data to be provided should not include patient names, contact information or any other identifiable information. This data will only be utilized for the specific project (entitled: *Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape, South Africa)* and be accessible only by the researchers involved. The source of this data will appropriately be acknowledged in reports and publications.

Should you agree that the specific dataset as described above be made available to the researchers, you are kindly requested to confirm this in writing. Please contact me should you require additional information.

Yours sincerely,



Cheri Pienaar
Researcher/ student
Email: cpienaar94@gmail.com
Telephone: (021) 6585406/5568

Dr Talita le Roux
Supervisor

Prof De Wet Swanepoel
Supervisor

Appendix G: Permission to the researcher to conduct research at RCWMCH Department of Audiology

Western Cape Government
Health

RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL
KLIPFONTEIN ROAD
RONDEBOSCH
7700

AUDIOLOGY DEPARTMENT (S24)
TEL.: 021 658 5406
FAX: 021 658 5070

30 July 2019

Ms Chéri Pienaar
University of Pretoria

Dear Ms Pienaar,

RE: APPROVAL OF RESEARCH

PROJECT TITLE: **OUTCOMES OF CHILDREN WITH CONDUCTIVE HEARING LOSS THAT ARE FITTED WITH HEARING AIDS IN THE WESTERN CAPE**

It is a pleasure to inform you that approval is hereby granted to conduct the above-mentioned study at the Audiology Department at Red Cross War Memorial Children's Hospital.

Yours sincerely,

Silva Kuschke
HoD: Audiology (RCWMCH)

Appendix H: Red Cross War Memorial Children's Hospital Department of Audiology research consent slips

RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL

Department of Audiology Tel: (021) 658 5406

Consent to use my child's audiological data for educational and research purposes

I, (caregiver) hereby give consent that my child's audiological data may be used for educational and research purposes. Confidentiality will be maintained at all times by anonymizing personal information.

Patient sticker

Signature: Caregiver

Signature: Audiologist

Date:

Appendix I: Verbal consent form for caregiver telephone survey

July 2020

TELEPHONIC SURVEY PARTICIPANT VERBAL CONSENT FORM

STUDY TITLE: *Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape*

Principal Investigator (PI): Chéri Pienaar

Supervisors: Dr Talita Le Roux & Professor De Wet Swanepoel

Institution: University of Pretoria, Department of Speech-Language Pathology and Audiology

DAYTIME AND AFTER-HOURS TELEPHONE NUMBER(S) FOR PI:

Daytime number/s: (021) 658 5568

After-hours number: 071 439 9271

DATE AND TIME OF TELEPHONIC CONVERSATION:

Day	**Month**	**Year**

:	:
Start Time	**End Time**

Call Duration: _____ minutes

TELEPHONIC SURVEY SCRIPT

Good day, my name is Chéri Pienaar. I am doing research for a master's degree at the University of Pretoria. Do you have a few minutes for me to discuss this study with you?

- If yes, continue below.
- If no, but interest is shown, attempt to determine a better time to call back and discuss the study.
- If no, thank them for their time.

I am inviting you to take part in this study because your child is/was fitted with a hearing aid/ hearing aids at Red Cross War Memorial Children's Hospital. This study aims to describe the outcomes and parental perceptions, experiences, and feelings, of children with conductive hearing loss that were fitted with hearing aids during the period of 2017-2019.

If you decide to take part in this study, you will be asked a series of questions that are related to your experiences when your child is/was using hearing aids.

Before you agree to take part in this study, there are some additional things that you should know about the study.

1. EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPECTED FROM PARTICIPANTS

This study involves answering a series of questions regarding your child's hearing aid use, your feelings and habits in terms of your child's hearing aid use, challenges related to your child's hearing aid use, and your thoughts and feelings regarding the hearing aids. Your answers will be scored and analysed by the researcher. This survey data will be used in addition to your child's demographical and audiological data as obtained from his/ her clinical record at the hospital (thus, for the purpose of this study, your child's hospital file information will be accessed and utilized).

2. POSSIBLE RISKS AND DISADVANTAGES INVOLVED

There are no risks associated with answering these questions. The only possible risk is taking the time to complete the series of questions. This should not take longer than 10-15 minutes.

3. POSSIBLE BENEFITS OF THIS STUDY

There will be no direct benefits from the study. Results of the study may help us to improve the way we work with and assist children with hearing loss.

4. COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

5. CONFIDENTIALITY

All information collected during this telephone survey, along with the information obtained from your child's clinical record at the hospital, will be kept private. Only the researcher will be able to identify you. In order to do this, we will not use your name or your child's name anywhere in this study. Results of this study may be published or presented, but your family details will always be kept private.

6. YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this telephone survey is voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your child's access to audiology services or other medical care.

7. CONSENT TO PARTICIPATE IN THIS STUDY

Do you have any questions?

- If yes, answer accordingly.
- If no, continue below.

Do you agree to participate in this study?

☐ Yes: Tick box and document verbal consent below. Continue with telephone survey.

☐ No: Thank them for their time.

Name of Subject:

_____

Relation to Child:

_____

PERSON OBTAINING CONSENT

I have read this form to the parent/ primary caregiver prospective participant. An explanation of the research study and procedures were given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgement, the participant has demonstrated comprehension of the information. The participant has provided verbal consent to participate in this study.

_____

Name and title (Please print)

_____ _____

Signature of person obtaining consent Date

Appendix J: Caregiver telephonic survey

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1919 - 2019
Department of Speech-Language Pathology & Audiology

TELEPHONE SURVEY QUESTIONS

Study title: *Outcomes of children with conductive hearing loss that are fitted with hearing aids in the Western Cape, South Africa*

Section A: Caregiver information

Child's name: _____

Home language of caregiver: _____

Language in which interview was conducted: _____

Primary caregiver: ☐ Mother ☐Father ☐Other: _____

Section B: Hearing aid use

1. Does your child still wear (use) his/her hearing aids?

   ☐ YES ☐NO*

   **If you have answered "No", please kindly answer the remaining questions thinking back to the time when your child was wearing hearing aids.*

1

a. If "Yes", why is it important to you and your child to wear the hearing aids?

_____

_____

b. If "No", what are the reasons for your child not wearing (using) his/ her hearing aid/s anymore?

_____

_____

2. Each day my child typically uses/used their hearing aids:

☐ all waking hours ☐ most of the day (8-10 hours) ☐ some of the day (5-7 hours) ☐ a portion of the day (less than 5 hours)

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Section C: Feelings & habits

My feelings & habits (Circle the number that best describes how much you agree with the statement)	Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree
1. I accept/accepted my child's hearing loss*	1	2	3	4	5
2. I am/was concerned with the appearance of my child's hearing aid(s)*	1	2	3	4	5
3. I am/was concerned about what others think*	1	2	3	4	5
4. I am/was concerned about how I will/would deal with my child's feelings about their hearing aid(s)*	1	2	3	4	5
5. I think the hearing aid(s) help/helped my child*	1	2	3	4	5
6. My child does not/did not need hearing aid(s)*	1	2	3	4	5
7. I think occasional hearing aid use is/was enough for my child to learn*	1	2	3	4	5
8. I feel/felt quite frustrated with handling the hearing aid(s) every day*	1	2	3	4	5
9. I feel/felt confused about how to keep the hearing aid(s) on my child*	1	2	3	4	5
10. I feel/felt confident I can tell when my child's hearing aid(s) are/were not working correctly*	1	2	3	4	5
11. I check/checked my child's hearing aid(s) every day*	1	2	3	4	5
12. Talking with other parents helps/helped me manage the hearing aid(s)*	1	2	3	4	5

13. The fact that the hearing aids are/were supposed to be temporary helps/helped me to manage them	1	2	3	4	5

**Adapted from Munoz et al., 2015. Pediatric Hearing Aid Use: Parent-Reported Challenges. Ear & Hearing, 36; 279–287*

Section D: Challenges relating to hearing aid use

My child's hearing aid use is/was affected by: (Circle the number that best describe how much you agree with the statement)	Strongly Disagree	Disagree	Not Sure	Agree	Strongly Agree
1. Distractions and needs of other children in the home*	1	2	3	4	5
2. Activities (e.g., playing outside, riding in the car)*	1	2	3	4	5
3. My child's behaviour*	1	2	3	4	5
4. Difficulty getting a set routine*	1	2	3	4	5
5. Long wait time to get an appointment with the audiologist*	1	2	3	4	5
6. Other caregiver's ability to manage hearing aid(s)*	1	2	3	4	5
7. The audiologist's lack of response to my questions during the appointment*	1	2	3	4	5
8. Difficulty coping with the demands of managing hearing aid(s)*	1	2	3	4	5
9. Frequent ear infection, i.e., leaking ears*	1	2	3	4	5

10. Frequent ear pain	1	2	3	4	5
11. Frequent feedback (whistling/squealing) from the hearing aid(s)*	1	2	3	4	5
12. My concern with the appearance of my child's hearing aid(s)*	1	2	3	4	5
13. Running out of batteries before my next appointment	1	2	3	4	5
14. The hearing aid(s) not working correctly*	1	2	3	4	5
15. My child's reaction to sounds when wearing the hearing aid(s)*	1	2	3	4	5
16. Difficulty keeping the hearing aid(s) on*	1	2	3	4	5

**Adapted from Munoz et al., 2015. Pediatric Hearing Aid Use: Parent-Reported Challenges. Ear & Hearing, 36; 279–287*

Section E: Parental thoughts and feelings regarding hearing aids

1. In your opinion, how did the hearing aids help your child?

_____

_____

2. In your opinion, what do/did you find most challenging about your child's hearing aid use?

_____

_____

3. What did you expect from the hearing aids when your child started using them?

_____

_____

4. Did you feel that the hearing aids did what you expected them to?

_____

_____

5. How did/does your child feel about wearing his/her hearing aids?

_____

_____

Appendix K: Proof of article acceptance for publication in the International Archives of Otorhinolaryngology

Decision Letter (IAO-2021-0687)

From: jotz@iaorl.org

To: cheri.pienaar@westerncape.gov.za

CC:

Subject: International Archives of Otorhinolaryngology (IAO) - Decision on Manuscript ID IAO-2021-0687

Body: 02-Dec-2021

Dear Miss Pienaar,

It is a pleasure to accept your manuscript entitled "Children with conductive hearing loss fitted with hearing aids: Outcomes and caregiver experiences, South Africa " in its current form for publication in International Archives of Otorhinolaryngology (IAO).

You find your manuscript as well as this decision letter in your Author Center under Manuscripts with Decisions.

Your manuscript will be forwarded to Georg Thieme Publishers. They will prepare your manuscript for printing. Thieme will contact you in the next weeks for further details.

Thank you for your contribution. Also on behalf of the reviewers of International Archives of Otorhinolaryngology (IAO), we look forward to your continued cooperation to the journal.

Sincerely,

Prof. Geraldo Pereira Jotz, MD. PhD.
Editor-in-Chief
IAO - International Archives of Otorhinolaryngology
jotz@iaorl.org
International Archives of Otorhinolaryngology (IAO)
jotz@iaorl.org

https://mc04.manuscriptcentral.com/iao-scielo

Date Sent: 02-Dec-2021