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Development and Evaluation of an Audiological Outcome Measure Guideline for Use with Infants, Toddlers, and Preschool Children

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Graduate Program in Health and Rehabilitation Sciences
A thesis submitted in partial fulfillment of the requirements for the degree in Doctor of Philosophy
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DEVELOPMENT AND EVALUATION OF AN AUDIOLOGICAL OUTCOME
MEASURE GUIDELINE FOR USE WITH INFANTS, TODDLERS, AND
PRESCHOOL CHILDREN

(Spine title: Audiological Outcome Measures for Children)

(Thesis format: Integrated Article)

by

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Graduate Program in Health and Rehabilitation Sciences

A thesis submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy

The School of Graduate and Postdoctoral Studies
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London, Ontario, Canada

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Abstract

The goals of the current work were to: 1) identify caregiver report questionnaires for inclusion in an outcome evaluation guideline for infants, toddlers, and preschool children who wear hearing aids and 2) evaluate the chosen tools to determine their usefulness for the population of interest. A critical review of auditory-related subjective outcome evaluation tools for infants, toddlers, and preschool children is presented (Chapter 2). Good psychometric properties and clinical feasibility were considered important elements for the guideline (Andresen, 2000). Existing norms for the chosen questionnaires were validated with normal hearing children from Canadian English-speaking families (Chapters 3 and 5). Finally, The University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP), how it was used to collect clinical data with children who wear hearing aids, and their performance on the questionnaires is provided (Chapter 4). Children with comorbidities and complex factors related to hearing aid use were also investigated.

The results of this work revealed two caregiver report questionnaires that were suitable for use within the UWO PedAMP (Chapter 2): the LittlEARS[®] Auditory Questionnaire (Tsiakpini, et al., 2004) and the Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Rating Scale (Ching & Hill, 2005). Both questionnaires were considered feasible for clinical use (Moodie, et al., 2011) and are supported by good psychometric properties. Norms for the questionnaires were found to be appropriate for use with normal hearing children (Chapters 3 and 5). Outcomes of children with hearing loss who wear hearing aids were investigated using the UWO PedAMP (Chapter 4). Results indicated typically developing children fitted with hearing aids displayed auditory development and performance similar to their normal hearing peers. Children with comorbidities displayed borderline normal auditory development which progressed as they got older. Children with complex factors related to hearing aid use displayed borderline normal development up to 12 months of age where it began to decline. This work also demonstrated that the UWO PedAMP can be used in a clinical setting to evaluate the outcome of hearing aid fitting to infants, toddlers, and preschool children.

This is an important finding because outcome evaluation guidelines for this population are lacking.

Keywords

outcome measures, outcome evaluation, audiological monitoring, caregiver report questionnaires, hearing loss in infants, hearing loss in toddlers, hearing loss in children, hearing aid verification in children, pediatric audiology, critical review, repeated measures observational study, LittEARS Auditory Questionnaire, PEACH Rating Scale, UWO PedAMP, Speech Intelligibility Index

List of Abbreviations

AAA: American Academy of Audiology
AAI: Aided Audibility Index
ABEL: Auditory Behavior in Everyday Life
ABR: Auditory brainstem response
ANSD: Auditory neuropathy spectrum disorder
ANSI: American National Standards Institute
ASFT: Aided sound field thresholds
BKB-SIN: Bamford-Kowal-Bench Sentences in Noise
BTE: Behind-the-ear
CAL: Child Amplification Laboratory
CASLPO: College of Audiologists and Speech Language Pathologists of Ontario
CHILD: Children's Home Inventory for Listening Difficulties
COSI-C: Client Oriented Scale of Improvement – Child Version
COW: Children's Outcome Worksheet
CP: Cerebral palsy
dB: Decibel
DIAL: Developmental Index of Audition and Listening
DPOAE: Distortion product otoacoustic emissions
DSL: Desired Sensation Level
EHDI: Early hearing detection and intervention
ELF: Early Listening Function
FAPI: Functional Auditory Performance Indicators
FEW: Family Expectations Worksheet
HABIT: Hearing Aid Benefit Scale for Infants and Toddlers
HL: Hearing level
IT-MAIS: Infant-Toddler Meaningful Auditory Integration Scale
JCIH: Joint Committee on Infant Hearing
MCHAS: Modernising Children's Hearing Aid Services
MPO: Maximum power output
NAL: National Acoustics Laboratories
OIHP: Ontario Infant Hearing Program
OPP: Observer-based psychoacoustic procedure
PCHI: Permanent childhood hearing impairment
PEACH: Parents' Evaluation of Aural/Oral Performance of Children
PTA: Pure tone average
REAR: Real-ear aided response
RECD: Real-ear-to-coupler difference
SHARP: Situational Hearing Aid Response Profile
SII: Speech Intelligibility Index
SPL: Sound pressure level
UK: United Kingdom
US: United States
USPSTF: United States Preventive Services Task Force

UWO PedAMP: University of Western Ontario Pediatric Audiological Monitoring Protocol

VRA: Visual reinforcement audiometry

VRASPAC: Visual Reinforcement Assessment of the Perception of Speech Pattern Contrasts

WHO-ICF: World Health Organization's International Classification of Functioning

Co-Authorship Statement

This dissertation includes six chapters: an introductory chapter providing the background information and rationale for the work (Chapter 1), four integrated manuscripts which have been either published (Bagatto, Brown, Moodie, & Scollie, 2011; Bagatto, Moodie, Malandrino, Richert, Clench, & Scollie, 2011; Bagatto, Moodie, Seewald, Bartlett, & Scollie, 2011) or accepted for publication (Bagatto & Scollie, Accepted), and a concluding chapter (Chapter 6). I, Marlene Bagatto, am responsible for the conception and design of this work, project coordination to support data collection, data collection and organization, statistical analyses, and interpretation of results. I am the lead author on all manuscripts included in this dissertation and am sole author of the introductory (Chapter 1) and concluding (Chapter 6) chapters. The introductory and concluding chapters were reviewed by Susan Scollie prior to inclusion in this document. Chapter 2 was co-authored by Sheila Moodie, Richard Seewald, Doreen Bartlett, and Susan Scollie. Sheila Moodie and Susan Scollie provided guidance on the design of the work presented in Chapter 2. All co-authors on this manuscript reviewed drafts of it and provided important comments. They also reviewed the final draft of the manuscript before submission. Chapter 3 was co-authored by Christine Brown, Sheila Moodie, and Susan Scollie. Christine Brown provided the majority of the data for this project and offered valuable input regarding clinical outcome measures. Susan Scollie provided support for data analyses and, along with Sheila Moodie, reviewed drafts of the manuscript prior to submission. Chapter 4 was co-authored by Sheila Moodie, April Malandrino, Frances Richert, Debbie Clench, and Susan Scollie. Sheila Moodie and Susan Scollie participated in the development of the University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP), which was used as a vehicle for data collection in this study. They also reviewed drafts of the manuscript prior to submission. April Malandrino, Frances Richert, and Debbie Clench provided data from a clinical audiology population and offered valuable feedback regarding the UWO PedAMP. Chapter 5 was co-authored by Susan Scollie. She offered suggestions regarding recruitment strategies and provided guidance for data analyses and interpretation. Dr. Scollie also reviewed drafts of the manuscript and provided important intellectual content prior to submission.

Dedication

I dedicate this work to my maternal grandfather (1916-2011). He was always quietly but profoundly supportive of me. He was a determined man who decided to get a hearing aid when he was 91 years old.

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Chapter 1

1 Audiological outcome measures for infants, toddlers, and preschool children

1.1 Background

Identification of permanent hearing loss in children is crucial in the early months of life due to the need for early intervention services. Many families with children who have permanent hearing loss choose personal hearing aids as part of an overall intervention plan. Hearing aids provide the child with access to sound to support speech, language, and communication development during the critical period. Technologies suitable for pediatric hearing aid fitting as well as evidence-based protocols support accurate and safe hearing aid intervention (i.e., American Academy of Audiology [AAA], 2003; Bagatto, Scollie, Hyde, & Seewald, 2010; Early Hearing Equipment Advisory Group, 2006; College of Audiologists and Speech Language Pathologists of Ontario [CASLPO], 2002; Modernising Children's Hearing Aid Services [MCHAS], 2005). The provision of amplification to patients with permanent childhood hearing impairment (PCHI) involves a process which includes the calculation of prescriptive targets based on accurate hearing assessment information, the selection of physical and electroacoustic elements of a hearing aid, verification that the specified acoustical prescriptive targets have been achieved, and outcome evaluation of device effectiveness in daily life. The majority of the stages in the pediatric hearing aid fitting process have been investigated and refined for clinical practice. The impetus for this work was the need to develop and evaluate a systematic, evidence-based approach for outcome measurement that is clinically feasible. Although most pediatric hearing aid fitting protocols mention the importance of monitoring the outcome of hearing aid fittings to children, specific strategies for doing so are not included in the protocol. Thus, there was a need to establish an outcome evaluation guideline suitable for use with infants, toddlers, and preschool children who wear hearing aids. In the context of modern Early Hearing Detection and Intervention (EHDI) systems, the evaluation of outcome from early amplification is done in the early years of life. Therefore, outcome measurement must take into consideration the auditory

development of the child, or perhaps use measures of auditory development as measures of outcome. For this reason, a summary of auditory development and methods for its measurement are described in the sections below.

1.2 Measurement of auditory development

There has been little research conducted on the auditory development of children with PCHI. However, there is a large body of literature describing the course of auditory development in typically developing children with normal hearing. Documenting normal auditory development provides guidance for researchers and clinicians to understand how hearing impairment may impact the developing auditory system and what one would expect should acoustic or electric stimulation be provided to the hearing impaired child. Hearing scientists have applied both physiological and behavioural methods to the study of auditory development. Although each technique has its limitations, a complete understanding of the development of the auditory system is obtained by studying the child's behavioural responses to sound (Werner, 1995). Support for this is demonstrated by the fact that although a newborn's inner ear is mature at birth, the development of hearing continues into adolescence (Leibold, Bonino, & Fleenor, 2007). A young infant's peripheral auditory system sends signals to the central auditory system where much of what is learned about sound takes place (Werner, 1996). Over time, a child learns about the different aspects of sound and what they mean so that he/she can ultimately understand complex sounds, such as speech, as well as adults do. The child must have experience with sound in order for auditory development to occur and the most salient way to study the development of the complete auditory system is to observe a child's behaviour in response to sound. This can be done in two ways: laboratory measures, which often employ psychophysical procedures, and real-world measures, which often rely on caregiver recall and report.

One psychophysical method for the measurement of early auditory behaviours is the observer-based psychoacoustic procedure ([OPP]; Olsho, Koch, & Halpin, 1987; Werner, 1995). The OPP supports reliable and valid measurement of auditory ability in very young infants. While not currently in widespread clinical use, the OPP is the primary method used in laboratory investigations of infant auditory development (Olsho, et al.,

1987; Werner, 1995; Werner & Marean, 1991). Some suggest that the OPP may be modified for clinical use so that it can be used by clinicians who provide habilitation services to their young patients. Specifically, clinical procedures for infant speech sound discrimination have been suggested for use as an outcome measure for children who use hearing aids or cochlear implants (e.g., Visual Reinforcement Assessment of the Perception of Speech Pattern Contrasts [VRASPAC]; Martinez, Eisenberg, Boothroyd, & Visser-Dumont, 2008). Many are not used routinely by clinicians as these procedures require more validation and are not available in common commercial systems. In the meantime, clinicians who fit children with hearing aids are in need of tools to measure the impact of the hearing aid fitting on the child's auditory development and how that compares to children with normal hearing. Psychoacoustic procedures are an option and can involve detection, discrimination, and recognition of speech sounds provided the child is in the correct age range (i.e., five to six months) and has the developmental capabilities to complete the task.

An alternative to psychoacoustic assessment of a child's auditory development is the use of real-world observation of a child's behaviours in response to sounds. This can be accomplished by using questionnaires that involve the caregiver to report on their child's auditory behaviours at different ages while wearing the hearing aids. The motivation for the current work lies with the fact that there are few tools for children that have been well-normed and validated or have the clinical feasibility and utility to be used consistently as part of a complete habilitation program. Additionally, there is little research related to what a typical outcome might be for a child who wears hearing aids or how to track the child's auditory development and performance over time. This is in part due to the lack of well-developed outcome measures available for use with children who wear hearing aids. To facilitate this, typical skills or behaviours related to various domains of a child's auditory development should be compared to existing good-quality norms. Children who have been identified as having a lifelong impairment will likely exhibit delays in certain aspects of their development, depending on the impairment. In these cases, the use of standard scores derived from typically developing children may not be suitable and normative data characterized from special populations would be more appropriate (Andresen, 2000). The following section will include the characteristics of

clinically appropriate normative data, with specific consideration of its applications for caregiver-report outcome measures of childhood auditory behaviours.

1.3 Normative data

Andresen (2000) describes the characteristics of normative data that contribute to the quality of an outcome measure. Normative data derived from the typically developing population as well as from a disordered population with different profiles are the most desirable (Andresen, 2000). Regardless of the population from which the normative data are being obtained, there are several additional key aspects that also must be considered when developing the data and providing it for use. The development and validation of a classification system used to describe gross motor function in children with cerebral palsy (CP) provides relevant information for developing normative data for children with hearing impairment (Palisano, et al., 1997). As part of the treatment of a child with CP, the measurement of functional change in posture and motor development over time is desirable. A standardized tool that has been shown to be valid and reliable in its ability to detect change in gross motor function in children with CP was used to validate a classification system that describes the severity of CP in children (Palisano, et al., 1997). This research provides a framework that can be applied to children with hearing loss by modeling how functional measures can be used to norm and validate a classification system for a specific population. In the case of hearing impaired children, the classification system exists but requires the generation of normative and validation information based on functional evaluation. Although the classification of hearing impairment is in widespread use by audiologists, it does not describe the patient's specific communication function or disability for a given level of hearing impairment.

Use of outcome measures to obtain norms for auditory development and performance for different levels of hearing loss in children is the focus of the current work. Some considerations for the collection and presentation of normative data for a given population are that they are reliable and valid for use with children with the impairment (e.g., PCHI; Palisano, Hanna, Rosenbaum, Russell, Walter, Wood, et al., 2000; Palisano, et al., 1997; Rosenbaum, et al., 2002; Wood & Rosenbaum, 2000). In addition, the stability and potential decline of these norms should be studied using both cross-sectional

and longitudinal data sources to provide an evidence-based understanding of the prognostic value of the outcome evaluation tool (Hanna, Rosenbaum, Bartlett, Palisano, Walter, Avery, et al., 2009; Rosenbaum, Walter, Hanna, Palisano, Russell, Raina, et al., 2002). Percentile ranks are also useful for each level of a classification system in relation to scores on the outcome evaluation tool to provide useful interpretation of normative data (Hanna, Bartlett, Rivard, & Russell, 2008). Finally, the impact and utility of the outcome evaluation tool in clinical, research, and educational settings is important to consider in order to gain a better understanding of the development of auditory skills in children with hearing loss (Morris & Bartlett, 2004). These facets are necessary considerations in the development and presentation of normative data.

1.4 Importance of outcome evaluation

The application of outcome evaluation is also essential for assessing the overall quality of an EHDI program. Johnson & Danhauer (2002) distinguish between program and process outcome measures. Program outcomes can be distinguished from process outcomes in that they are relevant to the administration of a program (Johnson & Danhauer, 2002). Process outcomes relate to *how* and *why* clinical practice is performed (Johnson & Danhauer, 2002). Both types of outcome measures may yield significant data on the function and impact of EHDI.

In 2001, the United States Preventive Service Task Force (USPSTF) surveyed the evidence regarding universal newborn hearing screening (United States Preventive Task Force, 2001). Although the Task Force found good evidence that newborn hearing screening leads to earlier identification and intervention of infants with hearing loss, the evidence that early intervention leads to significant speech and language improvements was deemed to be inconclusive. A systematic review to update the 2001 USPSTF recommendation was completed in 2008. The outcome of the 2008 USPSTF was a recommendation to screen all newborn infants for hearing loss. They indicated that more long-term studies are needed to support the current findings and that other outcomes should be assessed such as school performance and quality of life. The USPSTF also indicated that early intervention services be individualized for each child and family and include evaluation for amplification or sensory devices (United States Preventive

Services Task Force, 2008). Program outcomes such as *when* the hearing aid was fitted were often the focus of the reviewed studies. It is important to bear in mind clinical process outcomes such as *how well* the hearing aid was fitted when evaluating outcomes. This is an essential outcome to consider because the quality of a hearing aid fitting can impact the overall outcome of the child (Joint Committee on Infant Hearing [JCIH], 2007; Stiles, Bentler, & McGregor, 2012). Early steps in the hearing aid fitting process affect later steps and, if not followed in a systematic way, could impact the child's auditory, speech, and language development. For instance, preferred practice guidelines suggest that prescribed values be generated by the pediatric audiologist using a systematic approach to hearing aid fitting (i.e., Desired Sensation Level [DSL] Method; Scollie, et al., 2005). The values are then used as *targets* with which to adjust the hearing aid so speech can be heard by the child easily and comfortably. As part of the hearing aid verification process, the clinician measures whether the output of the hearing aid approximates the prescribed targets by placing a probe tube microphone in the child's ear canal to measure the sound pressure level. The most common way this is accomplished in children is by measuring the real-ear-to-coupler difference (Moodie, Seewald, & Sinclair, 1994). If the output of the hearing aid is significantly below the targets, for example, the child will not have access to the speech signal which may impact his/her ability to develop speech and language appropriately. Of the studies reviewed by the USPSTF, process outcomes such as those related to the hearing aid fitting were often lacking.

1.5 Recent studies of EHDI outcomes

Several recent outcome studies have reported amplification details (i.e., process outcomes) as part of the study methodology. Although not a large-sample outcome study, a two-part longitudinal investigation looked at phonetic development and transition to words in infants with hearing loss compared to normal hearing (Moeller, et al., 2007a; Moeller, et al., 2007b). All of the infants with hearing loss were enrolled in early intervention services and were fitted with amplification within one to five months of the diagnosis (Moeller, et al., 2007a). Probe-microphone measurements of gain and output were reportedly used in combination with Desired Sensation Level (DSL) v4.1 target values. During the course of the study, loaner hearing aids were provided during times

when a child's hearing aid needed to be sent to the manufacturer for repairs. This, along with parental support and encouragement, helped to maintain consistent use of hearing aids by the children in these studies. This type of reporting of clinical process outcomes for hearing aid fitting assists interpretation of findings, because consistent use of properly fitted hearing aids has been reported to impact outcome (Moeller, Hoover, Peterson, & Stelmachowicz, 2009). In addition, an aided audibility index ([AAI]; Amlani, Punch, & Ching, 2002) using the Situational Hearing Aid Response Profile ([SHARP]; Stelmachowicz, Kalberer, & Lewis, 1996) was provided. The SHARP is a computer program that illustrates the amount of audibility of speech for different spectra specific to a variety of pediatric listening conditions (e.g., cradle, caregiver's hip). It was used with the AAI to provide a prediction of speech audibility for the children in different listening situations while wearing their hearing aids. Findings suggested that early-identified children have delayed consonant and syllable structure development compared to their normal hearing peers. In addition, there appears to be a delay in the transition from babble to words in children with hearing loss, although they still develop this milestone in parallel to normal hearing children (Moeller, et al., 2007a). Although the outcomes of the children reported in this study were not optimal, reporting hearing aid fitting details is essential for interpreting outcomes. Knowing details of the hearing aid fitting process provides a more complete picture of the intervention being evaluated, regardless of outcome.

In a larger study, the National Acoustics Laboratories (NAL) in Australia has been conducting a longitudinal study of outcomes of early- and later-identified hearing impaired children. They reported clinical processes associated with preferred practice in pediatric amplification. For example, real-ear acoustics and electroacoustic measurements of hearing aid performance to NAL or DSL prescriptive targets were obtained for each initial fitting (Ching, Dillon, Day, & Crowe, 2007). Further, the "quality of audiological intervention was controlled by adherence to consistent protocols and procedures across all hearing service centres" involved in the study and that "strict criteria for matching hearing aids to prescriptive targets were observed in all fittings" (Ching, et al., 2007, p. 187). References to hearing aid fitting guidelines or the specific criteria used for matching to prescriptive targets were not provided in the report. Nevertheless, the hearing

aid fitting details provided in the report exceeds what has been provided in previous large-scale studies of EHDI outcomes. Interestingly, a follow-up publication reporting language development and everyday functioning of three-year-old children with hearing loss who wear hearing aids reported the hearing aid fitting age only; the quality of the fittings was not provided (Ching, et al., 2010).

Finally, a recent study investigated factors influencing auditory-based communication outcomes in children with hearing loss (Sininger, Grimes, & Christensen, 2010). Several details about the hearing aid fitting were included in the study methodology. The children were reportedly fitted with analog or digital signal processing, behind-the-ear (BTE) hearing aids coupled to soft earmolds. Filtered earhooks were *generally* applied to the BTEs and the volume control was either covered or deactivated (Sininger, et al., 2010). Simulated real-ear measures were conducted to verify the electroacoustic match to DSL v4.1 targets for gain and output. Real-ear-to-coupler difference (RECD) values were measured and age-appropriate predicted values were used when required. Adjustments to the devices were made to achieve as close a match to DSL targets as possible (Sininger, et al., 2010). In addition, speech intelligibility index (SII) values for a 65 decibel (dB) sound pressure level (SPL) speech input were recorded to provide a value indicating the proportion of audible speech available in the fitting. Although the investigators indicated that the SII data can be useful in further evaluating the adequacy of the hearing aid fitting and compare fittings across participants, they did not use the data in the final analysis. Despite this, a very detailed description of important hearing aid fitting characteristics was provided in this study of auditory-based communication outcomes. Program outcomes in this study indicated a significant effect of early intervention and degree of hearing loss. On the other hand, a different group of researchers investigated the predictability of aided SII values compared to pure tone average (PTA) on the lexical abilities of children with hearing loss who wear hearing aids (Stiles, et al., 2012). They found that aided SII values are a better predictor of lexical abilities than PTA in children who wear hearing aids. They postulated this was due to the fact that the SII is a representation of the benefit derived from the hearing aid fitting and is more functional than a description of the degree of hearing loss provided by the PTA. These studies provide a model for future studies to include similar hearing aid fitting details, and also

helps guide the development of outcome evaluation of amplification services for the pediatric population. The findings from these studies provide information about program outcomes of early language development in children with hearing loss who have accessed high-quality early intervention delivered with a known set of clinical processes. Having knowledge of the hearing aid fitting details provides insight about the potential reason for some of the noted delays as well as positive outcomes in the children studied within an EHDI program. Additionally, work described here contributes to a better understanding of auditory development in children with PCHI who wear hearing aids.

Several research studies have focused on the functional communication outcomes of children involved in EHDI programs and what factors may impact outcome (e.g., Bass-Ringdahl, 2010; Ching, et al., 2007; Fitzpatrick, Crawford, Ni, & Durieux-Smith, 2011; Meinzen-Derr, Wiley, & Choo, 2011; Moeller, 2000; Moeller, et al., 2007a; Moeller, et al., 2007b; Sininger, et al., 2010). These studies reveal imperative information about the parameters of outcome for children who are early- versus late-identified. For example, these studies show positive effects of early intervention and parental involvement, and limiting effects of both late identification and inconsistent hearing aid use. Individual clinicians and/or EHDI programs may be tempted to implement some or all of the outcome batteries of such studies when attempting to measure outcomes for individual children or across programs. Unfortunately, this strategy may not be successful: the protocols implemented in these studies were designed for the purposes of research, and may have barriers to implementation in clinical practice. These barriers include extensive test batteries which are impractical to administer and score in a typical clinical situation. Additionally, measuring auditory development and performance (i.e., functional) outcomes in very young patients are more within the scope of practice for pediatric audiologists as compared to speech or language outcomes that may be more appropriately evaluated by another professional (e.g., Speech-Language Pathologist). This provides further support for the usefulness of observing auditory behaviours and their application as part of a complete understanding of auditory development. For these reasons, the work presented here has attempted to develop and validate a clinical practice guideline for audiologists to use in clinical EHDI practice. An understanding of the clinical processes and course of auditory development in infants, toddlers, and preschool children with

hearing impairment who wear hearing aids were obtained with the use of clinical outcome evaluation tools.

1.6 Summary of chapters

The series of studies presented in the subsequent chapters aimed to evaluate existing audiological outcome measures for infants, toddlers, and preschool children, to develop a clinical practice guideline for outcome measurement, and to characterize clinical outcome in a typical caseload. A critical review of the existing outcome evaluation tools (Chapter 2) identified a subset that was further evaluated (Chapters 3, 4, and 5). Specifically, previously-developed normative properties of the identified tools were replicated with Canadian children with normal hearing (Chapters 3 and 5). Characterization of scores with infants, toddlers, and preschool children with various audiometric and medical profiles was also examined (Chapter 4). Research supporting a behavioural approach to the study of auditory development provided a solid background to accomplish this work with infants, toddlers, and preschool children with hearing impairment (e.g., Werner, 1995). A well-validated, clinically feasible monitoring protocol to track auditory development was developed in the process of this work. Known clinical tools with good normative properties, validity, feasibility, and utility supported the development of an evidence-based outcome evaluation guideline for the pediatric audiology population.

1.7 Purpose of the current research

One purpose of this work was to critically review the current status of auditory-related subjective outcome evaluation tools for infants, toddlers, and preschool children, thereby identifying a subset that was included and evaluated within guideline development. The complete guideline consists of a battery of subjective outcome evaluation tools chosen during the critical review process, as well as clinical process tools to assist with the evaluation of the hearing aid fitting which aids in interpreting the scores on the functional evaluation. The companion study to this work examined the use of the guideline by a network of pediatric audiologists in Canada (Moodie, et al., 2011). Using an integrated knowledge translation approach (Graham, et al., 2006), pediatric audiologists were

engaged in the development and refinement of the guideline from its inception. This helped foster clinical feasibility and uptake of the guideline (Moodie, et al., 2011).

A second purpose of this study was the evaluation of the existing normative properties of the identified tools with infants, toddlers, and preschool children with normal hearing. It was important to validate existing normative data to ensure that the previously developed norms are suitable for use within the Canadian population. Thirdly, cross-sectional characterization of scores on the outcome evaluation tools with infants, toddlers, and preschool children with various audiometric and medical profiles were examined. In this repeated measures longitudinal observational study, children with all degrees and configurations of hearing loss and intervention types as well as those with comorbidities and complex factors (e.g., inconsistent hearing aid use) were investigated. These children represent a complete and typical clinical caseload of a pediatric audiologist, which includes a significant proportion of children with hearing loss and other medical or developmental conditions (Tharpe, Fino-Szumski, & Bess, 2001). Including these children in this work is unique when compared to the previously mentioned studies that evaluated outcomes in children with hearing loss and no other associated complexities or medical factors. This ongoing work will enhance the generalizability of this work with a naturally-occurring clinical pediatric audiology population.

1.7.1 Research questions

This research was divided into five integrated manuscript-style chapters which aimed to address the following questions:

- 1) What auditory-related subjective outcome evaluation tools are available for infants, toddlers, and preschool children and which ones are of good quality? (Chapter 2)
- 2) Are the existing norms for the chosen questionnaire(s) appropriate for use with Canadian English-speaking normal hearing children? (Chapters 3 and 5)
- 3) a) How do children with hearing loss who wear hearing aids perform on the chosen questionnaire(s)? (Chapter 4)
b) How well do the existing norms work for children with aided PCHI who have modern hearing aid technology? (Chapter 4)

c) How do children with hearing loss who wear hearing aids and have comorbidities or complex factors related to hearing aid use perform on the chosen questionnaire(s)? (Chapter 4)

1.8 Methods

The critical review (Chapter 2) involved a detailed search of the available subjective audiological outcome measures for infants, toddlers, and preschool children. Measures were considered subjective if they could be completed interview-style or independently by the child's caregiver. Subjective outcome measures were included in the critical review instead of objective psychoacoustic outcome measures due to their real-world relevance. The concepts of objective and subjective testing relate to the World Health Organization's International Classification of Functioning, Disability, and Health (WHO-ICF) in that they both seek to measure the activity and participation of children with hearing loss (World Health Organization, 2001). The difference is that objective measures assess the child's *capacity* (i.e., what the child can do in the clinic/laboratory) and subjective measures assess the child's *performance* (i.e., what the child can do in the real-world; Rosenbaum & Stewart, 2004). A combination of objective and subjective outcome evaluation tools may provide a multi-dimensional approach to tracking a child's auditory-related performance over time. A test battery of outcome evaluation tools may provide caregivers and clinicians with a way to measure the audiological performance of children during the early months as well as later years of hearing aid use or non-use (i.e., if the child has a known hearing loss but does not wear a device). It was a goal of this work to develop a guideline that would be clinically feasible for a naturally-occurring pediatric audiology population. This includes children who are not typically developing and those who are too young to perform objective tasks reliably within the constraints of clinical practice. These children were an integral part of this work, so subjective outcome evaluation tools were the initial focus. Further details regarding the rationale for choosing subjective outcome evaluation tools for this work are provided in Chapter 2. The critical review identified two subjective outcome evaluation tools that were used in a two-stage developmental approach in this study. The LittleEARS[®] Auditory Questionnaire assesses auditory development and was used for infants and toddlers (see Appendix A). The

Parents' Evaluation of Aural/Oral Performance (PEACH) Rating Scale assesses auditory performance and was used for toddlers and preschool children provided certain criteria were met (see Appendix B).

The remaining chapters involved a large-scale repeated measures longitudinal observational study that was mainly retrospective in nature (i.e., participants for Chapter 5 were actively recruited). Five pediatric audiologists at four clinics in Ontario, Canada were involved in data collection from March 2009 until October 2011. Since 2001, the Ontario Ministry of Children and Youth Services has managed the Ontario Infant Hearing Program (OIHP). This program offers universal newborn hearing screening, audiological assessment, and intervention services to all babies born in Ontario until entrance into grade one. Evidence-based clinical protocols, clinician training, and standardized equipment are hallmarks of this world-class program. Clinicians involved with the current study were OIHP-trained clinicians who followed evidence-based provincial hearing assessment and hearing aid fitting protocols (Bagatto, et al., 2010; Ontario Ministry of Children and Youth Services, 2008). Caregivers of children with normal hearing and those identified as having PCHI completed the subjective outcome evaluation tools during routine clinical appointments. The outcome evaluation tools used in this work were implemented based on age and developmental level (see Chapter 4). Therefore, caregivers of the children involved in this study may have filled out different outcome evaluation tools depending on the child. In addition, the repeated measures nature of this work meant that the tools were administered from one to five times for a given child, depending on the number of times they were seen in the clinic during the course of this investigation. The number of administrations of each outcome evaluation tool administered for children with and without hearing aids is provided in Table 1-1.

Table 1-1: Number of administrations of each outcome evaluation tool administered in the overall study.

Outcome Evaluation Tool	Children Without Hearing Aids	Children With Hearing Aids	Total Administrations
LittleEARS	431	126	557
PEACH	111	188	299

For those children who wore hearing aids, details of the fitting were documented by the clinician and provided de-identified to the project coordinator (M. Bagatto). This provided clinical process outcomes to support the interpretation of functional outcomes obtained through the subjective outcome evaluation tools. Additionally, hearing aid fitting details supply information about *how well* the hearing aids were fitted for a child's degree of hearing loss. Given that outcome measures are within the scope of clinical audiology practice and the data was de-identified and retrospective in nature, consent was waived. Caregivers participating in the validation work presented in Chapter 5 signed a consent form if they were actively recruited from outside of the audiology clinic. The overall study was approved by the Ethics Review Board at the Office of Research Ethics at the University of Western Ontario

1.8.1 Participants

The main participants for this investigation were children within the age range of 1.3 to 115.3 months (mean age = 28.6 months) and their caregiver(s). This approximates the age range serviced by the OIHP. Although it was of interest to monitor the child's auditory development and performance, the nature of the subjective outcome evaluation tools and the age of the children required caregiver participation. Therefore, the child's caregivers also served as participants but detailed information about them was not documented. The age range of the children spanned several age categories typically used to define different pediatric stages. Categories used in this investigation followed recommendations from a

recent publication from the American Academy of Pediatrics (Shah, 2011) and are as follows:

- Infancy: 0 to 1 year
- Toddler Years: 1 to 3 years
- Preschool Years: 3 to 6 years
- School-aged Child: 7 to 12 years

Therefore, this work focused on infants, toddlers, and preschool children. Throughout the chapters, the term ‘children’ is used to refer to all pediatric categories involved in the current work. The specific age categories are referred to where relevant.

In total, 459 children were involved in the study. Two hundred and sixty seven had normal hearing; 18 (6.7%) of which had identified comorbidities. For the purposes of the validation work with normal hearing children, those with comorbidities were not included in the analyses. Children with an identified hearing loss of any type (i.e., sensorineural, conductive, mixed, permanent conductive, auditory neuropathy spectrum disorder [ANSND]) made up 192 of the total sample. One hundred and two (53.1%) of them were typically developing, 36 (18.8%) had comorbidities, and 54 (28.1%) had complex factors related to hearing aid use. Of the children with hearing loss, 38 were unilateral and 154 were bilateral. The majority of the children (142) had sensorineural hearing loss and 121 of these children were fitted with hearing aids. Table 1-2 provides a detailed description of the children with hearing loss involved in this study. A breakdown of children by degree of hearing loss for those children with hearing aids can be found in the addendum in Chapter 4.

Table 1-2: Children with hearing loss involved in the overall study.

Hearing Loss Type	Unilateral	Bilateral	Total
Sensorineural	21	121	142
Conductive	1	5	6
Permanent Conductive	14	7	21
Mixed	0	3	3
ANSD	2	18	20

1.9 Summary

The four phases of this work support the development and evaluation of an outcome measure guideline for infants, toddlers, and preschool children with PCHI. Although there are auditory-related outcome evaluation tools available, many have not been well-normed, validated or are not part of a systematic clinical guideline. Chapter 2 of this work aimed to critically review current subjective outcome evaluation tools for use with infants, toddlers, and preschool children using a published grading system (Andresen, 2000). As a result, the chosen tools have good statistical and feasibility properties to support successful clinical implementation. Chapters 3 and 5 evaluated the appropriateness of existing norms of the chosen questionnaires for normal hearing children. Chapter 4 evaluated the norms, or characterized them, for children with hearing loss who wear hearing aids. Ultimately, this work supports the implementation of a pediatric outcome evaluation guideline for use with infants, toddlers, and preschool children seen in audiology clinics.

1.10 References

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Chapter 2

2 A critical review of audiological outcome measures for infants, toddlers, and preschool children¹

2.1 Background

Pediatric audiologists share a common goal of providing children who have permanent hearing loss appropriate access to early intervention. One component of intervention for many children is access to sound through the use of hearing aids. Suitable technology and evidence-based hearing aid fitting protocols support accurate and safe hearing aid fittings (i.e., American Academy of Audiology [AAA], 2003; Bagatto, Scollie, Hyde, & Seewald, 2010; College of Audiologists and Speech Language Pathologists of Ontario [CASLPO], 2002; Early Hearing Equipment Advisory Group, 2006; King, 2010; Modernising Children's Hearing Aid Services [MCHAS], 2005). This assists children identified with permanent childhood hearing impairment (PCHI) in developing language and literacy skills. The aim of providing hearing aids is to improve functional auditory capacity and participation in hearing- and communication-specific situations. The provision of amplification is a process that includes the calculation of prescriptive targets based on accurate hearing assessment information, the selection of the physical and electroacoustic elements of a hearing aid, verification that the specified acoustical prescriptive targets have been achieved, and outcome evaluation of device effectiveness in daily life. Of these stages, outcome evaluation does not currently have a systematic approach described in many pediatric hearing aid fitting protocols. The development of spoken language depends on the reception and transmission of information through the auditory channel. For a child with PCHI, this channel is impaired, therefore, the function of the auditory system with acoustic input should be monitored closely. There is little research related to what a typical outcome might be for a child who wears hearing aids or how to track the child's auditory development and performance over time. This is in part due to the lack of well-developed outcome measures available for use with infants,

¹ A version of this chapter has been published (see Appendix G): Bagatto, M. P., Moodie, S. T., Seewald, R. C., Bartlett, D. J., & Scollie, S. D. (2011). A critical review of audiological outcome measures for infants and children. *Trends in Amplification*, 15(1), 23-33. doi: 10.1177/1084713811412056

toddlers, and preschool children who wear hearing aids. Early steps in the hearing aid fitting process affect later steps and if not followed in a systematic way, they could impact the child's auditory, speech, and language development. Receptive and expressive language development as well as speech perception and production are important aspects of outcome evaluation. Most pediatric hearing aid fitting protocols do, however, mention the importance of monitoring overall outcome even when specific strategies for doing so are not provided (e.g., AAA, 2003; Bagatto, et al., 2010). Additionally, monitoring outcomes for children at high risk of developing late-onset or progressive hearing impairment or those with PCHI who do not wear hearing aids (i.e., due to family choice) are an important aspect of pediatric audiology services. Both of these tasks would be supported by well-validated, clinically feasible monitoring protocols to track auditory development. Known clinical tools with good normative properties, validity, feasibility, and utility would support the development of an evidence-based outcome evaluation guideline for the pediatric audiology population. The purpose of this article is to review the current status of such tools, thereby identifying a subset that will be considered within a suggested guideline for their implementation (Moodie, Bagatto, et al., 2011). The sections below include the various types of outcome measurements available, consider the properties to be appraised, and provide a critical review of available outcome evaluation tools within the category of caregiver-report questionnaires.

2.2 Types of outcome measures

Monitoring the hearing-related outcomes of infants, toddlers, and preschool children with hearing loss can be accomplished both objectively and subjectively. One example of an objective measure is the use of aided sound field thresholds (ASFT). ASFT can be conducted in the sound field with the child wearing his or her hearing aids. This measures the child's aided ability to detect low-level sounds, and is considered an *objective* measure. Limitations of ASFT include the impact of room and hearing aid circuit noise, off-frequency listening with steeply sloping hearing losses, and patient responses to low-level sounds do not provide an indication of performance to moderate levels (Hawkins, 2004). Other examples of aided sound field testing are speech-sound discrimination and early measures of speech recognition that require the use of age-appropriate tests. Speech

stimuli (e.g., Ling 6 sounds) can be included to obtain information about the child's speech sound detection thresholds. Later, the child can be conditioned to discriminate between various speech sound patterns (i.e., "ahhhh" vs. "ah ah ah") at supra-threshold levels and ultimately perform speech recognition testing. This hierarchy of functional auditory assessment will provide more objective information about the child's auditory skills. In contrast, questionnaires, diaries, and structured interviews are examples of *subjective* ways to assess a child's auditory behaviours in real-world environments. A combination of objective and subjective outcome evaluation tools may provide a multidimensional approach to tracking a child's auditory-related performance over time. A test battery of outcome evaluation tools provides caregivers and clinicians with a way to measure the auditory performance of a child during the early months as well as later years of hearing aid use or nonuse (i.e., if the child has a known hearing loss but does not wear a device).

One advantage of objective measures is that they provide a direct measure of the child's hearing while wearing hearing aids and can therefore be used as a way to determine the impact of the intervention. In cases in which the child's ability to make use of aided sound is in question, for example children with auditory neuropathy spectrum disorder (ANS), this may provide critical information for the management of the child. Disadvantages of objective speech recognition testing are that the specific measurement technique and stimuli that are appropriate to use with a child of a given age and developmental level vary considerably. For an infant, early measurement techniques described in the literature focus on gross abilities such as detection or discrimination of large contrasts (e.g., visual reinforcement assessment of the perception of speech pattern contrasts [VRASPAC]; Martinez, Eisenberg, Boothroyd, & Visser-Dumont, 2008); later measures may focus on more complex tasks such as word or sentence recognition in closed or open set tasks (e.g., Bamford-Kowal-Bench Sentences in Noise [BKB-SINTM]; Etymotic Research, 2005). Although the need to increase the complexity of speech tasks is encouraging because it reflects the child's progress and development, it also means that an age-appropriate protocol for the use of objective measures requires careful consideration of the hierarchy of tasks, including how this hierarchy should be applied to

children with typical development versus developmental delays. Objective measures may be difficult to obtain in cases of children with complex factors (e.g., difficult to test, speak languages other than those of the tests used, and so on). These same children may also present assessment and/or management difficulties more generally. In the early years, clinicians expend exorbitant efforts to obtain an audiogram from some children. Objective outcome measurement involves the same equipment (e.g., test booth), the same child state (e.g., alert, cooperative, responsive), and the same clinician state (e.g., at the equipment, engaged with the child in a structured test procedure) as is required for audiometric evaluation. Objective speech tests overlap with the basics of getting a full test of hearing sensitivity and getting the hearing aid fitting individualized. Focusing on objective strategies as the primary strategy for outcome evaluation, therefore, is not likely to be successful on those very cases in which outcome measures are needed the most.

In contrast, caregiver reports can be done while caregivers are waiting for the clinician to execute hearing tests or simulated real-ear verification procedures and therefore hold the possibility of adding information to the process without fully adding time and space requirements to the situation. Therefore, subjective measures may seem like less of a barrier in some instances. Finally, objective measures of speech detection and recognition only tell us about performance within the highly controlled acoustic conditions of a sound booth. They do not indicate how the caregiver perceives the auditory abilities of his or her child, or how the child performs in real world environments that include competition, distance, and interactive communication. Subjective measures focus on the child's responses to various sounds in real-life situations, as reported by the caregiver.

Practically speaking, some administration barriers may arise with caregiver reports. For example, questionnaires are more appropriately administered in the native language of the family and there may be challenges for caregivers who have literacy issues (Johnson & Danhauer, 2002). These barriers can be overcome through the use of questionnaires in various languages or administering the tool using an interview style. Overall, this type of outcome measurement provides rich and important information that can support the more objective tests that clinicians perform as well as being more applicable to children with complex needs. Therefore, this critical review focused on the evaluation of subjective

outcome evaluation tools that assess auditory-related behaviours in infants, toddlers, and preschool children.

As previously noted, there are many clinically relevant tools for the pediatric population with hearing loss that have incorporated rigor in their design, have compelling face validity, and/or that have been evaluated for reliability and validity, as required for inclusion in an evidence-based guideline. A *critical review* is characterized by an extensive review of the literature and critical evaluation of its quality (Grant & Booth, 2009). It goes beyond a simple description to include the degree of analysis and a conceptual innovation resulting in a hypothesis or model (Grant & Booth, 2009). Therefore, the development of an outcome evaluation guideline involved a review of the literature related to pediatric subjective outcome evaluation tools. This was followed by an assessment of the relevant tools, using a specific grading system, to support the inclusion of the chosen measures in a guideline. This article describes the review of the literature including the grading system that was used, the tools that were graded, and the outcome of the critical review. The subjective outcome evaluation tools chosen from the critical review are included in a guideline that will be described in detail in Chapter 4 (Bagatto, et al., 2011).

2.3 Characteristics of a good outcome evaluation tool

Several researchers have described criteria for assessing the quality of outcome evaluation tools in rehabilitation (Andresen, 2000; Cox, et al., 2000; Hyde, 2000). For example, a good outcome evaluation tool should have *conceptual clarity* to ensure that it covers the relevant domains intended to be measured. Additionally, *normative data* for comparison purposes are a valuable aspect of any outcome evaluation tool. Published norms allow the clinician to compare the results obtained from the tool to standards for normal hearing and hearing impaired children. The *measurement model* of a good quality tool should be able to capture the true breadth and detail of the differences in the group being measured. Tools that consistently result in responses at the bottom (i.e., floor) or top end (i.e., ceiling) of the scale are not measuring the true range of the population being assessed. The outcome evaluation tool should *not have bias* either within the items or the

instrument as a whole; the responses should not be affected by differences in culture or social circumstances. Statistically, the tool should have good test–retest *reliability*, internal consistency, *validity*, and *responsivity*. Of equal importance is the feasibility and utility of the outcome evaluation tool so that it is more likely to be implemented in clinical practice (Andresen, 2000; Graham, et al., 2006). Therefore, excessive *respondent and administrative burden* should be avoided; the length and the content should be acceptable to the respondent and the tool should be reasonable to administer, score, and interpret by the clinician. In addition, the tool should have alternative modes of administration (i.e., electronically, brail) and/or language adaptations for different cultures, if possible.

With these characteristics in mind, subjective outcome evaluation tools for infants, toddlers, and preschool children with PCHI were examined. Based on a system developed by Andresen (2000), operational definitions of grades were used in appraising a variety of auditory-related pediatric outcome evaluation tools. This system has been used to evaluate disability outcome evaluation tools for children and youth, such as the ABILITIES index and the Gross Motor Function Measure (Loller, Simeonsson, & Nanda, 2000). The result of this analysis was a report card, in which each outcome evaluation tool received a grade, on each appraisal criterion, of A, B, C, or U (unknown). This type of analysis provides a brief yet detailed comparison of outcome evaluation tools across appraisal criteria, supporting a critical review. Such information is not currently available for outcome evaluation tools used to assess the performance of children with permanent hearing impairment. A detailed description of the appraisal criteria, as well as the grading system for each criterion as it applies to pediatric audiology is presented in Table 2-1.

Table 2-1: Appraisal criteria as well as the grading system for each criterion as it applies to pediatric audiology.

Characteristic	Description	Grade Criteria
Conceptual Clarity	Tool covers relevant domains intended to be measured (e.g., detection, localization, speech understanding).	A = Completely covered B = Adequately covered C = Inadequately covered
Norms and Standard Values	Large scale normative data for children with normal hearing and PCHI. Experimental data collected using the tool is also considered given the lack of large scale norms available.	Published data are available from: A = A large number children with normal hearing and with PCHI who wear hearing aids B = A large number of children with normal hearing C = Experimental data using the tool with children with normal hearing and PCHI who wear hearing aids
Measurement Model	There should not be ceiling or floor effects in measurement, particularly when used to measure the abilities of children with hearing loss.	A = No issues B = Few or marginal evidence of skewing C = Substantial skewing
Item / Instrument Bias	The tool, and items within it, must not show evidence of bias when used with children who have PCHI. Bias-free tools have been evaluated on population subgroups and/or have had the response scale of the tool evaluated with Rasch analysis.	A = Tool/items have been reviewed by parents of children with PCHI and acceptability is published <i>or</i> Rasch analysis is good B = Adequate face-validity to support low bias <i>or</i> factor analysis is good/ Rasch analysis shows some issues C = Bias is evident or tested <i>or</i> inadequate statistical analysis

Table 2-1: Continued

Characteristic	Description	Grade Criteria
Respondent Burden	The tool should be brief and clear enough for the parent/caregiver to complete. The terminology used should not be offensive to those with hearing loss or deafness.	The tool is: A = Brief (≤ 15 min) and has high acceptability for caregiver B = Either appropriately longer or some reported problems of acceptability C = Lengthy and acceptability is problematic
		The tool is: A = Scored by hand and the resulting metric is relevant and interpretable for the clinician and caregiver B = Scored by a computer and interpretation is obscure C = Costly and complex scoring; interpretation by another professional required
Administrative Burden	The tool should be easy to administer, score, and interpret.	Internal Consistency Coefficient Alpha: A ≥ 0.80 ; B < 0.80 , > 0.70 ; C < 0.70 Retest Intraclass Correlation Coefficient: A ≥ 0.75 ; B > 0.40 , < 0.75 ; C ≤ 0.40
Reliability	The tool should give consistent results, within itself, and across time and testers.	A = Strong, expected direction, supported by clinical evidence B = Moderate or conflicting evidence C = Weak or based solely on statistical evidence
Discriminant Validity	The scores should differ for two subgroups of the population who would be expected to have different scores (e.g., normal hearing vs. hearing impaired children, on some items related to hearing).	

Table 2-1: Continued

Characteristic	Description	Grade Criteria
Convergent (criterion- related) Validity	The tool should have been validated against a gold-standard measure, and/or the subscale structure of the tool has been statistically evaluated.	A = Correlation of ≥ 0.60 ; confirmed factor structure
		B = Correlations of $> 0.30, < 0.60$; few problems with factor structure C = Correlation of ≤ 0.30 ; weak or not confirmed factor structure
Ecological Validity*	The tool evaluates the child's responses within the context of specific, realistic environments and assesses the child as an active participant.	A = Specific, realistic environments assessed
		B = Some situations are applicable and realistic for the child C = Environments are unrealistic and non-specific
Responsiveness	The scores on this tool have been shown to change, in the expected direction, when important changes are made to hearing status, hearing aid intervention, or therapy.	Criteria for change are:
		A = Strong, supported by patient and clinical evidence B = Moderate or conflicting evidence C = Weak or based solely on statistical evidence
Alternate / Accessible Forms	The tool has been experimentally evaluated for use with different administration formats (e.g., paper and pencil versus computer-assisted versus interview format administration).	A = Appropriate or varied modes are available and have been tested
		B = Some accommodations or testing among caregivers of children with PCHI C = No accommodations or mode information for special groups

Table 2-1: Continued

Characteristic	Description	Grade Criteria
Culture / Language Adaptations	The tool has been adapted and re-evaluated for use with different languages and/or cultures (e.g., translations, use within Deaf culture, with those who are deaf/blind).	A = Evidence of testing and applicability for cultural subgroups and interpretations B = Evidence of translations or testing with subgroups; some problems C = No evidence of testing or applicability to groups

Source: Adapted from Andresen (2000).

*Not included as part of Andresen's (2000) list of characteristics for outcome measures.

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2.4 Critical review objectives

Although there are several outcome evaluation tools available for the pediatric population, the intention was to evaluate tools that met the needs of the population identified by the Network of Pediatric Audiologists of Canada: birth to six years of age who wear hearing aids (see Moodie, Kothari, et al., 2011). In addition, administration of the outcome evaluation tools by the audiologist to the caregiver at follow-up appointments will be an important aspect of this guideline. This will facilitate the caregivers becoming good observers of their child's listening behaviours while also allowing them to share a common language with their audiologist. The outcome evaluation tools will assist with re-evaluating the previous stages of the amplification process, evaluating the overall impact of the hearing aid fitting, and sharing this outcome with the family in a systematic way. The following section includes the procedure used to grade each outcome evaluation tool with the goal being to identify the best tools for inclusion in a guideline for the population identified.

2.5 Data collection and critical review

2.5.1 Search strategy

Subjective outcome evaluation tools that measure auditory-related behaviours for the pediatric population were located within several sources from December 2008 through

February 2009. The sources included health-related electronic databases (CINAHL, PubMed), visually scanning reference lists from relevant studies, hand-searching key journals and conference proceedings, searching relevant internet resources, contacting experts in the area including the Network of Pediatric Audiologists of Canada, and citation searching. Key words used for searching included outcome evaluation, pediatric, infant, toddler, child, questionnaires, checklists, auditory development, auditory performance, hearing, hearing loss, and hearing aids. Various combinations of these keywords were used in the search domains. When a relevant tool or reference was obtained, the selection criteria listed below were applied. If the tool met the criteria, it was included in the review.

2.5.2 Selection criteria

As noted, Early Hearing Detection and Intervention (EHDI) programs are in need of high quality outcome evaluation tools for infants, toddlers, and preschool children from birth to six years of age. With this in mind, the following selection criteria were applied to the available pediatric outcome evaluation tools prior to including them in the review:

- Age range = birth to six years
- Questionnaire- or interview-based
- Caregiver respondent
- Audiologist administered and scored
- Auditory-related outcomes measured
- Application to infants, toddlers, and preschool children who wear hearing aids

Tools were selected by the first author based on the stated criteria. The tools selected for critical review along with a brief description of each are listed in Tables 2-2 and 2-3.

2.5.3 Critical evaluation

The outcome evaluation tools identified through the review process were graded for each characteristic listed in Table 2-1 using the grading system described by Andresen (2000). The first author carried out all grading and presented the results to the second author and modifications were made when necessary to come to agreement. As specified in Table 2-1, a grade of “A” is the highest and was assigned only when high-quality evidence

existed that the tool met the accepted standards for good performance. This was followed by Grades “B” and “C”, or Grade “U” if published data for evaluation did not exist. The results of the evaluation of each tool are summarized in Table 2-4.

2.6 Results

Twelve auditory-related subjective pediatric outcome evaluation tools were identified through the search process and subjected to the grading process (Table 2-2). Of these tools, seven use a rating scale or yes/no response format (e.g., Auditory Behavior in Everyday Life [ABEL], Children’s Home Inventory for Listening Difficulties [CHILD], Early Listening Function [ELF], Functional Auditory Performance Indicators [FAPI], Hearing Aid Benefit Scale for Infants/Toddlers [HABIT], LittleEARS, Parents’ Evaluation of Aural/Oral Performance of Children [PEACH] Rating Scale); three use a goal-setting and assessment format (e.g., Children’s Outcome Worksheet [COW], Client Oriented Scale of Improvement – Child Version [COSI-C], Developmental Index of Audition and Listening [DIAL]); and two use a caregiver interview response format (e.g., Infant-Toddler Meaningful Auditory Integration Scale [IT-MAIS], PEACH Diary). Each of these tools were evaluated against the appraisal criteria shown in Table 2-1. The evaluations are discussed in further detail below, within the general categories of conceptual clarity, norms, measurement model, item/instrument bias, respondent and administrative burden, reliability, different types of validity, responsiveness, alternate/accessible forms, and language adaptations.

Table 2-2: Subjective outcome evaluation tools selected for critical review along with a brief description of each: Part 1

Outcome Evaluation Tool	Description				
	Number of Items	Response Format	Scoring Format	Age Range	
Auditory Behavior in Everyday Life (ABEL)	24	7-point scale	Averages	4 to 14 years	
Children's Home Inventory for Listening Difficulties (CHILD)	15	8-point scale	Total and average	3 to 12 years	
Children's Outcome Worksheet (COW)	5	5-point scale	Average	—	
Client Oriented Scale of Improvement - Child Version (COSI – C)	3 to 5	5-point scale	Degree of change	>0	
Developmental Index of Audition and Listening (DIAL)/Family Expectations Worksheet (FEW)	3 to 5	5-point scale	Degree of change, overall average	Birth to 22 years	
Early Listening Function (ELF)	12	Yes/maybe/no	Complex	Birth to 3 years	
Functional Auditory Performance Indicators (FAPI)	31	Not present/emerging/acquired	Sum score per category	Birth to childhood	
Hearing Aid Benefit Scale for Infants/Toddlers (HABIT)	10	3-point scale	Not specified	Birth to 3 years	
Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)	10 probes	Observation then structured interview	Score based on examples	Older infancy through childhood	
LittLEARS Auditory Questionnaire	35	Yes/no	Total 'yes'	Birth to 24 months	
Parents' Evaluation of Aural/Oral Performance of Children (PEACH)	Diary	13	Observation then structured interview	Percentage based on examples	Infancy through childhood
	Rating Scale	13	5-point scale	Percentage	

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Table 2-3: Subjective outcome evaluation tools selected for critical review along with a brief description of each: Part 2

Outcome Evaluation Tool	Description	
	Factors Assessed	Reference
Auditory Behavior in Everyday Life (ABEL)	Aural-oral, auditory awareness, social/conversational	Purdy, et al., 2002
Children's Home Inventory for Listening Difficulties (CHILD)	Understanding sound at home	Anderson & Smaldino, 2000
Children's Outcome Worksheet (COW)	Individually defined needs and outcomes	Williams, 2004
Client Oriented Scale of Improvement - Child Version (COSI - C)	Parent-defined goals	National Acoustics Laboratories, 2000
Developmental Index of Audition and Listening (DIAL)/Family Expectations Worksheet (FEW)	Auditory behaviours, organized in a developmental hierarchy	Palmer & Mormer, 1999
Early Listening Function (ELF)	Furthest distance at which the child consistently responds in real life	Anderson, 2002
Functional Auditory Performance Indicators (FAPI)	Seven categories of auditory behaviours, in developmental order	Stredler-Brown & Johnson, 2004
Hearing Aid Benefit Scale for Infants/Toddlers (HABIT)	Hearing aid benefit	Geier, 1998
Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)	Vocalization behaviour, alerting to sounds, meaning from sound	Zimmerman-Phillips, et al., 2000
LittLEARS Auditory Questionnaire	Three categories of auditory behaviours, organized in a developmental hierarchy	Tsiakpini, et al., 2004
Parents' Evaluation of Aural/Oral Performance of Children (PEACH)	Diary	Hearing aid use, loudness discomfort, communication in quiet and noise, phone use, environmental sounds
	Rating Scale	Ching & Hill, 2005b

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Table 2-4: Grade report for each outcome evaluation tool assessed in this critical review.

	Outcome Evaluation Tool											
	ABEL	CHILD	COW	COSI-C	DIAL	ELF	FAPI	HABIT	IT-MAIS	LittLEARS	PEACH Diary	PEACH Scale
Conceptual clarity	B	A	B	C	A	B	A	B	B	A	B	B
Normative data	U	U	U	U	U	U	U	C	C	B	A	U
Measurement model	U	U	U	U	U	U	U	A	B	A	B	U
Item/scale bias	U	U	U	U	U	U	U	U	U	A	A	U
Respondent burden	A	B	B	B	B	C	B	A	C	A	C	A
Administrative burden	A	A	B	B	C	C	B	A	C	A	C	B
Retest reliability	A	B	U	U	U	U	U	A	B	A	A	U
Discriminant validity	U	U	U	U	U	U	U	A	U	B	B	U
Convergent validity	A	C	U	U	B	C	C	A	A	A	B	U
Ecological validity	A	B	A	A	A	A	A	A	B	A	A	A
Responsiveness	A	B	U	U	U	U	U	A	B	U	A	U
Alternate/accessible forms	C	B	B	B	C	B	C	C	B	C	B	B
Other languages	C	C	C	C	C	C	C	C	C	A	B	C

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2.6.1 Conceptual clarity

The majority of the tools received an “A” or “B” grade on the conceptual clarity domain, indicating that the relevant domains intended to be measured were covered by the tool.

The tools that received an “A” grade (i.e., CHILD, DIAL, FAPI, LittLEARS) covered the relevant content domains well by containing many items that thoroughly cover auditory-related content. Those that received a “B” grade (i.e., ABEL, COW, ELF, HABIT, IT-

MAIS, PEACH Diary, PEACH Rating Scale) were rated to have not adequately covered the relevant content domains because they had fewer items that did not completely address as much auditory-related content. The COSI-C (National Acoustics Laboratories) received a “C” grade due to the fact that the goals are set collaboratively by the audiologist and caregiver and there were no examples provided as with the COW (Williams, 2004).

2.6.2 Normative values

Normative values gathered from a large group of children with normal hearing and PCHI who wear hearing aids are available for the PEACH Diary (Ching & Hill, 2005a), therefore the tool was assigned a grade of “A” for normative values. The LittleEARS Auditory Questionnaire (Tsiakpini, et al., 2004) received a grade of “B” because the authors gathered norms from 218 normal hearing children from German-speaking families to create their normative data. Many of the tools did not have normative values gathered from a large scale study with which to compare individual children’s scores for clinical interpretation and utilization of the tool (e.g., ABEL, CHILD, COW, COSI-C, DIAL, ELF, FAPI, PEACH Rating Scale²). Both the HABIT (Geier, 1998) and the IT-MAIS (Zimmerman-Phillips, Osberger, & Robbins, 2000) received a “C” grade for reporting on experimental rather than large scale clinical data gathered using the tool on children with normal hearing and PCHI with a hearing device.

2.6.3 Measurement model and item/scale bias

Information regarding the measurement model and item/scale bias was typically not available for the outcome evaluation tools that were reviewed (e.g., ABEL, CHILD, COW, COSI-C, DIAL, ELF, FAPI, PEACH Rating Scale²). The HABIT, IT-MAIS, LittleEARS and PEACH Diary received grades of “A” or “B” for their data regarding ceiling or floor effects (i.e., measurement model) within these tools and the LittleEARS and PEACH Diary received “A” grades for reporting good acceptability and/or Rasch

² It is possible that the PEACH Diary characteristics could be used for the PEACH Rating Scale. See Chapter 5 (Bagatto & Scollie, accepted March 8, 2012).

analysis of the items (i.e., no item/scale bias) within the questionnaire (Ching & Hill, 2005a; Tsiakpini, et al., 2004).

2.6.4 Respondent and administrative burden

Respondent and administrative burden were assessed either through publications, the current authors' clinical experiences with the tool, and/or expert reports from members of the Network of Pediatric Audiologists of Canada. During a focus group meeting of the Network Audiologists many reported that time was one of the main barriers to routine outcome evaluation in their clinical practice. They preferred tools that did not take up too much of the caregiver's or clinician's time, and discussed that a ten minute duration for this procedure may be feasible. In addition to time, interview-based scoring can contribute to administration and respondent burden and therefore variability with scores. A study looking at the relationship of cortical evoked potentials and functional measures in infants with hearing loss found the results of the PEACH Diary to be highly variable (Golding, et al., 2007). The authors indicated that the caregiver's ability to observe their child varied and may have been limited by competing factors in the household (i.e., number of children, wellness of the child, lifestyle). Golding and colleagues (2007) also noted that an inexperienced interviewer may have had difficulty extracting useful examples from the parents even though the interviewer received instructions on how to administer the PEACH. This observation was also noted in a research study conducted in the University of Western Ontario Child Amplification Laboratory (CAL; S. Scollie, personal communication Nov 2010; Ching, et al., 2010). Therefore, tools that required lengthy interviews and/or scoring were given a "C" grade because they were too lengthy and not widely accepted either by the caregivers or clinicians (i.e., IT-MAIS, PEACH Diary). Outcome evaluation tools that performed well in terms of their lack of respondent and administrative burden were the ABEL (Purdy, Farrington, Moran, Chard, & Hodgson, 2002), CHILD (Anderson & Smaldino, 2000), HABIT, LittleEARS and PEACH Rating Scale (Ching & Hill, 2005b). These tools had a reasonable number of items with either a yes/no or rating response format that was scored in a straightforward manner and did not require lengthy interviews to complete the tool.

2.6.5 Reliability, validity, and responsiveness

The authors of the ABEL, CHILD, HABIT, IT-MAIS, LittleEARS and PEACH Diary reported good reliability of their outcome evaluation tool and the grades in Table 2-4 reflect this. Discriminant validity was either strong or moderate with the HABIT, LittleEARS, and PEACH Diary and was assigned either a grade of “A” or “B”. The remaining tools did not have data available for this characteristic and were assigned a “U” grading. Other than the goal-setting tools (e.g., COW, COSI-C), the majority of the tools evaluated had good to excellent convergent validity. Ecological validity was also good to excellent for the outcome evaluation tools assessed in this critical review. The responsiveness of the ABEL, CHILD, HABIT, IT-MAIS, and PEACH Diary were assessed and received an “A” or “B” grade. The remaining tools did not have responsiveness data available at the time of this review.

2.6.6 Alternate/accessible forms and language adaptations

Alternate and/or accessible forms were available for a good portion of the questionnaires as many are now available online or in computer software format. The final category that was evaluated was availability in other languages. The LittleEARS and PEACH Diary received the highest grades for having the tools available in other languages; the LittleEARS was available in 19 languages and the PEACH Diary was available in six at the time of this review.

2.6.7 Overall grades

Overall, the HABIT, IT-MAIS, LittleEARS, and PEACH Diary received “A” or “B” grades for the majority of the reviewed characteristics. Although the HABIT is applicable for the infant population, has low respondent and administrative burden and high reliability, validity, and sensitivity, the main limitations are that the normative data are lacking and the questionnaire is an unpublished doctoral dissertation rendering it virtually unknown to the clinical community. The IT-MAIS is more widely available, however large scale norms are not provided for English-speaking normal hearing or hearing impaired children with hearing aids. Additionally, the interview format of the IT-MAIS increases the respondent and administrative burden, which may influence the feasibility and utility of the questionnaire which may ultimately impact the clinical uptake of the

tool (Andresen, 2000; Graham, et al., 2006). The LittlEARS received high grades on most characteristics and is accessible to the clinical community for a fee. The PEACH Diary has large scale normative values for normal hearing and hearing impaired children, which increases the clinical utility of the tool. However, the PEACH Diary's interview-style format introduces the same clinical feasibility and utility concerns as the IT-MAIS. For this reason, the PEACH Rating Scale may be more successfully used in a clinical setting provided the statistical characteristics from the PEACH Diary can be applied to the items in the PEACH Rating Scale. The items in the two PEACH tools are extremely similar, but the administration format of the tool (interview/diary vs. ratings only) differs significantly.

In light of this critical review, the LittlEARS Auditory Questionnaire and the PEACH Rating Scale scored most favorably in the majority of the review categories. To ensure the target age range from birth to six years is properly represented for the outcome evaluation guideline, both the LittlEARS and PEACH Rating Scale were chosen to be included. The LittlEARS targets children from birth through the first two years of hearing and the PEACH items appear to target toddlers and older children. Therefore, it is possible that a guideline could provide a two-stage process whereby the LittlEARS is used with caregivers of infants until they reach a ceiling score and/or age on the tool. This would indicate a certain level of auditory development has occurred within the infant and he/she will be developmentally ready to be evaluated by the items in the PEACH Rating Scale. These and other administration issues will be further addressed in the description of the guideline and supporting data provided in Chapter 4 (Bagatto, et al., 2011).

2.7 Conclusions

A critical review of auditory-related pediatric subjective outcome evaluation tools was completed as part of the development of an outcome evaluation guideline. Although there are many subjective tools available for the pediatric population, few have the relevant psychometric and/or feasibility characteristics necessary to promote clinical uptake within a guideline. Prior to considering a caregiver-report questionnaire within a

guideline, a review of the existing outcome evaluation tools for infants, toddlers, and preschool children aged birth to six years followed by a systematic grading of the tools was necessary. Twelve outcome evaluation tools with specified criteria were identified prior to assigning grades for thirteen psychometric and feasibility characteristics (Andresen, 2000). Results indicated that four out of the 12 tools received high grades in most of the characteristics and of these four, only two would be considered clinically feasible within an outcome evaluation guideline for infants, toddlers, and preschool children. Based on these results, the LittleEARS Auditory Questionnaire and the PEACH Rating Scale were considered for inclusion in an outcome evaluation guideline (see Appendix A and B). The next step in the guideline development process was to consult with the Network of Pediatric Audiologists of Canada and have them systematically evaluate the chosen questionnaires. Moodie and her colleagues (Moodie, Bagatto, et al., 2011) provide the results of this evaluation.

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Chapter 3

3 External validation of the LittEARS[®] Auditory Questionnaire with English-speaking families of Canadian children with normal hearing³

3.1 Introduction

The primary goal of Early Hearing Detection and Intervention (EHDI) programs is to provide effective intervention by six months of age to maximize the child's natural potential to develop language and literacy skills. Intervention with hearing aids is a common choice among families of children identified as having permanent childhood hearing impairment. Audiologists have access to scientifically-based strategies and clinical tools to ensure the hearing aids are fitted appropriately to the child (American Academy of Audiology [AAA], 2003; Bagatto, Scollie, Hyde, & Seewald, 2010; College of Audiologists and Speech Language Pathologists of Ontario [CASLPO], 2002; Early Hearing Equipment Advisory Group, 2006; King, 2010; Modernising Children's Hearing Aid Services [MCHAS], 2005). Outcome evaluation is a key component of the pediatric hearing aid fitting process, however, there is little research related to what a typical outcome might be for a child who wears hearing aids and how to systematically track the child's auditory development and performance over time. A lack of clinical tools with well-developed normative properties, feasibility, validity, and utility has been a barrier to outcome evaluation in children with hearing aids. A tool that has been identified as suitable for use with infants and toddlers is the LittEARS[®] Auditory Questionnaire (Tsiakpini, et al., 2004). The LittEARS is a 35-item questionnaire that assesses the auditory development of children during the first two years of hearing. Norms have been developed from German-speaking families (Weichbold, Tsiakpini, Coninx, & D'Haese, 2005), it has been validated in children with cochlear implants in Germany and Italy (Kuehn-Inacker, Weichbold, Tsiakpini, Coninx, & D'Haese, 2003), and it is reliable and

³ A version of this chapter has been published (see Appendix H): Bagatto, M. P., Brown, C. L., Moodie, S. T., & Scollie, S. D. (2011). External Validation of the LittEARS[®] Auditory Questionnaire with English-speaking families of Canadian children with normal hearing. *International Journal of Pediatric Otorhinolaryngology*, 75(6), 815-817. doi: 10.1016/j.ijporl.2011.03.014

has good internal consistency and predictive accuracy (Coninx, et al., 2009). The norms have also been validated in 15 different languages in children with normal hearing (Coninx, et al., 2009).

The English version of the questionnaire has not been externally validated with Canadian normal hearing children from English-speaking families. Externally validating the tool with children from Canada will support the use of this questionnaire for the population in Canada. The work by Coninx and colleagues (2009) validated the German-derived LittleEARS Auditory Questionnaire (Tsiakpini, et al., 2004) normative values with normal hearing children from families who speak one of 15 different languages. The questionnaire was adapted from German into the following languages: Bulgarian, Chinese, Dutch, Finnish, French (France), German, Greek, Polish, Romanian, Russian, Serbian, Slovakian, Slovenian, United States English, and United States Spanish. A total of 3309 children with normal hearing from 16 different countries were involved in the study and there were no fewer than 48 children per language involved. Quadratic regression curves for all of the languages were not statistically different from the German norm curve. The authors of the paper indicated that validation of the tool in each individual language is encouraged. This allows for language-specific norms as well as shows language independency of the tool. Therefore, this paper reports on the external validation and internal consistency of the United Kingdom (UK) English version of the LittleEARS questionnaire with English-speaking families of normal hearing children in Canada to further contribute to the work by Coninx and his colleagues (2009). This work will support the future use of this questionnaire with children who have hearing loss and wear hearing aids.

3.2 Method

3.2.1 Participants

The LittleEARS was administered to families of normal hearing children during regular appointments at three audiology clinics within the province of Ontario, Canada. The children were seen as part of the Ontario Infant Hearing Program and provincial protocols for assessment were followed (Ontario Ministry of Children and Youth

Services, 2008). Normal hearing was determined by age-appropriate hearing level testing (e.g., frequency-specific auditory brainstem response [ABR] or visual reinforcement audiometry [VRA] with insert earphones) as well as otoscopy, immittance, and distortion product otoacoustic emissions (DPOAEs) in each ear. Ethics approval for the study was obtained from the following data collection sites: The H.A. Leeper Speech and Hearing Clinic at the University of Western Ontario, Humber River Regional Hospital, and Rouge Valley Health System in Toronto, Ontario (see Appendix C).

Typically developing children who were born full term and were 23 months of age or younger at the time of administration were included in this study. The participants were part of a larger data collection initiative that included children born prematurely and who had other medical issues. These children were excluded from the present analysis that focuses on external validation of the German-derived norms in Canadian children. Therefore, the LittlEARS was administered to caregivers of 130 typically developing, full-term normal hearing infants and toddlers (mean age = 8.1 months; age range = 2 to 23 months; females = 57; males = 73).

3.2.2 Materials

The UK English version of the questionnaire was administered to the caregivers of the infants and toddlers with normal hearing involved in this study. This version differs from the United States (US) English version by minor wording differences in some items. The differences do not appear to change the meaning of the questions or associated examples. A list of differences between the UK and US English versions of the LittlEARS can be found in Table 3-1. Due to the minor differences and the accessibility of the UK version at the time of this study, the UK English version was administered. The caregiver completed the questionnaire in the presence of the audiologist.

Table 3-1: Wording differences between the United Kingdom and United States versions of the LittleEARS Auditory Questionnaire.

Item	United Kingdom Version	United States Version
4: Example	squeezing toy	squeaking toy
6: Example	turns towards the sound	turns toward the sound
8: Example	You try to comfort the child with a soft voice or song. Without eye contact.	You try to comfort the child with a soft voice or song without eye contact.
10: Question	“recognise”	“recognize”
10: Example	Musical box by bed	Music box by bed
11: Example	You call or say something, the dog barks, etc. and the child looks and finds the sources	You call or say something or the dog barks, and the child looks and finds the sound source
12: Question	Does your child react to his/her name?	Does your child react to his/her name when called?
15: Question	recognise	recognize
16: Example	The child moves arms/legs to the music	The child moves arms/legs to music
17: Example	The child hears the sound of an aeroplane and looks towards the sky	The child hears the sound of an airplane and looks toward the sky
18: Question	Does your child appropriately respond to short and simple remarks?	Does your child respond to short and simple remarks appropriately?
19: Example	-although the child does not see you (!)-	-although the child does not see you-
20: Example	Where is...: daddy, mummy, Mark, ...	Where is...: Daddy, Mommy, Mark, ...?
23: Example	“Where is your tummy?”; “Where is daddy?”	“Where is your nose?”; “Where is the ball?”
26: Example	“Vurrm” with car	“Vrroom” with car

Table 3-1: Continued

Item	United Kingdom Version	United States Version
27: Example	cock-a-doodle-do = cockerel/rooster	“cock-a-doodle-do” = rooster
30: Question	Does your child select the right object from a number of objects when asked?	Does your child select the correct object from a group of objects when asked?
30: Example	coloured	colored
32: Example	“Say ‘Hello’ to grandma”	“Say ‘Bye-Bye’ to grandma”

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3.3 Results

3.3.1 Analysis

Data were analyzed using a quadratic regression curve, as this was the regression used with the Coninx and colleagues (2009) validation data. The Canadian norm curve had the following equation: $y = -0.013x^2 + 1.55x + 6.55$; where x = age and y = total score ($F = 108$, $df = 127$, $p < 0.01$; Figure 3-1). A high correlation between age and total score was found for Canadian English with the Pearson’s correlation coefficient equal to 0.793, $p < 0.01$. Internal consistency using Cronbach’s alpha equaled 0.885 which exceeds the 0.7 acceptable criteria. This means that the items in this version of the LittleEARS measure the same construct. A two-tailed independent samples t-test revealed that there were no significant differences between scores obtained by females compared to males involved in the study ($t(128) = -0.322$, $p = 0.748$). The Canadian norm curve was compared to the German norm curve and Pearson’s correlation coefficient revealed very good comparability of the curves ($r = 0.993$). These results revealed there was no significant difference between the Canadian and German norms.

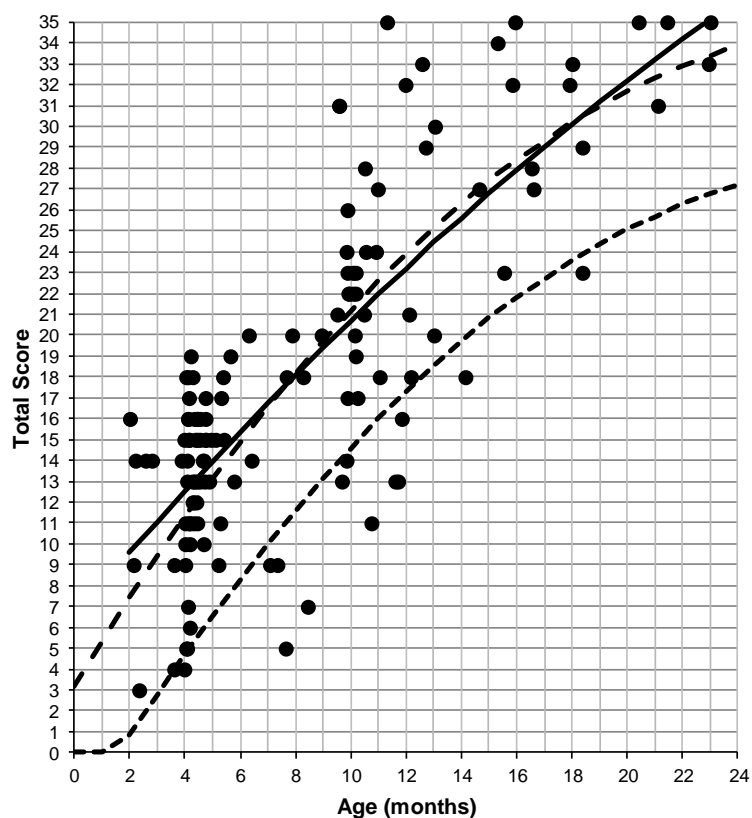


Figure 3-1: LittleEARS external validation data from Canadian normal hearing children. Filled circles are the raw LittleEARS scores (y-axis) from typically developing normal hearing children 23 months of age and younger plotted by age in months (x-axis). The large dashed line is the German-derived norm curve and the solid line is the Canadian-derived norm curve. The small dashed line represents the minimum 95% confidence interval values from the German-derived norms. The correlation coefficient of the two norm curves is $r = 0.993$.

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3.4 Conclusions

The LittleEARS is a short questionnaire that assesses auditory development in the first two years of life. German-derived normative values have been validated with several different languages. This paper externally validated the existing norms with the UK English version of the questionnaire. Results indicated that the LittleEARS is a valid outcome evaluation tool for use with English-speaking families of normal hearing infants and toddlers in Canada. This addition to the study by Coninx and colleagues (2009) further validates the LittleEARS Auditory Questionnaire with English-speaking families of normal hearing children in Canada. This external validation work on typically developing Canadian children 23 months of age and younger reveals that the German-derived norms are valid for use with the Canadian English-speaking population.

Given that auditory development of children who wear hearing aids is an important aspect of the hearing aid fitting process in infants, toddlers, and preschool children, it is of interest to continue this work with children who have hearing loss who wear hearing aids. This will allow for an evaluation of the impact of degree of hearing loss. Future work will continue in order to characterize scores on this tool for infants, toddlers, and preschool children with permanent hearing loss who wear hearing aids. This will support the use of the LittleEARS Auditory Questionnaire as part of a routine outcome evaluation tool for children.

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Chapter 4

4 The University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP)⁴

4.1 Introduction

The primary goal of Early Hearing Detection and Intervention (EHDI) programs is to provide effective intervention by six months of age to maximize the child's natural potential to develop language and literacy skills (Joint Committee on Infant Hearing [JCIH], 2007). Intervention with hearing aids, as part of a larger intervention plan, is a common choice among families. Audiologists have access to scientifically based strategies and clinical tools to ensure the hearing aids are fitted appropriately to the child. Outcome evaluation is a recommended component of the pediatric hearing aid fitting process (American Academy of Audiology [AAA], 2003; Bagatto, Scollie, Hyde, & Seewald, 2010; College of Audiologists and Speech Language Pathologists of Ontario [CASLPO], 2002; Early Hearing Equipment Advisory Group, 2006; King, 2010; Modernising Children's Hearing Aid Services [MCHAS], 2005), however, there is little research related to what a typical outcome might be for a child who wears hearing aids and how to systematically track the child's auditory development and performance over time. This may in part be due to the lack, or perceived lack, of well-normed and validated auditory-specific outcome measures available for use with infants, toddlers, and preschool children who wear hearing aids. Several research studies have focused on the overall communication outcomes of children involved in EHDI programs and what factors may affect outcome (e.g., Bass-Ringdahl, 2010; Ching, Dillon, Day, & Crowe, 2007; Fitzpatrick, Crawford, Ni, & Durieux-Smith, 2011; Moeller, 2000; Moeller, et al., 2007a; Moeller, et al., 2007b; Sininger, Grimes, & Christensen, 2010). These studies reveal important information about the parameters of outcome for children who are early-

⁴ A version of this chapter has been published (see Appendix G): Bagatto, M. P., Moodie, S. T., Malandrino, A. C., Richert, F. M., Clench, D. A., & Scollie, S. D. (2011). The University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP). *Trends in Amplification*, 15(1), 57-76. doi: 10.1177/1084713811420304

versus late-identified. For example, these studies show positive effects of early intervention and parental involvement and limiting effects of late identification and poor audibility from the hearing aid. Individual clinicians and/or EHDI programs may be inclined to implement some or all of the outcome batteries of such studies when attempting to measure outcomes for individual children or across programs.

Unfortunately, this strategy may not be successful in a non-research context: the protocols implemented in these studies were designed for the purposes of research and may have barriers to implementation in clinical practice. These barriers include extensive test batteries that are impractical to administer and score in a typical clinical situation.

The focus of this article is to describe a clinically feasible guideline for monitoring auditory-related outcomes in infants, toddlers, and preschool children, giving equal priority to properties such as normative data, sensitivity, specificity, and reliability as well as to clinical feasibility and utility (Andresen, 2000). Companion articles to this chapter include a critical review of existing pediatric outcome evaluation tools (Bagatto, Moodie, Seewald, Bartlett, & Scollie, 2011; Chapter 2) as well as a systematic evaluation of the chosen measures by the Network of Pediatric Audiologists of Canada (Moodie, et al., 2011). In the present article, these two sources of information are integrated, and a specific guideline for outcome measurement in a clinical context as well as data for children with hearing loss who wear hearing aids are provided. This guideline is called the University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP). The UWO PedAMP is intended to be used with children with permanent hearing loss from birth to six years of age who wear hearing aids. Audiological monitoring is an important aspect of pediatric audiology whether or not the child has received hearing aids (e.g., the child has unilateral or mild bilateral hearing loss and is not aided). The UWO PedAMP can be used for monitoring children who have unaided hearing loss; however, the focus of this article will be on the application of the guideline with children who wear hearing aids.

The investigation reported here was a repeated measures longitudinal observational study. The purpose of this study was to compare data from a clinical population of

infants, toddlers, and preschool children with permanent childhood hearing impairment (PCHI) on a set of outcome evaluation tools to existing norms. Characterization of scores on the tools with infants, toddlers, and preschool children with various audiometric and medical profiles was examined. In this study, children with all degrees and configurations of hearing loss and intervention types as well as those with comorbidities and complex factors (e.g., inconsistent hearing aid use) were investigated. Including these children in this work was unique when compared to the previously mentioned studies that evaluated outcomes in children with hearing loss and no other associated complexities or medical factors. This ongoing work will greatly enhance the understanding of auditory development and performance of a naturally occurring clinical pediatric audiology population.

4.2 Method

4.2.1 Guideline rationale

The UWO PedAMP is an extension of current pediatric hearing aid fitting protocols (e.g., Bagatto, et al., 2010) and includes two types of outcome evaluation tools: (a) clinical process outcome measures to characterize the implementation of the previous stages of the hearing aid fitting process (e.g., verification) to aid in the interpretation of functional outcomes and (b) individual patient functional outcome measures in a two-stage process by developmental level. The functional outcome measures are (a) the LittlEARS[®] Auditory Questionnaire (Tsiakpini, et al., 2004) and (b) the Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Rating Scale (Ching & Hill, 2005a). These measures were chosen based on the results of a critical review (Bagatto, Moodie, et al., 2011; Chapter 2) as well as input from pediatric audiologists associated with the Network of Pediatric Audiologists of Canada (Moodie, et al., 2011). The questionnaires were deemed to have a high level of evidence and feasibility as described in the companion articles, which supports their inclusion in the UWO PedAMP.

For younger children (see details below), the LittlEARS Auditory Questionnaire is used. For older children, the PEACH Rating Scale is used. Therefore, the tools included in the UWO PedAMP are as follows:

1. Aided Speech Intelligibility Index (SII) Normative Values Worksheet;
2. Hearing Aid Fitting Summary;
3. LittlEARS[®] Auditory Questionnaire (Tsiakpini, et al., 2004; Copyright MED-EL, 2004);
4. Parent's Evaluation of Aural/Oral Performance of Children (PEACH; Ching & Hill, 2005a; Copyright Australian Hearing, 2005).

Prior to measuring functional outcomes (LittlEARS and PEACH), summary measures of the hearing aid fitting process are made to characterize that process. These are included in the UWO PedAMP as clinical process outcomes (e.g., Aided Speech Intelligibility Index [SII] Normative Values Worksheet, Hearing Aid Fitting Summary). Hearing aids are used or worn for a trial period by the majority of children who have been identified with PCHI. Evidence-based pediatric hearing aid fitting protocols are followed to positively support the impact of the child's hearing aid on his or her ability to develop auditory skills in daily life (e.g., AAA, 2003; Bagatto, et al., 2010; Early Hearing Equipment Advisory Group, 2006; MCHAS, 2005). In the UWO PedAMP, functional outcome evaluation follows the hearing aid verification stage of the fitting process to measure the impact of the fitting. There are two primary reasons to monitor hearing aid fitting process outcomes as part of the UWO PedAMP prior to measuring functional outcomes.

The first reason is to determine whether an *individual child's fitting* is providing a typical degree of audibility for a given degree of hearing loss. Clinicians and caregivers will have a better understanding of how the child is progressing with respect to audiological outcomes when details of the hearing aid fitting are tracked as part of an overall outcome evaluation guideline. For example, if the output of the hearing aid is significantly less than would be typical for other children with similar losses, the child's ability to use sound for development may be limited relative to a child with a typical fitting.

The second reason for monitoring hearing aid fitting details is *at the level of the program* as a whole. The brief fitting details gathered in this protocol help to determine, for example, the typical rate at which real-ear-to-coupler difference (RECD) measures are

made, or the typical amount of audibility provided by the hearing aids. This information may allow EHDI programs to monitor program-wide clinical process outcomes for such purposes as monitoring protocol use and practice quality.

4.2.2 Clinical context

The participants in this study were caregivers of children who were seen as part of the Ontario Infant Hearing Program (OIHP). The OIHP is an example of a comprehensive EHDI program that identifies children born deaf or hard of hearing and provides the supports and services they need to develop the language and literacy skills necessary to achieve success in school (Bagatto, et al., 2010). The program provides services for children from birth to six years of age who are identified with PCHI and their families/caregivers. As well, it monitors those children born with, or who acquire risk indicators for permanent hearing loss throughout early childhood. Program protocols are in place to provide universal newborn hearing screening, audiological assessment, and amplification and communication development services for children found to be deaf or hard of hearing. The OIHP utilizes systematic, evidence-based procedures for hearing aid fitting, including the use of the Desired Sensation Level (DSL) v5.0a prescriptive formula (Scollie, et al., 2005), measured RECD values, simulated real-ear verification, and hearing aid orientation.

Every year in the province of Ontario, about three in 1,000 babies are either born with a permanent hearing loss or will develop a hearing loss early in their childhood. With a yearly birthrate of approximately 130,000, about 400 babies or preschool children are identified with impaired hearing every year in Ontario. In the fiscal year 2010/2011, 95% of the babies born in Ontario had their hearing screened. In addition, of the 371 children identified with PCHI in 2010/2011, 47 were identified through surveillance of at-risk children and 173 were from other referral routes (e.g., acquired risk, acquired hearing loss, newly identified) and received an assessment prior to entry into grade one. From these routes combined, approximately 2,855 were identified with PCHI (2,252 bilateral, 602 unilateral) from program inception in November 2001 to March 31, 2011. The families of 1,709 of these children chose hearing instruments, 98 children wear cochlear

implants⁵ and the remainder (979) chose neither option or were in the process of obtaining hearing instruments. Reasons for choosing neither option vary and include such factors as opting for manual communication and watchful waiting for children with mild and/or unilateral hearing loss. University of Western Ontario ethics approval was obtained so that five clinicians at four participating clinical sites in Ontario could provide de-identified data (see Appendix C). The clinicians were pediatric audiologists with at least ten years of experience working with infants, toddlers, and preschool children. Three of the clinics were in the Toronto Region of the OIHP (Humber River Regional Hospital, Markham Stouffville Hospital, Centenary Hospital) where two audiologists collected data and one clinic was in the Southwest Region of the OIHP (University of Western Ontario H.A. Leeper Speech and Hearing Clinic) where three audiologists collected data.

Since April 2010, the UWO PedAMP has been implemented as an extension of the OIHP's Provision of Amplification Protocol in Ontario, Canada (Bagatto, et al., 2010). Facilitating successful clinical implementation of the UWO PedAMP has been an important consideration for the introduction of this guideline in an EHDI program, such as the OIHP. For this reason, a suggested administration timeline is provided to outline when each outcome evaluation tool is used as part of the guideline. The grid in Figure 4-1 summarizes the administration of each outcome evaluation tool within the UWO PedAMP during a hearing impaired child's routine follow-up. Each outcome evaluation tool within the UWO PedAMP is listed down the left hand side of the figure. The clinicians involved in this study were able to determine whether a tool should ("✓") or should not ("X") be administered during the specific appointments listed across the top of the figure. Each tool within the UWO PedAMP was administered during a routine clinical appointment.

⁵ The first fitting of a device is usually tracked in the OIHP database. Data for those infants who received a cochlear implant following the use of a hearing instrument have not been formally tracked within the program. This may reduce the number of reported cochlear implant users in the OIHP relative to programs that track all children who receive cochlear implants regardless of referral path.

4.2.3 Participants

Participants included 352 caregivers of infants, toddlers, and preschool children with various audiometric and medical profiles (mean age = 21.7 months; age range = 1.3 to 107.1 months). Eighty-six children were from the Toronto Region of the OIHP and 266 children were from the Southwest Region of the OIHP. Of the total children, 223 had normal hearing and 129 had permanent hearing loss. The purpose of including the normal hearing children was to evaluate existing normative values and clinical feasibility of the tools.

		Appointment Type (Aided)							
		Initial Assessment	Prefitting	Initial Fitting	30 Day Recheck	3 month Rechecks	6 month Rechecks	Yearly Rechecks	Event Driven
Outcome Evaluation Tool	Hearing Aid Fitting Details	×	×	✓	×	✓	✓	✓	✓
	LittIEARS	✓ Establish Unaided Baseline: Administer at one of these appointments			✓ If score ≥ 27 , stop LittIEARS, use PEACH.	✓ If score ≥ 27 , stop LittIEARS, use PEACH.	✓ If score ≥ 27 , stop LittIEARS, use PEACH.	✓ If score ≥ 27 , stop LittIEARS, use PEACH.	✓
	PEACH	×	×	×	↓	↓	↓	↓	✓

Figure 4-1: Administration guidelines for children with PCHI who wear hearing aids. The top row specifies the appointment type and the far left column indicates the outcome evaluation tool within the UWO PedAMP that should be administered. Within the grid, ‘✓’ and ‘X’ designates when an outcome evaluation tool should or should not be administered at a particular appointment.

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Hearing losses ranged from mild to profound and were unilateral ($n = 35$) or bilateral ($n = 94$) sensorineural ($n = 84$) or permanent conductive ($n = 18$). Twenty-seven children in this sample had auditory neuropathy spectrum disorder (ANS) and were not fitted with hearing aids at the time of inclusion in the study. Sixty-eight of the children with PCHI were fitted with hearing aids and 61 had no hearing aids at the time of inclusion. Thirty-

three of the children with hearing aids were from Humber River Regional Hospital, 18 were from Markham Stouffville Hospital, six were from Centenary Hospital, and eleven were from the H.A. Leeper Speech and Hearing Clinic at UWO. Children with hearing aids had hearing losses ranging from mild to profound and were unilateral or bilateral sensorineural (pure tone average = 48.41 decibel [dB] hearing level [HL]; range = 16.67 to 110.00 dB HL; see Table 4-1).

Table 4-1: Number of children with PCHI who wear hearing aids by hearing loss category (dB HL) and outcome evaluation tool.

Degree of PCHI	LittleEARS Data	PEACH Data	Number of Children	Number of Administrations
Mild (between 20 and 40 dB HL)	Bilateral = 11	Bilateral = 15	Bilateral = 24	38
	Unilateral = 1	Unilateral = 1	Unilateral = 1	
Moderate (between 41 and 55 dB HL)	Bilateral = 18	Bilateral = 18	Bilateral = 24	51
	Unilateral = 0	Unilateral = 0	Unilateral = 0	
Moderately-severe (between 56 and 70 dB HL)	Bilateral = 9	Bilateral = 10	Bilateral = 14	34
	Unilateral = 1	Unilateral = 1	Unilateral = 1	
Severe (between 71 and 90 dB HL)	Bilateral = 0	Bilateral = 0	Bilateral = 0	4
	Unilateral = 1	Unilateral = 1	Unilateral = 1	
Profound (91 dB HL or greater)	Bilateral = 2	Bilateral = 2	Bilateral = 3	6
	Unilateral = 0	Unilateral = 0	Unilateral = 0	
Number of Children	43*	48*	68	
Number of Administrations	58	75		133

**Note:* Some children have multiple data for the LittleEARS, the PEACH, or both that are not presented here.

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In this study sample, children with comorbidities and complex factors were included as well as typically developing children. Comorbidities included medical issues such as Down Syndrome, cerebral palsy, and genetic syndromes. Children in this study were identified as having a comorbidity based on clinician report. Children with comorbidities comprised approximately 12.5% ($n = 44$) of the total sample. Of the 68 children fitted with hearing aids, 32.35% ($n = 22$) had comorbidities. Complex factors included nonmedical complicating issues that may affect hearing aid outcome such as inconsistent hearing aid use and delayed hearing aid fitting. Approximately 33.82% ($n = 23$) of the hearing impaired children with hearing aids had complex factors in this sample. This left 33.82% ($n = 23$) typically developing children from the total sample of children with hearing loss who wear hearing aids.

The following sections provide an overview of the tools included in the UWO PedAMP: the Aided Speech Intelligibility Index (SII) Normative Values Worksheet, the Hearing Aid Fitting Summary, the LittEARS, and the PEACH questionnaires. Information about where to locate the different tools within the UWO PedAMP as well as items and score sheets for the LittEARS and PEACH questionnaires can be found in Appendix A, B, D, E and F. Data from the use of these tools will be presented within a large-scale study in which the UWO PedAMP was administered during routine clinical practice.

4.2.4 Clinical tools

4.2.4.1 Hearing aid fitting details

As part of the UWO PedAMP, two tools are provided to monitor and assess the clinical process of hearing aid fitting and include (a) Aided SII Normative Values: Birth to 6 Years Worksheet and (b) the Hearing Aid Fitting Summary. Used together, they provide helpful information for the audiologist, caregivers, and health policy makers about the hearing aid fitting as part of this outcome evaluation guideline. The UWO PedAMP is an extension of the hearing aid fitting process and assumes that the audiologist has followed preferred practice guidelines for pediatric hearing assessment and the fitting of hearing aids to children (Bagatto, et al., 2010). Several steps are followed in the verification stage of the pediatric hearing aid fitting process and include simulated (or predicted) real-ear

measurements of hearing aid performance using RECD measurements (Bagatto, et al., 2010). Figure 4-2 displays one example of this procedure that is explained in detail in the protocol (Bagatto, et al., 2010).

In this guideline, the aim was to minimize the time needed to capture the hearing aid fitting details. For this reason, the exact fit to targets at each frequency and test level was

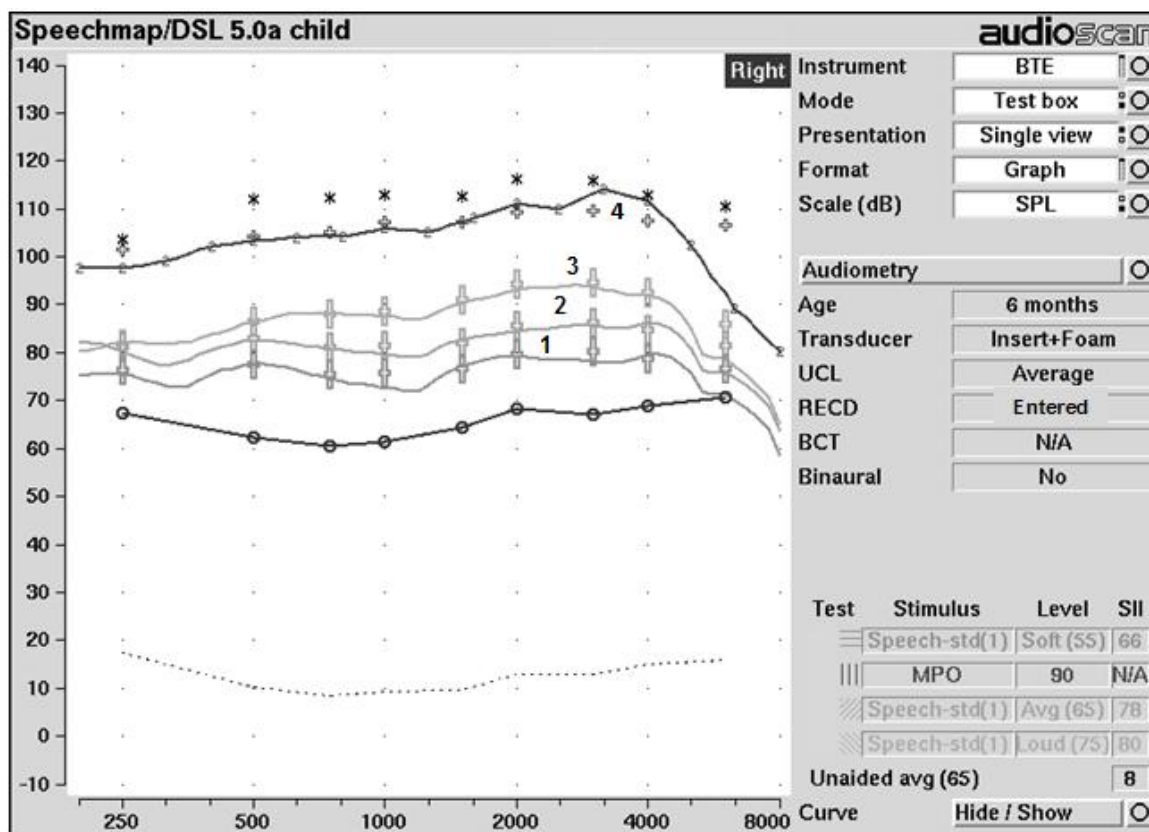


Figure 4-2: Display of hearing instrument performance in relation to pediatric DSL v5.0a targets for a child with a PTA of 52 dB HL. The solid lines represent the output of the hearing instrument for soft (1), average (2), loud (3) speech inputs and MPO (4) in relation to the various speech targets (large +) and MPO targets (small +). Thresholds (o) and upper limits of comfort (*) are also displayed.

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not documented. Instead, the goodness of fit to targets was assessed by the clinician. The overall outcome of the fitting was assessed using three indicators of clinical process: (a) whether the RECD was measured, predicted, or entered from previous file data; (b) whether the clinician measured the maximum power output (MPO); and (c) the amount of audibility provided for low and moderate level speech (via the aided SII).

For both individual-level and program-level outcome evaluation, it was of interest to know whether the RECD was *individually measured* or *predicted*. Individually measured RECDs are more desirable for hearing aid fitting than predicted RECD values due to the substantial between-subject variability noted in RECD measures in children (Bagatto, Scollie, Seewald, Moodie, & Hoover, 2002). Although age appropriate, currently available predicted RECD values only provide a gross estimate of actual RECD values in the pediatric population (Bagatto, et al., 2002). Therefore, current pediatric hearing aid fitting protocols require the audiologist to attempt a measurement of the RECD to individualize the fitting for the patient (e.g., Bagatto, et al., 2010). It was therefore of interest to know if the RECD was individually measured or predicted. To understand practice fidelity and clinical process outcomes, the clinician therefore indicated whether the RECD was measured or predicted for each ear. Also, if an RECD was measured on one ear and applied to the other ear, or previously measured values were used, these options were available (Table 4-2).

Since the MPO is measured using a narrowband signal and not speech, there is no associated speech audibility index value (i.e., SII) provided. Therefore, the clinician indicated whether or not the MPO was measured during the child's hearing aid fitting and any follow-up visits. For outcome evaluation of the individual child, this simply documents that this important step was fulfilled (Table 4-2). At the program level, this information can be used to evaluate program-wide adherence to the recommended protocol.

For many pediatric hearing aid fitting protocols, measurement of the real-ear aided response (REAR) for low and moderate speech inputs are required (e.g., AAA, 2003;

Bagatto, et al., 2010; Early Hearing Equipment Advisory Group, 2006). Since hearing aid verification systems provide an associated SII value for all REARs, the next step was to document the SII values. Including the *SII for low and moderate speech* in the outcome evaluation process provided information about how typical the hearing aid fitting was for each ear for a particular patient. A complete clinical process outcome measure for the SII included a value from zero to 100 for low- (55 dB SPL) and moderate-level (65 dB SPL) speech inputs. In summary, two SII values per hearing aid fitting were tracked (see Table 4-2).

Table 4-2: Summary of hearing aid fitting details.

Hearing Aid Fitting Detail	Data to be Tracked (For Each Aided Ear)
Real-ear-to-coupler difference (RECD)	Measured Predicted Other Ear Values Previously Measured
Maximum Power Output (MPO)	Measured (yes/no)
SII for Soft Speech input (55 dB SPL)	Value from 0 to 100
SII for Average Speech input (65 dB SPL)	Value from 0 to 100

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The SII is a value representing the proportion of speech that is audible to the listener through his or her hearing aids (American National Standards Institute [ANSI], S3.5, 1997). It is an electroacoustic measure, not a behavioural prediction of speech recognition. The SII provides a value that clinicians, caregivers, and teachers can use to conceptualize the proportion of speech that is available to the child. SII values are provided from hearing aid verification systems (e.g., Audioscan Verifit[®], Interacoustics Affinity[®]). If a clinician performs speech-based real-ear verification of the young child's hearing aids, the SII is computed for each input level tested. For example, in Figure 4-2, the measured real-ear performance of the child's hearing aids for an average speech input

provides an associated SII value, which indicates that 78% of moderate-level speech is audible to the wearer. The clinician will also be provided with SII values for verification measures made with other speech input levels. In this example, 66% of soft speech is audible.

Recently, normative data for fit to Desired Sensation Level (DSL) Method version 5.0a targets have become available (Moodie, 2009, 2010). These were derived from pediatric fit to target data from 161 ears. The fittings ranged from 1 dB below to 4 dB above the prescribed target on average from 250 to 4000 Hz. From these data, the SII values were extracted to analyze the relation between SII and unaided pure tone average (PTA) hearing threshold levels, using a linear regression (see Figure 4-3). The results indicated that aided SII values decrease from 100% to 40% as hearing level increases from 20 dB HL to 90 dB HL. Within this range, the data vary by approximately 30% in more than 95% of fittings. This trend is due to the application of the level distortion factor within the SII calculation and narrower bandwidth typical of higher gain fittings (ANSI, S3.5, 1997). Above 90 dB HL, there was too little data to establish a clear trend.

Within the UWO PedAMP guideline, this trend was used, as well as the 95% confidence interval surrounding it, to determine whether a given fitting was considered typical for that PTA hearing loss. The Aided SII Normative Values Worksheet was developed for this purpose. Due to the lack of data in the region above 90 dB HL PTA, a typical trend for SII values in this region is not provided. The norms on the worksheet can therefore be used clinically to conceptualize audibility after some fit to target criteria (e.g., within 5 dB for losses with a PTA \leq 70 dB HL) have been established.

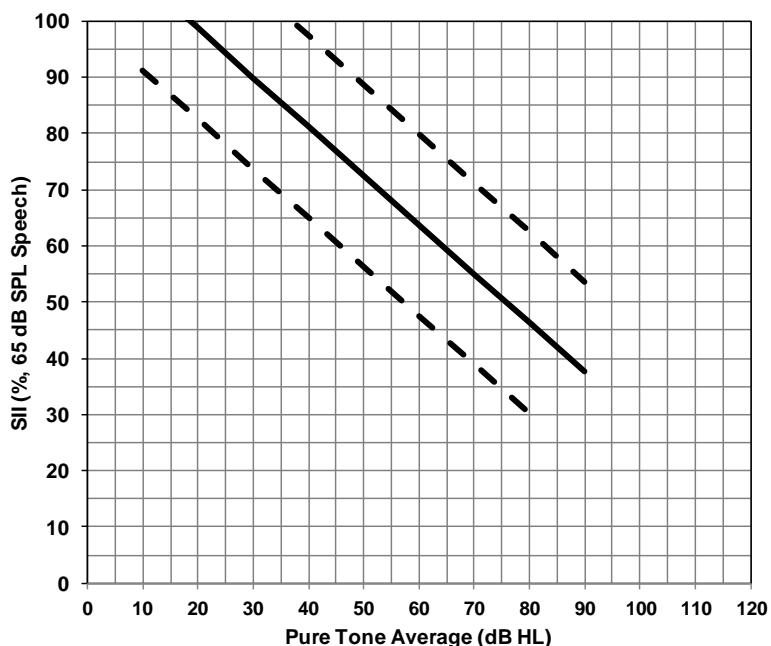


Figure 4-3: Graph from the Aided SII Normative Values Worksheet displaying SII values for a 65 dB speech input. The regression line was obtained from hearing aid fittings on 161 ears of infants and children. The solid line represents the linear fit to the data and the dashed lines represent the upper and lower 95% confidence interval ranges. An SII value that falls between the dashed lines is considered to be typical audibility for that pure tone average.

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Within the context of the OIHP, all clinicians within the program received training on measurement of all of these indicators, and other mechanisms within the program allow for specific file audit to look at practice quality in detail. The main interest, therefore, lies in the protocol elements present in a given hearing aid fitting, or across hearing aid fittings program-wide, as a means of either (a) measuring how often clinicians employ

these protocol elements and/or (b) having a means to characterize cases in which protocols were followed versus not followed.

4.2.4.2 Reporting hearing aid fitting details

To facilitate the collection of relevant hearing aid fitting details, the UWO PedAMP provides a Hearing Aid Fitting Summary Form. This form provides a way of recording, at regular intervals, important information about the hearing aid fitting, such as the details of the RECD measurement, the SII values associated with low and moderate level speech inputs, and whether an MPO measurement was made. These clinical process variables were recorded at the initial hearing aid fitting and at routine three-month, six-month and yearly follow-up visits (see Figure 4-1). Hearing aid fitting details were also recorded in event-driven situations.

4.2.4.3 The LittleARS Auditory Questionnaire

The LittleARS Auditory Questionnaire is a caregiver-report functional outcome evaluation tool. It is included in the UWO PedAMP for evaluation of infants and toddlers, as discussed below. According to the authors, the purpose of the LittleARS Auditory Questionnaire is to assess the auditory behaviour of infants and toddlers with PCHI who wear hearing aids or cochlear implants (Coninx, et al., 2009; Tsiakpini, et al., 2004, Copyright MED-EDL, 2004). The 35 items in the LittleARS assess auditory development during the first two years of hearing in the real-world and tap into receptive and semantic auditory behaviour as well as expressive-vocal behaviour. The questions are listed in an age-dependent order and are in a yes/no format. The total of all “yes” answers provide a score that can be compared to average and minimum age-dependent values. These values are provided in one-month age categories based on normative data (Coninx, et al., 2009). The LittleARS is designed to be answered by caregivers and is not affected by how it is administered (i.e., under professional guidance or independently). It has been suggested that using a caregiver observation tool in the early stages may be helpful to caregivers who are starting to navigate through the world of hearing loss and hearing aids (Harrison, 2000). The LittleARS supports this function for caregivers because the items provide examples that introduce them to early auditory behaviours and prepares them to understand what auditory behaviours can be observed at later stages of development.

A validation study of the LittleEARS questionnaire was conducted on 218 normal hearing children from German-speaking families (Coninx, et al., 2009). Results indicated that the questionnaire is reliable (split half $r = 0.88$), has good internal consistency (Cronbach's $\alpha = 0.96$), and predictive accuracy (Guttman's $\lambda = 0.93$). There is also high correlation between the overall score and the age of the children ($r = 0.91$). The data collected from the caregivers were used to obtain normative values for the development of early auditory behaviour in normal hearing children and used to derive average and minimum values for scoring. A validation study was conducted with 63 children in Germany and Italy who wear cochlear implants. The results indicated that the LittleEARS questionnaire is appropriate for use with children provided with cochlear implants early in life and the results can be compared to the normative data (Kuehn-Inacker, Weichbold, Tsiakpini, Coninx, & D'Haese, 2003). Currently there is a validation study being conducted in the United States with English-speaking children who wear cochlear implants (www.ClinicalTrials.gov Identifier NCT00785707). The questionnaire has also been validated in 15 different languages with families of normal hearing infants and toddlers up to 24 months of age (Bagatto, Brown, Moodie, & Scollie, 2011; Coninx, et al., 2009). Regression curves for each language were essentially equivalent to the German-derived norms.

Further review of the feasibility of the LittleEARS questionnaire in clinical practice indicated that changes to the score sheet would facilitate its use with children who experience developmental delay (Moodie, et al., 2011). For this reason the score sheet shown in Appendix E was developed. This tool maintains the original normative trajectory and cutoff scores but extends the age range that may be plotted. This revised score sheet is included as part of the UWO PedAMP and was considered a useful addition to the guideline by the Network of Pediatric Audiologists of Canada (Moodie, et al., 2011).

4.2.4.4 The Parents' Evaluation of Aural/Oral Performance of Children (PEACH)

The Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Rating Scale is included as a caregiver-report functional outcome evaluation tool for use after the LittleEARS questionnaire is no longer appropriate. The PEACH in its original diary form is conducted using a structured interview format and has questions that address quiet and noisy situations as well as hearing device and telephone usage (Ching & Hill, 2005b). The PEACH Diary requires caregivers to observe their child for at least one week and record their observations for the 13 scenarios over that time period. They are also asked to rate the frequency of each behaviour and provide examples of when the child did or did not exhibit a particular response. After the observation period, the audiologist meets with the caregiver to address each item in a face-to-face interview. The interview is structured to solicit detailed information from the caregiver, rather than yes/no answers. Normative data for the PEACH Diary were obtained from 90 parents of normal hearing children and 90 parents of children with PCHI who wear hearing aids (Ching & Hill, 2007). The tool demonstrated good internal consistency (Cronbach's $\alpha = 0.88$) and high test-retest reliability ($r = 0.93$). Normal hearing children (age range = 0.25 to 46 months) demonstrated an increase in performance from about six months of age and close to perfect performance (i.e., 90%) was achieved by about three years of age. Children with increasing hearing loss showed a decrease in performance (age range = 4 months to 19 years). Descriptive statistics for the PEACH Diary were also reported indicating an overall test mean of approximately 62% for children with PCHI, with similar mean scores for the quiet and noise subscales. The authors noted that the children with hearing loss were late-identified, and the functional performance of children who are early identified may be improved (Ching & Hill, 2007). A follow-up study with children with severe-to-profound hearing loss demonstrated that the PEACH Diary is sensitive to changes in frequency response slopes in hearing aids (Ching, Hill, & Dillon, 2008).

The observation and interview process required for the PEACH Diary was found to be heavy in administrative and respondent burden as reported by the Network of Pediatric Audiologists of Canada (Moodie, et al., 2011). Specifically, the time it takes to administer and score the PEACH Diary is longer and more involved compared to the

PEACH Rating Scale. In addition, literacy barriers for some families may prevent completion of the PEACH Diary due to the independent nature of the diary version. These limitations were reflected in the PEACH Rating Scale being rated more favorably in the critical review (Bagatto, Moodie, et al., 2011) and accepted by a higher percentage of participants in the Network (Moodie, et al., 2011) compared to the PEACH Diary. In addition, as reported in a research study (Golding, et al., 2007) the caregiver's ability to observe their child may have varied and may have been limited by competing factors in the household (i.e., number of children, wellness of the child, lifestyle; Golding, et al., 2007). Also, an inexperienced interviewer may have had difficulty extracting useful examples from the caregivers even though the interviewer received instructions on how to administer the PEACH (Golding, et al., 2007).

A Rating Scale version of the PEACH (Ching & Hill, 2005a) has been made available and includes most of the scenarios from the original PEACH Diary (Ching & Hill, 2005b). The PEACH Rating Scale (referred to as the PEACH for the remainder of this chapter) appears to be more acceptable to clinicians and caregivers because the respondent and administrative burden have been reduced (Moodie, et al., 2011). The instructions ask caregivers to recall their child's behaviour in everyday life over the past week and rate their child's hearing performance across a range of hearing and communication scenarios. The nature of the rating scale allows it to be answered by the caregiver during an appointment with guidance from the clinician, reducing respondent and administrative burden (Bagatto, Moodie, et al., 2011). Therefore, the PEACH was selected for use in the UWO PedAMP, with toddlers and preschool children who have attained ceiling performance on the LittleEARS Auditory Questionnaire. Ceiling performance on the LittleEARS occurs when the minimum score of 27 or greater has been achieved. This facilitates the use of the LittleEARS with children of various developmental trajectories by providing a stopping rule based on score and not by chronological age before moving to the PEACH. Also, items on the LittleEARS display similar content as the PEACH around Item 27. Therefore, for children involved in this study, the LittleEARS was administered until the child reached a ceiling score of 27, regardless of age. Then, the PEACH was administered at the next routine follow-up appointment. The modified administration guidelines for both the LittleEARS and the

PEACH based on the results of this study are outlined in the discussion section of this chapter.

4.3 Results⁶

4.3.1 Hearing aid fitting details

The RECD and MPO were both reported for 75.0% of the children involved in this study. The RECD was measured 56.8% of the time and predicted values were used 27.5% of the time. Reasons for using predicted values were most often due to excessive cerumen in the ear canal or a very active child. RECD values from the other ear were used for the ear with the better PTA 5.9% of the time. Previously measured values were used 9.8% of the time.

SII values for soft speech inputs were reported for 62 out of 68 children (91.2%) with PCHI who wear hearing aids in this study. These SII values had an average percentage of 66.2 (range = 11.0 to 96.0%). For average speech inputs, 64 out of 68 SII values (94.1%) were reported for children with hearing aids. Percentages were 74.9% on average for these SII values (range = 21.0 to 97.0%). The SII values for average speech have been plotted within the Aided SII Normative Values Worksheet by degree of hearing loss (Figure 4-4). It can be seen that for the children involved in this study, the majority of the SII values for average speech are considered to be typical for the degree of hearing loss.

⁶ Results for the first 12 months of data collection are presented in the next sections. Following publication of this chapter, data was collected for six more months and the updated results are presented in an addendum (Section 4.7).

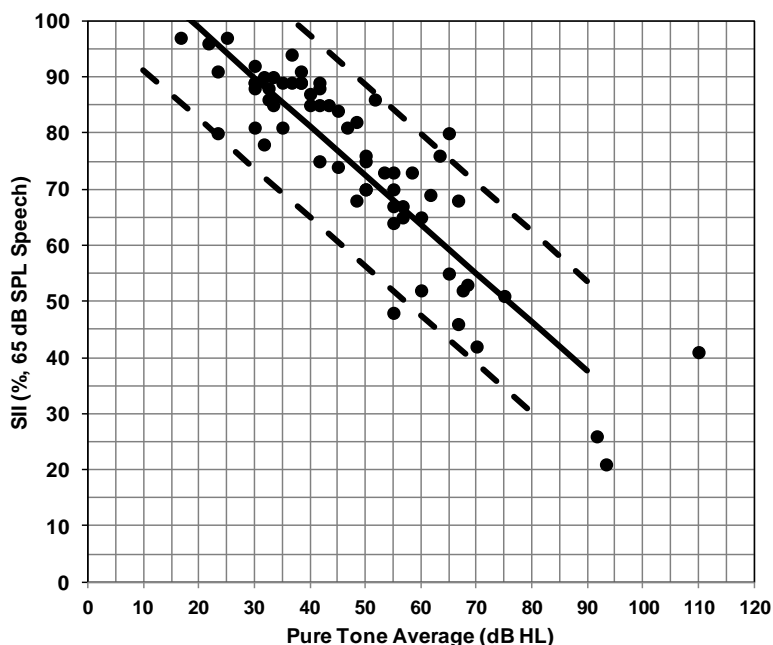


Figure 4-4: SII values for average speech inputs by PTA for children with hearing aids involved in this study (filled circles; n=64). Solid and dashed lines are from the Aided SII Normative Values Worksheet. The solid line is the average SII normative values and the dashed lines are the upper and lower 95% confidence interval ranges.

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4.3.2 LittleARS data from children with hearing loss who wear hearing aids

Of the total participant sample, 43 caregivers of children (mean age = 27.3 months; age range = 6.9 to 72.7 months) with PCHI who wear hearing aids were administered the LittleARS a total of 58 times. Twenty-eight children received a single administration, and 15 children received repeated administrations, ranging in number from two to five longitudinal repetitions. Many of the children in this sample were identified as having comorbidities (39.5%; $n = 17$) and complex factors (32.6%; $n = 14$). A total of 27.9% of children ($n = 12$) in this LittleARS sample were typically developing and had no complex factors related to amplification (see Figure 4-5).

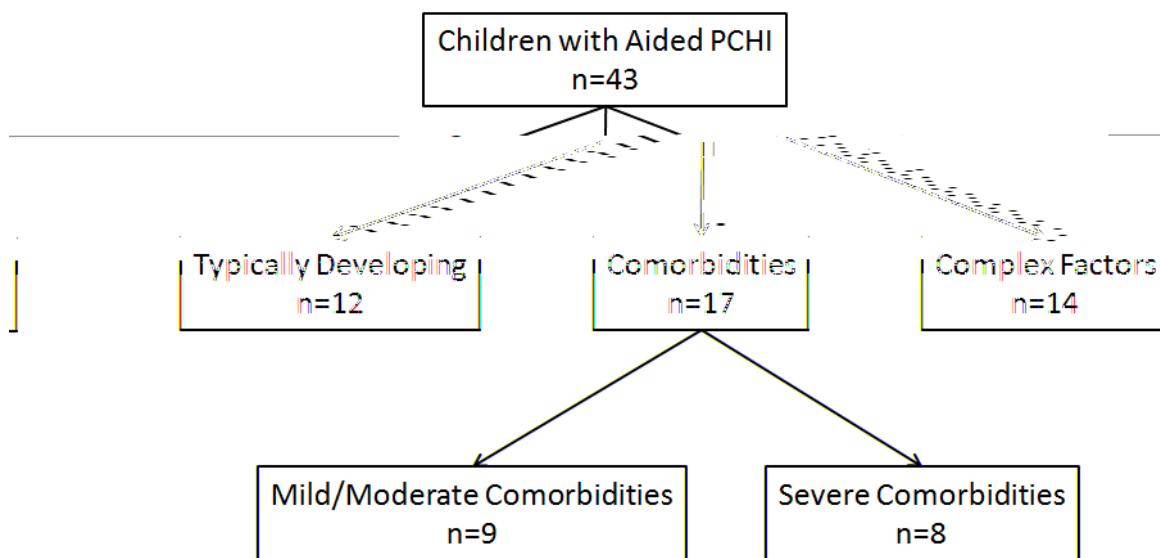


Figure 4-5: Subgroup flowchart for children with hearing aids whose caregivers were administered the LittleARS Auditory Questionnaire. Of the total sample with hearing aids, these children were grouped into those with typical development, comorbidities, and complex factors.

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Children with comorbidities included those who were premature (i.e., born 37 weeks gestational age or earlier relative to a 40-week term) as well as those with other medical issues beyond PCHI. These children were further separated into a group with mild to moderate comorbidities ($n = 9$) and a group with severe comorbidities ($n = 8$). Children with severe comorbidities were born full-term and were indicated by the clinician to have a severe manifestation of a disorder or a syndrome causing multiple issues that could potentially interfere with auditory performance.

Caregivers' responses on the LittleARS indicated that children with severe comorbidities were not meeting auditory development milestones for their age and their individual scores were less than 27 out of 35, regardless of age (see Figure 4-6). Given the small

sample size and therefore low power in this group (Lee, 2004), these data were not subjected to further analysis. More data will be obtained to further characterize this important subpopulation. Children with mild to moderate comorbidities were analyzed as a separate group.

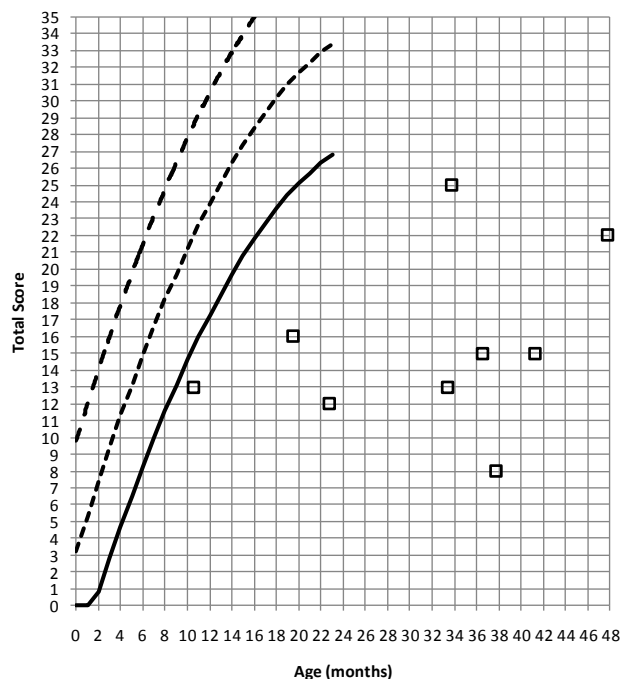


Figure 4-6: LittleEARs scores from children with hearing aids who were born full term and have severe comorbidities. The solid line indicates the minimum expected score, the small dashed line indicates the average expected score and the large dashed line indicates the maximum expected score from the German-derived norms. Open squares indicate LittleEARs scores from children with PCHI who have severe comorbidities in this sample (n=8; 1 repeat administration). Children with scores above the solid line are considered to be meeting auditory development milestones for their age and children with scores below the solid line are considered to not be meeting milestones.

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The LittlEARS scores for the remainder of the children were grouped into the following categories prior to analyses: (a) typically developing, (b) mild to moderate comorbidities, and (c) complex factors. Regression analyses were conducted on each group separately to characterize the cross-sectional trajectory of scores by age, per group. For children who were typically developing, a quadratic regression curve provided the best fit to the data ($R^2 = 0.60$; $F = 8.20$, $df = 13$, $p < 0.01$): this was the curve type used with the validation data from the normative study for this questionnaire (Coninx, et al., 2009). The regression equation and the quadratic curve fit to the data can be found in the top left panel of Figure 4-7. The scores from the children with mild to moderate comorbidities were best fitted with an s-shaped function ($R^2 = 0.62$; $F = 18.27$, $df = 13$, $p < 0.01$), with the regression equation and curve fit noted in the top right panel of Figure 4-7. Finally, the scores for children with complex factors were fitted using a quadratic regression curve, as seen in the bottom left panel of Figure 4-7 ($R^2 = 0.43$; $F = 7.26$, $df = 13$, $p < 0.01$). Comparing the regression lines from each subgroup to each other as well as to the normative values (bottom right panel of Figure 4-7) indicates that children who are typically developing are generally meeting auditory development milestones across age. Children with mild to moderate comorbidities show typical auditory development up to about 12 months of age where their scores begin to decline compared to normative data. Finally, children with complex factors associated with hearing aid use appear to be performing in parallel, but have lower scores, compared to typically developing children without complex factors.

4.3.3 PEACH data from children with hearing loss who wear hearing aids

Forty-eight caregivers of children with PCHI who wear hearing aids were administered the PEACH a total of 75 times. Twenty-eight children received a single administration, and 20 children received two to five repeated administrations of the PEACH. Of the children involved, 29.2% ($n = 14$) were born 37 weeks gestational age or earlier relative to a 40-week term and/or had other identified medical issues besides hearing loss (i.e., comorbidities). In addition, 37.5% ($n = 18$) of the children were noted to have a complex factor related to amplification (i.e., inconsistent hearing aid use, delayed fitting due to late identification or other factors). The remaining 33.3% ($n = 16$) children were full-

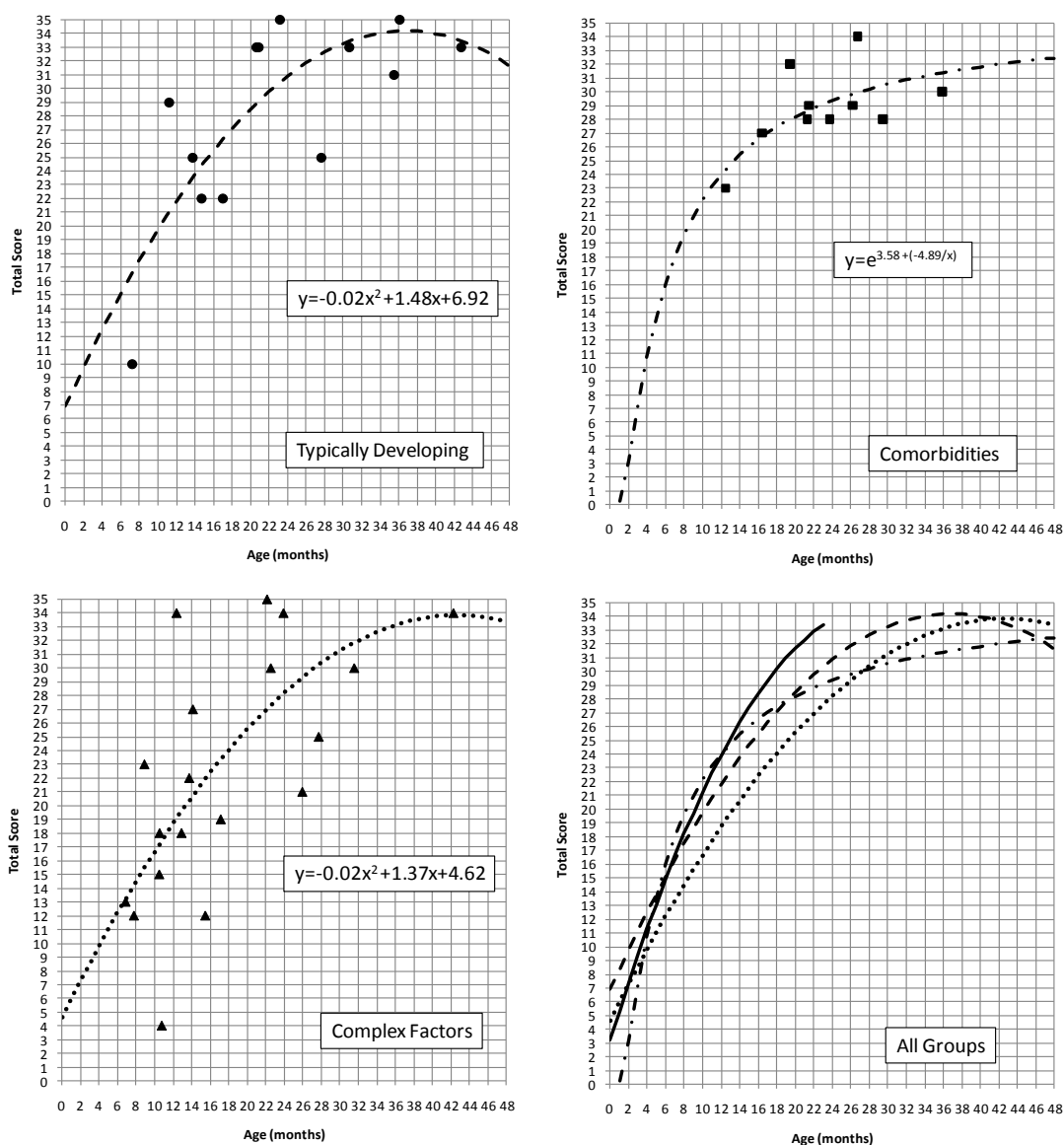


Figure 4-7: LittleEARS scores (y-axis) by age (x-axis) and regression lines from children with hearing aids who: a) are typically developing and have no comorbidities or complex factors (filled circles; n=12); b) have mild to moderate comorbidities (filled squares; n=9); and c) have complex factors (filled triangles; n=14). The various lines indicate the regression for each set of data: a) large dashed; b) dotted-dashed; and c) small dashed. Regression equations are noted within each figure. The bottom right panel displays all regression lines on a single graph and compares them to the average normative values (solid line).

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term, typically developing, early identified, enrolled early in programs of intervention, and did not have complex factors related to amplification.

Descriptive statistics are reported on a version of the PEACH score sheet (see Appendix F) for children who are typically developing (Figure 4-8). The average overall score was 84.5% ($SD = 11.04$) and the quiet and noise subscales were 86.0% ($SD = 12.65$) and 82.3% ($SD = 12.94$), respectively. This indicates that children who were identified and fitted early with high-quality amplification and who are typically developing achieve high scores on the PEACH. In fact, the scores of children with hearing aids in this sample are approaching the high score of 90% achieved by normal hearing children by age three years.

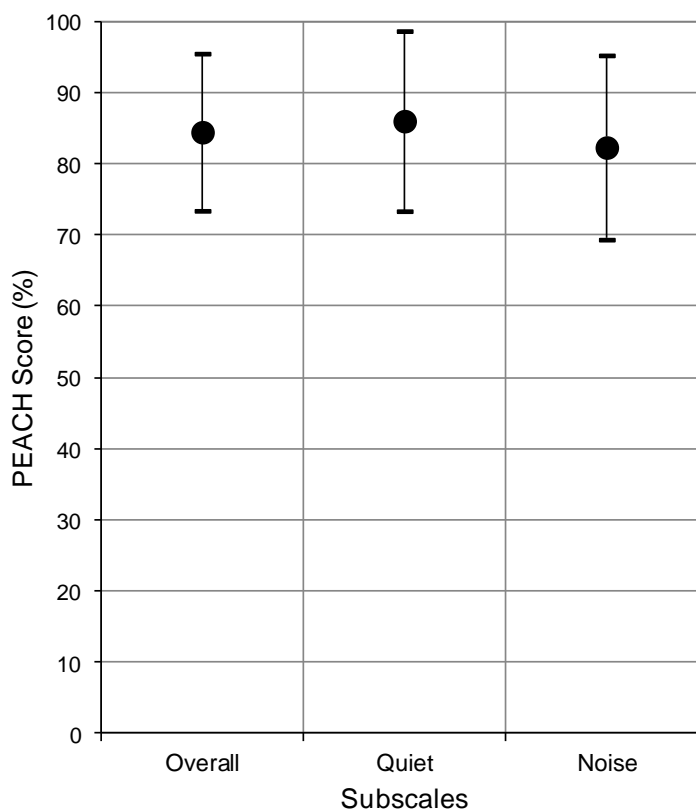


Figure 4-8: PEACH scores from typically developing, full-term children with hearing aids (n=16; 7 repeat administrations). Circles represent average percentage scores for each subscale and vertical bars represent the standard deviation around the mean. Note that all scores are within the ‘Typical Performance’ range for this sample of children.

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4.3.3.1 Analysis 1

The total sample of children were grouped into the following categories prior to regression analyses: (a) typically developing, (b) those with mild to moderate comorbidities, and (c) those with complex factors. There were no children in this sample with severe comorbidities as described in the LittleEARS results section. Regression analyses were conducted on each group separately. For all children who were typically developing, an s-shaped curve provided the best fit to the data ($R^2 = 0.13$; $F = 4.36$, $df = 30$, $p < 0.05$), where the dependent variable was the overall PEACH score and the independent variable was age in months. The regression equation and the s-shaped curve fit to the data can be found in Figure 4-9.

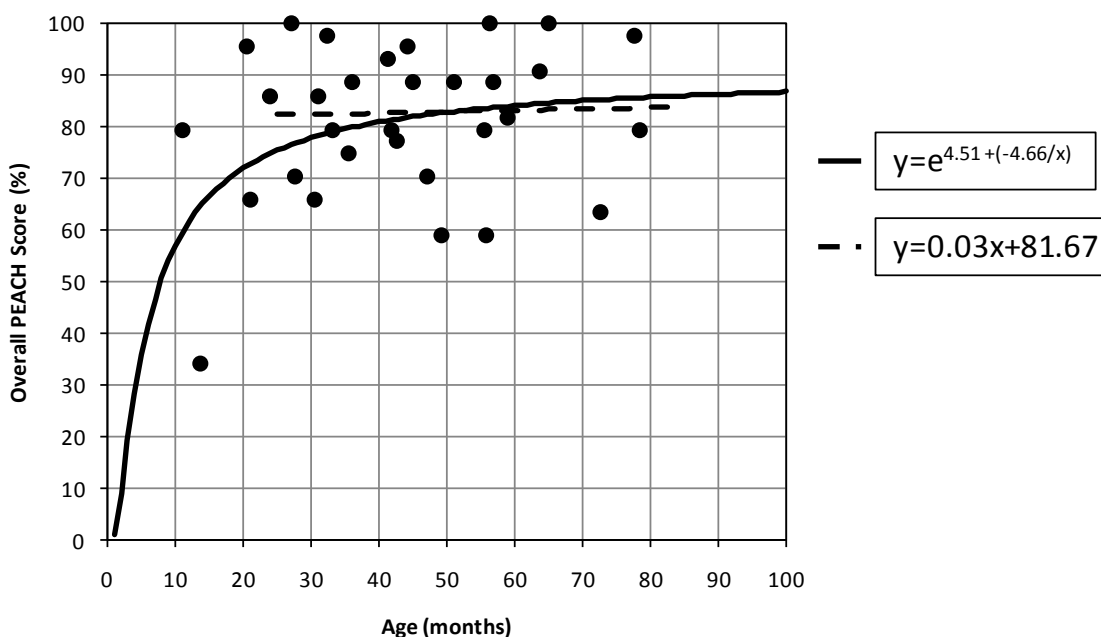


Figure 4-9: PEACH scores (y-axis) by age (x-axis) and regression lines from typically developing children (filled circles; n=16; 7 repeat administrations) with hearing aids. The solid line is an s-shaped regression for typically developing children of all ages involved in this study. A non-significant linear regression is shown with the dashed line for typically developing children over the age of 24 months. Regression equations are noted in the figure.

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It can be noted that there were approximately five children under the age of 24 months included in this analysis, which may have contributed to the significant s-shaped regression curve. Recall that the UWO PedAMP functional outcome evaluation tools were administered using a two-stage process by developmental level. The LittleEARS has a suggested age range of birth to 24 months but this was adjusted to use a score-based stopping rule within the UWO PedAMP for this study because some of the items on the PEACH were considered to be beyond the developmental range of children younger than 24 months. Therefore, the young children were removed and a regression analysis was repeated on typically developing children older than 24 months. The result of this analysis was a nonsignificant linear regression ($R^2 = 0.009$; $F = 0.02$, $df = 25$, $p > 0.05$; Figure 4-9). This provides support to the idea that the PEACH may be used for children who are typically developing and older than 24 months without the need for age-corrected scoring. A comparison of the curves plotted in Figure 4-9 indicate that there is no significant age effect on overall PEACH scores after 24 months of age, which supports using the PEACH questionnaire for children older than 24 months of age.

4.3.3.2 Analysis 2

A multivariate analysis of covariance (MANCOVA) was conducted to determine the impact of degree of hearing loss and complexity (e.g., comorbidities and complex factors combined) on the scores for the PEACH quiet and noise subscales. With complexity as the independent variable and the degree of hearing loss as the covariate, results indicated that the multivariate effect of degree of hearing loss was significant, $F(2, 54) = 5.713$, $p < 0.05$, $\eta^2 = 0.175$, but complexity was not, $F(2, 54) = 1.643$, $p > 0.05$, $\eta^2 = 0.057$.

Univariate effects confirmed that children who are typically developing or have complexities did not differ on their PEACH scores for either the Quiet, $F(1, 55) = 2.366$, $p > 0.05$ or Noise, $F(1, 55) = 3.163$, $p > 0.05$, subscales. However, the degree of hearing loss was found to have a significant impact on PEACH scores for both the Quiet, $F(1, 55) = 11.473$, $p < 0.05$ and Noise, $F(1, 55) = 4.177$, $p < 0.05$ subscales.

4.4 Discussion

This observational study of clinical practice evaluated pediatric outcome evaluation tools chosen for the UWO PedAMP to assess auditory development (LittleEARS) and auditory

performance (PEACH) in children with PCHI who wear hearing aids. Auditory-specific outcomes are one way to measure how well a child with PCHI is performing with his or her hearing aids. It is also important to consider overall communication outcomes, including speech and language-based outcomes. However, the current work focused on auditory-specific outcomes. In addition to these functional outcomes, clinical process outcomes were assessed by tracking hearing aid fitting details using clinical tools. This important aspect of the UWO PedAMP provided a description of the hearing aid verification process without the need to report fit to target details but by using the SII to provide a gross index of a typical fit to target for the child's PTA. The clinical process tools provided useful information for the interpretation of the functional outcomes measured by the LittleEARS and the PEACH questionnaires. The majority of hearing aid fitting details were reported and values reflected good hearing aid verification process. Evaluation of the LittleEARS with children with hearing aids indicated the typically developing children in this sample were meeting auditory development milestones across age. Children with mild to moderate comorbidities showed typical auditory development during the first year of life then showed a decline in scores compared to existing norms for normal hearing children. Children with severe comorbidities were too small of a sample to conduct an analysis, but more data collection will help to further characterize this group. Children with complex factors related to hearing aid use appeared to have lower scores compared to normal hearing children but did show the same rate of improvement across age. The PEACH results indicated no effect of age on auditory performance as shown by a nonsignificant trend for typically developing children above the age of 24 months. Further analysis indicated that the degree of hearing loss affects scores on the PEACH but complexity does not.

Limitations of this study include the fact that the pediatric audiologists involved in this work had several years of experience with fitting hearing aids to children. Including an outcome evaluation guideline in their routine practice may have been more of a challenge had the clinicians not been familiar with strategies used in the prior stages of the hearing aid fitting process (e.g., RECD measures, simulated real-ear verification procedures). Therefore, extending the hearing aid fitting process to include the UWO PedAMP was

likely less of a barrier for daily clinical practice for the audiologists involved in this study. In addition, the clinicians had the support of the OIHP and regional coordinators to add outcome evaluation tools to their regular clinical routine. The clinicians reported that the UWO PedAMP takes approximately 15 to 20 min of extra clinical time including working with the parents and completing forms for the patient's chart. This may be a barrier in some clinics where time is limited and clinical managers do not see the importance of measuring outcomes of children who wear hearing aids. One final limitation of this study is the sample size and the fact that children with comorbidities and complex factors were included as study participants. Of the 68 children in the study with hearing loss who wear hearing aids, a total of 23 were typically developing. This was further divided into 12 typically developing children with LittIEARS data and 16 typically developing children with PEACH data (many had repeat administrations). These numbers are approaching the suggested sample size of 20 (Lee, 2004) for each group, however, at this point, the current sample size for each questionnaire may be insufficient to draw firm conclusions about the functional performance of typically developing children who wear hearing aids. Since the publication of this chapter, more data has been collected and analyzed and is presented in the addendum at the end of this chapter.

Through this work, clinical administration guidelines were developed to improve the feasibility and potential clinical implementation of the guideline used in this study. This work is unique compared to other outcomes studies in that the guideline implemented here was designed for clinical use and not solely for the purposes of research. Therefore, a focus on reducing barriers to implementation in clinical practice was an important aspect of the development of the UWO PedAMP (Moodie, et al., 2011). As such, children with other medical issues in addition to hearing loss as well as complex factors related to hearing aid use were included as participants in this study. This may support a better understanding of the clinical application of the LittIEARS and PEACH in a typical clinical population. Also, application of these tools in clinical practice resulted in clinical administration modifications (e.g., extending the age range of administration for the LittIEARS, particularly for children who have developmental delays) and the design of

useful score sheets for record keeping and interpretation. These modifications are described below for each functional outcome evaluation tool. Clinical score sheets can be found in Appendix E and F. In addition, case examples are provided below to illustrate the use of the UWO PedAMP in clinical practice. We hope that the results of this clinical research and subsequent modifications to existing outcome evaluation tools will provide clinicians with a systematic, evidence-based outcome evaluation protocol to implement as part of a complete pediatric hearing aid fitting.

4.4.1 LittleEARS administration guidelines

Within the UWO PedAMP, the LittleEARS Auditory Questionnaire can be administered for children with normal hearing as well as for children with hearing loss who wear hearing aids. The LittleEARS uses a simple “yes/no” format and has items that allow a gradual progression through the tool as the child develops. Therefore, it is recommended that all of the questions be answered, regardless of the number of consecutive “no” answers or the child’s hearing aid status. The tool was developed for children in their first two years of life, however, the work presented here has revealed that it is also suitable for children older than two years of age who may be premature, who present with atypical development, or who are in the early stages of hearing aid use. Therefore, the score sheet was revised to include a wider age range of use with children up to 48 months of (adjusted) age (see Appendix E). Further data collection will facilitate the characterization of LittleEARS scores for children with various audiometric profiles for application in a clinical context. For example, when a score is obtained for a child with aided severe PCHI, the clinician will be able to relate that score to data collected from a group of typically developing children with the same aided degree of hearing loss. On the other hand, many of the children in this initial data set have other medical issues or complex factors and these children may ultimately be characterized differently with future data collection.

It is recommended that administration of the LittleEARS occur at some point prior to hearing aid fitting and at regular follow-up visits (see Figure 4-1 for administration guidelines). If the child is not wearing hearing aids but has an identified hearing loss, the

questionnaire may also be useful for monitoring auditory development and tracking progress over time although data supporting this use are not yet available. In this case, the LittEARS should be administered at every regular follow-up visit. The total “yes” score is entered on the score sheet at the point where age and score meet. A child with a score in the shaded region is considered to not be meeting auditory development milestones for his or her age. A child with a score above the shaded region is considered to be meeting auditory development milestones for his or her age. Within the UWO PedAMP, when a minimum score of 27 or better is achieved on this tool, the child’s performance is considered to be at a ceiling. If ceiling is reached *and* the child is older than 24 months of age, the LittEARS should no longer be administered. Instead, the clinician can begin to administer the PEACH, either at that appointment or at the next follow-up visit. This modification is supported by the outcome of the LittEARS Auditory Questionnaire on those children with severe comorbidities and the fact that the items on the questionnaire display similar content as the PEACH around Item 27. This is further discussed in the next section.

4.4.2 PEACH administration guidelines

Within the UWO PedAMP, the PEACH may be administered to children with normal hearing as well as to children with hearing loss who wear hearing aids. A comparison of the LittEARS and the PEACH in terms of developmental range indicates that some items on the PEACH may not be within the developmental abilities of infants and toddlers. Roughly 17 children with moderate to moderately-severe hearing impairment were younger than 50 months of age in the PEACH normative data (Ching & Hill, 2007). Scores from these younger children and their normally hearing peers are lower, with normally hearing children reaching ceiling performance by three years of age. While results from this study, as well as others, reveal the PEACH appears to be sensitive to levels of hearing loss, its age-sensitivity may be due to the difficulty of items for infants or toddlers. Therefore, in this guideline a two-stage developmental process for administration is recommended: the LittEARS is administered until a ceiling score and age criteria are met then the PEACH is administered. This is supported by the current PEACH data indicating there is no age effect on scores for children above 24 months of

age. Having the caregiver of an infant complete the PEACH may be discouraging at the early stages as some questions may not be developmentally appropriate, making it seem as though the infant is not performing well (i.e., respondent burden may be too high). Although the authors suggest certain modifications of items for use with infants, the specific age range for modification is not known. At young ages, the LittlEARS questionnaire includes items that are developmentally appropriate without modification. Therefore, based on the findings of this study the UWO PedAMP guideline has been modified such that *administration of the PEACH begins when the child has reached a score of 27 or greater (i.e., ceiling performance) on the LittlEARS Auditory Questionnaire and the child is older than 24 months of age*. These prerequisites should help to ensure that the child's auditory skills are more likely within the range of the PEACH.

An accompanying PEACH score sheet was developed as part of the UWO PedAMP and provides assistance with interpretation of individual scores (Appendix F). Results from previous studies of the PEACH as well as the current work have been included on the current version of the PEACH score sheet and can assist with interpretation of individual scores. The unshaded and shaded regions can be used as benchmarks against which to interpret individual scores. As the PEACH is routinely used in clinical practice, the performance ranges on the score sheet will be validated and the results will be incorporated into future versions of the UWO PedAMP as needed.

Providing guidance for administration and interpretation of the tools supports the implementation of an evidence-based clinical guideline for outcome evaluation in the pediatric population. In addition, case examples are suggested as a way to support clinical implementation of the UWO PedAMP beyond the research results of this study (Kassirer, 2010). For this reason, two case examples demonstrating the use of the UWO PedAMP are provided below.

4.5 Case examples

4.5.1 Case example 1: Michael

Michael was born full-term without complications with no reported family history of hearing loss. He was identified with a mild sloping to moderately-severe sensorineural hearing loss in both ears (PTA right = 43.3 dB HL; PTA left = 46.6 dB HL) when he was approximately four months old. Prior to obtaining hearing aids, Michael's mother completed the LittlEARS Auditory Questionnaire. The total unaided LittlEARS score was six. As seen on the score sheet shown in Figure 4-10, Michael was meeting minimum auditory development milestones for his age without hearing aids. At five months of age, Michael was fitted binaurally with hearing aids and the fit to targets were assessed during electroacoustic verification. Hearing aid fitting details were recorded on the Hearing Aid Fitting Summary form. Following a fit to targets assessment, the SII values were transferred to the Aided SII Normative Values Worksheet to determine whether the child had typical audibility from the hearing aids. In this example, the SII for an average speech input for the right (86%) and left (82%) ears fell within the 95% confidence interval (dashed lines) for Michael's degree of hearing loss (Figure 4-11). When compared to aided SII norms, it can be seen that both hearing aids were providing a typical degree of audibility for Michael's degree of hearing loss for an average speech input. If the SII values fell below the lower dashed line, the values would be considered to be lower than a typical SII for Michael's degree of hearing loss. If this situation occurred, the clinician could consider modifying the hearing aid fitting to obtain a closer match to targets and thus an improved SII value prior to proceeding with the functional outcome evaluation tools in the UWO PedAMP.

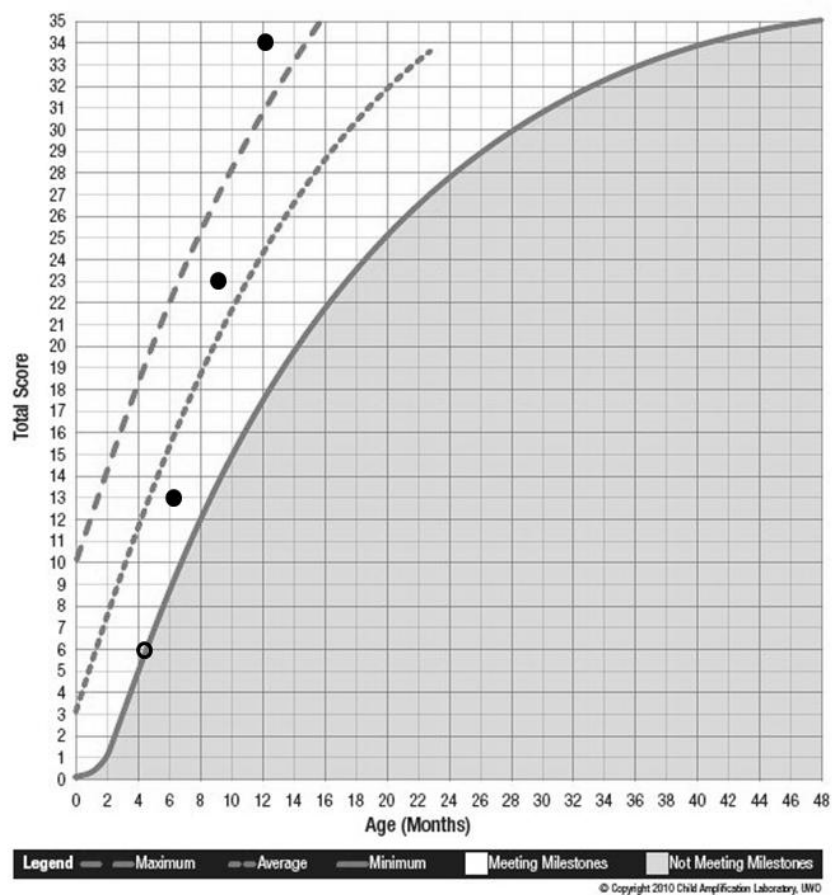


Figure 4-10: LittleEARS score sheet for Case Example: Michael. The solid line indicates the minimum expected score, the small dashed line indicates the average expected score and the large dashed line indicates the maximum expected score from the German-derived norms. Circles represent the LittleEARS Score (y-axis) plotted by the child's age in months (x-axis). The open circle is the unaided score and the filled circles represent scores in the aided condition. Scores in the non-shaded region indicate the child is meeting auditory development milestones for his age and scores in the shaded region indicate the child is *not* meeting auditory development milestones for his age. Michael was meeting minimum auditory development milestones for his age prior to being fitted with amplification. While wear the hearing aids, Michael's scores improved to where he was showing progress and meeting auditory development milestones for his age.

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After experience with the hearing aids for one month, Michael's mother completed the LittEARS questionnaire thinking about Michael's auditory behaviours while wearing the hearing aids. The score was 13 at approximately six months of age, indicating that Michael was meeting *typical* auditory development milestones for his age in the aided condition (Figure 4-10). At the three-month hearing aid follow-up appointments, when Michael was nine and 12 months of age, he was still meeting auditory development milestones for his age with scores of 23 and 34, respectively, on the LittEARS (Figure 4-10). Since Michael's score on the most recent LittEARS exceeded a score of 27, which is considered the ceiling score for the UWO PedAMP, the PEACH was administered at his next followup appointment. He scored 75% on the overall, quiet, and noise subscales, which is in the target performance range for the PEACH (Figure 4-12). As discussed above, given that Michael was less than 2 years of age at the time of administration of the PEACH, performance on the tool may improve as he gets older. This example illustrates the result from the group analysis that some children may be too young for the PEACH and scores should be interpreted with caution. For this reason, our current recommendation is that the LittEARS should be administered until the child is at least two years of age and continues to meet the ceiling score criteria.

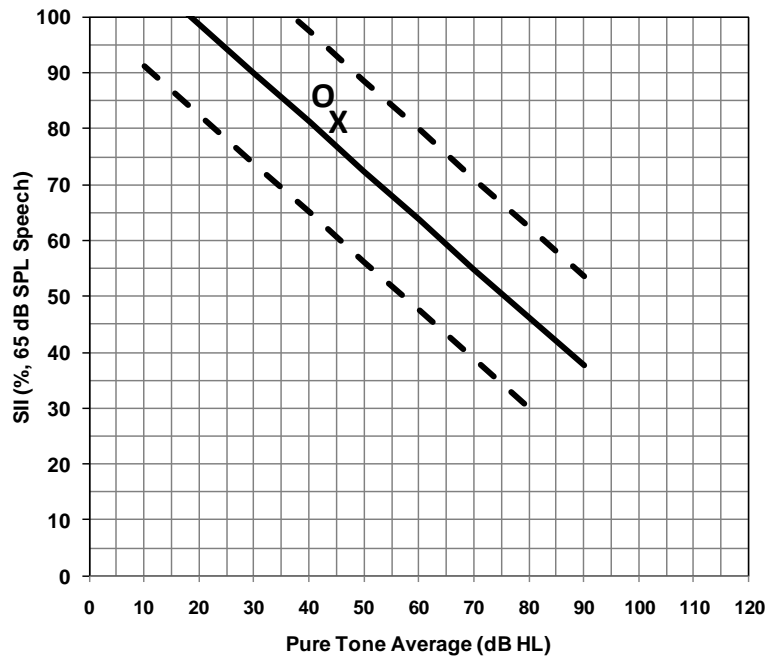


Figure 4-11: Aided SII values for Case Example: Michael. SII values (y-axis) for an average speech input are plotted for the right (O) and left (X) hearing aid fittings by Michael's PTA (x-axis). Since the symbols fall within the 95% confidence intervals (dashed lines), it can be concluded that Michael's hearing aid fitting is providing a typical degree of audibility for his degree of hearing loss, in both ears.

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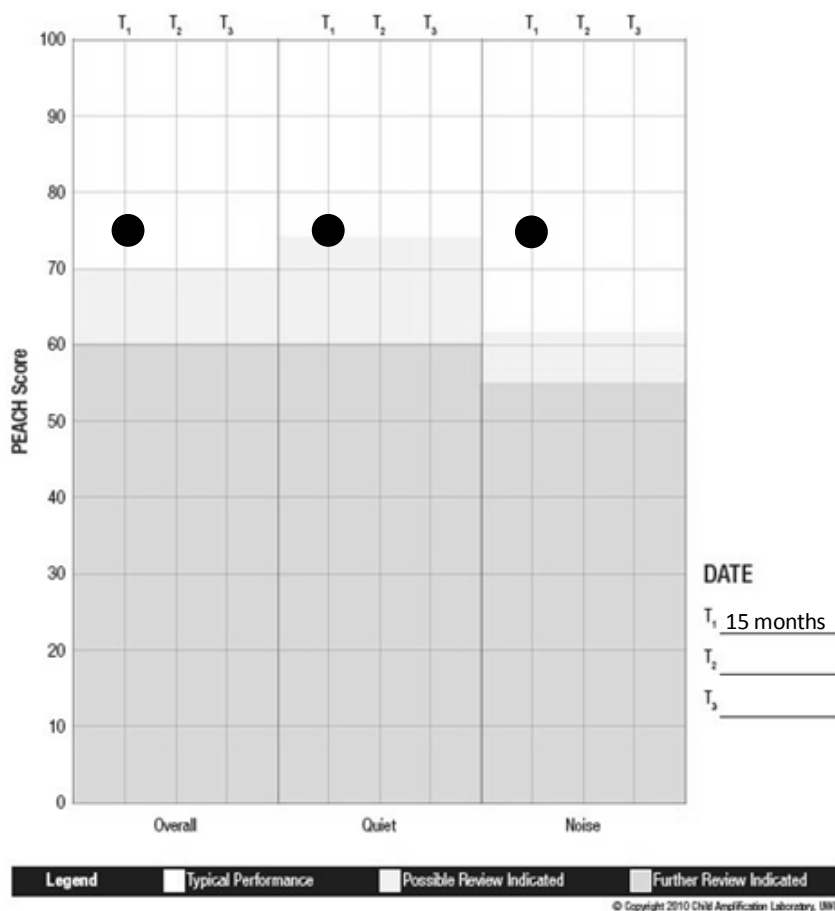


Figure 4-12: PEACH score sheet for Case Example: Michael. The PEACH percentage scores (y-axis) are plotted within each subscale (x-axis) for this case example. Results indicate the Michael is demonstrating typical auditory performance while wearing the hearing aids.

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Michael's results on the UWO PedAMP indicate that intervention with hearing aids (e.g., clinical process) and supporting communication development intervention resulted in functional outcome evaluation scores that show good auditory development and performance.

4.5.2 Case example 2: Emma

Emma was born full term without complications with no reported family history of hearing loss. She had her hearing screened at birth and did not pass in either ear. Her parents did not pursue follow-up hearing screening or further audiological assessment until they suspected an issue when Emma was four years old. This late identification and intervention is tracked as a “complex factor” in the present study. Emma was identified with a moderate to moderately-severe sensorineural hearing loss in the right ear and a moderate rising to mild sensorineural hearing loss in the left (PTA right = 51.7 dB HL; PTA left = 40.0 dB HL) and was fitted with hearing aids immediately. Following a fit to targets evaluation, the SII values were plotted on the Aided SII Normative Values Worksheet to conceptualize the audibility of the fitting relative to the normative data. Results indicated that the SII values for an average speech input (Right = 70%; Left = 75%; Figure 4-13) for Emma’s degree of hearing loss falls within the 95% confidence interval and therefore would be considered to have typical audibility. Therefore the clinician proceeded with using the functional outcome evaluation tools (i.e., LittleEARS, PEACH) with the knowledge that the hearing aid fitting was providing typical audibility for the child’s degree of hearing loss.

Emma is older than two years of age and has normal developmental status. Therefore, prior to being fitted with hearing aids, Emma’s mother completed the PEACH. Scores ranged from 65%, 70%, to 60% for the overall, quiet, and noise subscales, respectively, for the unaided condition (Figure 4-14). After two months of experience with the hearing aids, Emma’s scores on the PEACH increased to 80%, 91%, and 65% for the same subscales. With five months of hearing aid experience, Emma’s scores improved to 88%, 91%, and 85% on the overall, quiet, and noise subscales, respectively, (Figure 4-13). An improvement in the noise score may have coincided with the introduction of a noise management program. This was prompted by the child’s descriptions of problematic listening while in the shopping center, which may not have been a topic of discussion had the PEACH not been administered.

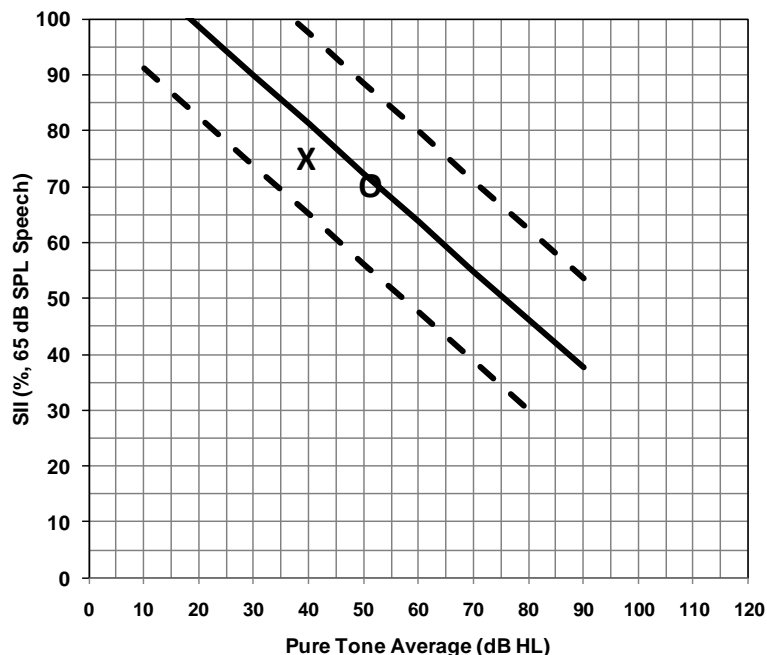


Figure 4-13: Aided SII values for Case Example: Emma. SII values (y-axis) for an average speech input are plotted for the right (O) and left (X) hearing aid fittings by Emma's PTA (x-axis). Since the symbols fall within the 95% confidence intervals (dashed lines), it is concluded that Emma's hearing aid fitting is providing a typical degree of audibility for her degree of hearing loss, in both ears.

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This demonstrates that the PEACH is sensitive to auditory performance in the unaided and aided conditions and shows progression in scores with more experience with hearing aids. In this case, a positive outcome with intervention was documented by systematically tracking the child's auditory performance over time. Although this child was late identified, which resulted in late intervention with hearing aids, initiating intervention that followed an evidence-based protocol improved the child's auditory performance compared to when intervention was not provided.

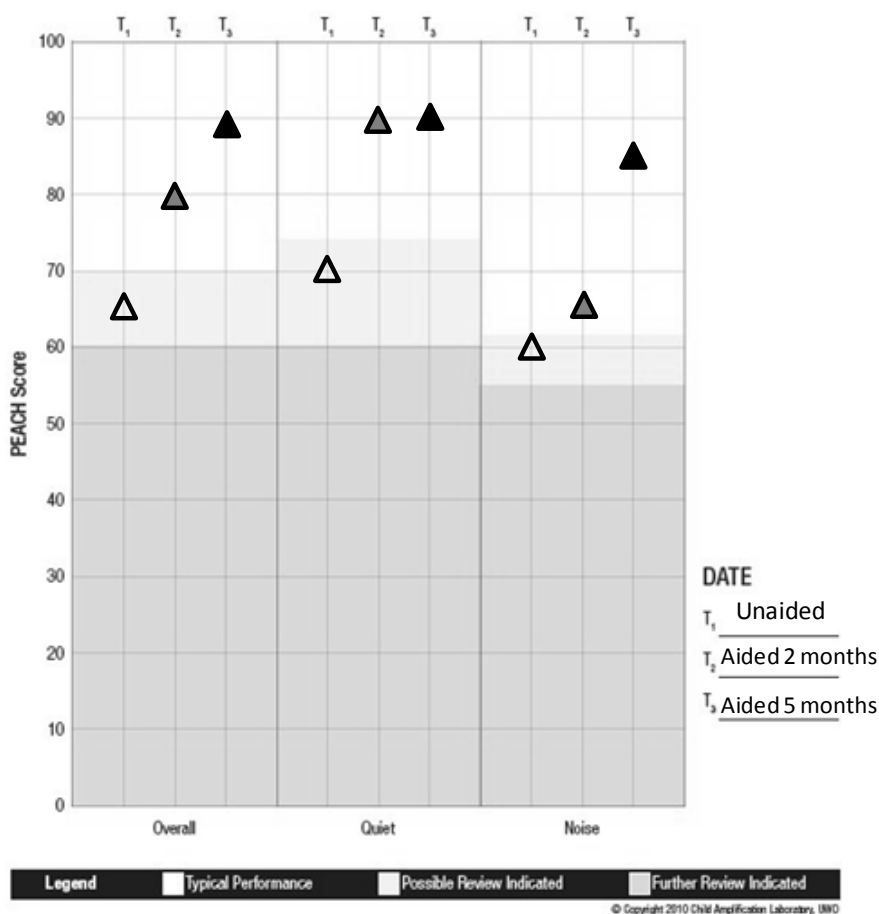


Figure 4-14: PEACH score sheet for Case Example: Emma. The PEACH percentage scores (y-axis) are plotted within each subscale (x-axis) for this case example. Open triangles indicate the unaided condition, hatched triangles indicate two months of hearing aid use and filled triangles indicate five months of hearing aid use. Results indicate that prior to the use of hearing aids, Emma was demonstrating atypical auditory performance. As she gained experience with amplification she demonstrated an improvement in auditory performance over time in all subscales.

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4.6 Summary and clinical implications

Outcome evaluation is a key stage in the pediatric hearing aid fitting process. An evidence-based and clinically feasible guideline for systematically measuring the impact of hearing aid intervention in infants, toddlers, and preschool children has been an

identified need in pediatric audiology (Moodie, et al., 2011). A critical review of existing pediatric outcome evaluation tools revealed some caregiver-report functional outcome tools that have the characteristics to be included in a clinical guideline as well as be implemented clinically (Bagatto, Moodie, et al., 2011). With input from the Network of Pediatric Audiologists of Canada, the systematically chosen tools were included in the UWO PedAMP (Moodie, et al., 2011). The first version of the UWO PedAMP includes outcome evaluation tools that aim to measure auditory-related outcomes in infants, toddlers, and preschool children who wear hearing aids, including subjective assessment of early auditory development (LittleEARS) and subjective ratings of auditory performance in daily life (PEACH). In addition, clinical process outcomes to assess the appropriateness of the hearing aid fitting are also included. Furthermore, their clinical implementation was supported by the data presented here along with administration guidelines and score sheets to help with interpretation. Overall, the work presented here will contribute to a better understanding of existing norms for the LittleEARS and the PEACH as well as provide a guideline for outcome evaluation for infants, toddlers, and preschool children who wear hearing aids. Further work has been completed to characterize the performance of a larger group of hearing impaired children with varying clinical profiles (see Addendum). This is necessary for EHDI programs where hearing aids are a common intervention choice for families and outcome evaluation is an important stage of the hearing aid fitting process.

4.7 Addendum: Updated results for the UWO PedAMP

4.7.1 Introduction

One limitation of the data presented in the work just described was the small sample size for children in each of the subgroups. Although there were 68 children with hearing aids involved in the initial analyses, they were divided into three groups (i.e., typically developing, comorbidities, and complex factors) to investigate potential contributing factors on outcome, which reduced the sample size for individual group analysis. Therefore, data collection continued in order to further characterize the auditory development and performance of children within the three subgroups. Following the submission of the first phase of this work for publication in April 2011, data collection at

the four clinical sites continued until October 2011. During this time, outcome measures were completed with existing participants as well as with newly-identified children with hearing loss who were fitted with hearing aids. The new data was combined with the previous data and is presented here. A detailed description of the participants as well as the analyses and results are provided.

4.7.2 Participants

The total number of participants involved in this work included 459 caregivers of children with various audiometric and medical profiles (mean age = 28.6 months; age range = 1.3 to 115.3 months). One hundred and twenty-four children were from the Toronto Region of the OIHP and 349 children were from the Southwest Region of the OIHP. Of the total children, 267 had normal hearing and 192 had permanent hearing loss. The purpose of including the normal hearing children was to evaluate existing normative values and clinical feasibility of the tools as seen in Chapters 3 and 5. Hearing losses ranged from mild to profound and were unilateral ($n = 38$) or bilateral ($n = 154$) sensorineural ($n = 142$) or permanent conductive ($n = 21$). Twenty children in this sample had ANSD and were not fitted with hearing aids at the time of inclusion in the study. One hundred and twenty-one of the children with PCHI were fitted with hearing aids and 71 had no hearing aids at the time of inclusion. Of the 121 children with hearing aids, five did not have outcome measures completed in the aided condition and were therefore not included in the analysis presented here. Therefore, 116 children with hearing aids were included in the overall analysis reported. Fourty-one of these children were from Humber River Regional Hospital, 24 were from Markham Stouffville Hospital, 16 were from Centenary Hospital, and 35 were from the H.A. Leeper Speech and Hearing Clinic at UWO. Children with hearing aids had hearing losses ranging from mild to profound, unilateral or bilateral sensorineural (pure tone average = 52.25 dB HL; range = 21.25 to 117.50 dB HL; see Table 4-3).

Table 4-3: Updated number of children with PCHI who wear hearing aids by hearing loss category (dB HL) and outcome evaluation tool.

Degree of PCHI	LittleEARS Data	PEACH Data	Number of Children	Number of Administrations
Mild (between 20 and 40 dB HL)	Bilateral = 15	Bilateral = 24	Bilateral = 29	84
	Unilateral = 2	Unilateral = 1	Unilateral = 2	
Moderate (between 41 and 55 dB HL)	Bilateral = 26	Bilateral = 26	Bilateral = 39	98
	Unilateral = 1	Unilateral = 1	Unilateral = 1	
Moderately-severe (between 56 and 70 dB HL)	Bilateral = 19	Bilateral = 19	Bilateral = 23	77
	Unilateral = 1	Unilateral = 2	Unilateral = 3	
Severe (between 71 and 90 dB HL)	Bilateral = 9	Bilateral = 11	Bilateral = 15	50
	Unilateral = 1	Unilateral = 1	Unilateral = 1	
Profound (91 dB HL or greater)	Bilateral = 2	Bilateral = 1	Bilateral = 2	6
	Unilateral = 0	Unilateral = 0	Unilateral = 0	
Number of Children	76	86	115	
Number of Administrations	126	189		315

Note: Some children have multiple data for the LittleEARS, the PEACH, or both that are not presented here. One child with PEACH data was missing hearing thresholds.

Similar to the work in the first phase, children with comorbidities and complex factors were included as well as typically developing children. Comorbidities included medical issues such as Down Syndrome, cerebral palsy, and genetic syndromes. Children in this study were identified as having a comorbidity based on clinician report. Children with comorbidities comprised 11.8% ($n = 54$) of the total sample. Of the 116 children fitted with hearing aids involved with the study, 23.5% ($n = 27$) had comorbidities. Complex factors included nonmedical complicating issues that may affect hearing aid outcome such as inconsistent hearing aid use and delayed hearing aid fitting. Approximately 40.9% ($n = 47$) of the hearing impaired children with hearing aids had complex factors in

this sample. This left 36.2% ($n = 42$) typically developing children from the total sample of children with hearing loss who wear hearing aids.

4.7.3 Results

4.7.3.1 Hearing aid fitting details

The RECD and MPO were both reported for 89.7% of the children involved in this study. The RECD was measured 37.9% of the time and predicted values were used 24.1% of the time. Reasons for using predicted values were most often due to excessive cerumen in the ear canal or a very active child. RECD values from the other ear were used 11.2% of the time for the ear with the better PTA. Previously measured values were used 16.4% of the time.

SII values for both soft and average speech inputs were reported for 113 out of 116 children (97.4%) with PCHI who wear hearing aids in this study. SII values for soft inputs had an average percentage of 63.1 (range = 12.0 to 99.0%). For average speech inputs, SII values were 72.2% on average (range = 21.0 to 98.0%). The SII values for average speech have been plotted within the Aided SII Normative Values Worksheet by degree of hearing loss (Figure 4-15). It can be seen that for the children involved in this study, the majority of the SII values for average speech are considered to be typical for the degree of hearing loss.

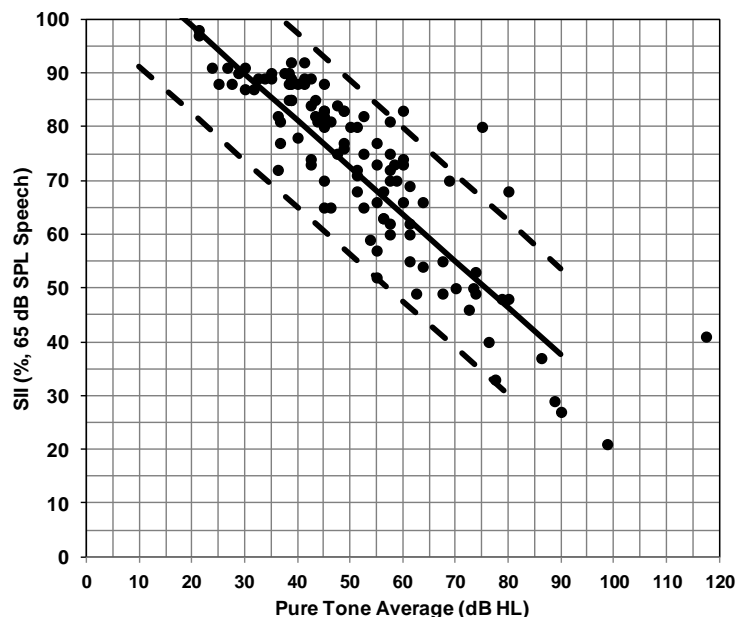


Figure 4-15: Updated SII values for average speech inputs by PTA for children with hearing aids involved in this study (filled circles; $n=113$). Solid and dashed lines are from the Aided SII Normative Values Worksheet. The solid line is the average SII normative values and the dashed lines are the upper and lower 95% confidence interval ranges.

4.7.3.2 Updated LittleEARS data from children with hearing loss who wear hearing aids

Of the total participant sample, 76 caregivers of children (mean age = 26.2 months; age range = 3.6 to 72.7 months) with PCHI who wear hearing aids were administered the LittleEARS a total of 126 times. Forty-two children received a single administration, and 34 children received repeated administrations, ranging in number from two to five longitudinal repetitions. For children with repeated administrations, the result from the first administration has been included in the current analyses. Many of the children in this sample were identified as having comorbidities (25.0%; $n = 19$) and complex factors (35.5%; $n = 27$). A total of 39.5% of children ($n = 30$) in this LittleEARS sample were typically developing and had no complex factors related to amplification (see Figure 4-16).

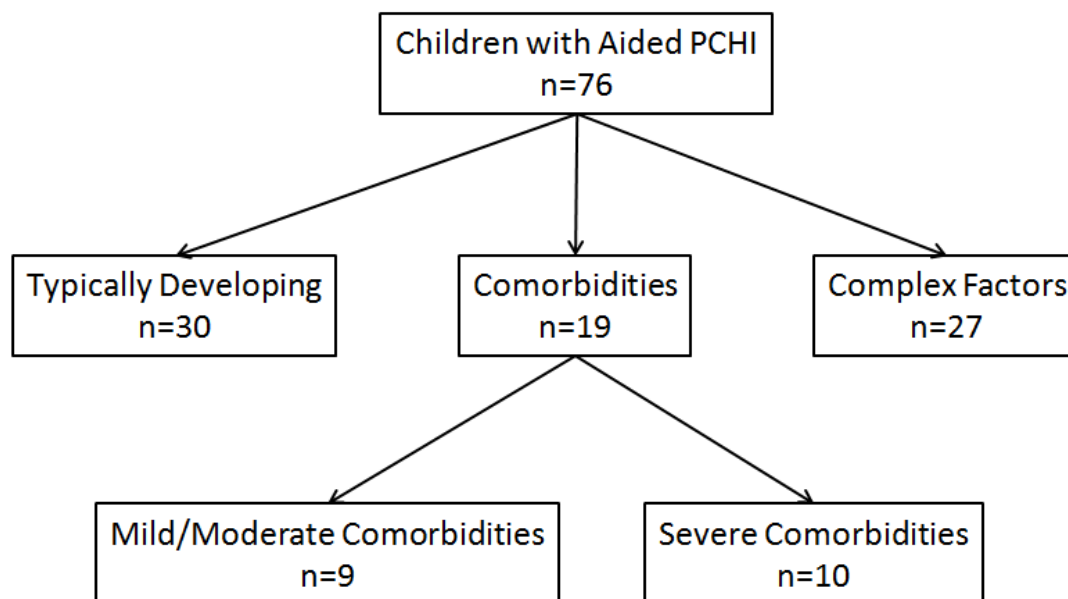


Figure 4-16: Updated subgroup flowchart for children with hearing aids whose caregivers were administered the LittEARS Auditory Questionnaire. Of the total sample with hearing aids, these children were grouped into those with typical development, comorbidities, and complex factors.

Children with comorbidities included those who were premature (i.e., born 37 weeks gestational age or earlier relative to a 40-week term) as well as those with other medical issues beyond PCHI. These children were further separated into a group with mild to moderate comorbidities ($n = 9$) and a group with severe comorbidities ($n = 10$). Children with severe comorbidities were born full-term and were indicated by the clinician to have a severe manifestation of a disorder or a syndrome causing multiple issues that could potentially interfere with auditory performance.

Caregivers' responses on the LittEARS once again indicated that children with severe comorbidities were not meeting auditory development milestones for their age. Their individual scores were less than 27 out of 35, regardless of age (see Figure 4-17), which replicates the results of the previous analysis. An attempt at curve estimation revealed no

significant trend for either linear or curvilinear estimations. Children with mild to moderate comorbidities were analyzed as a separate group.

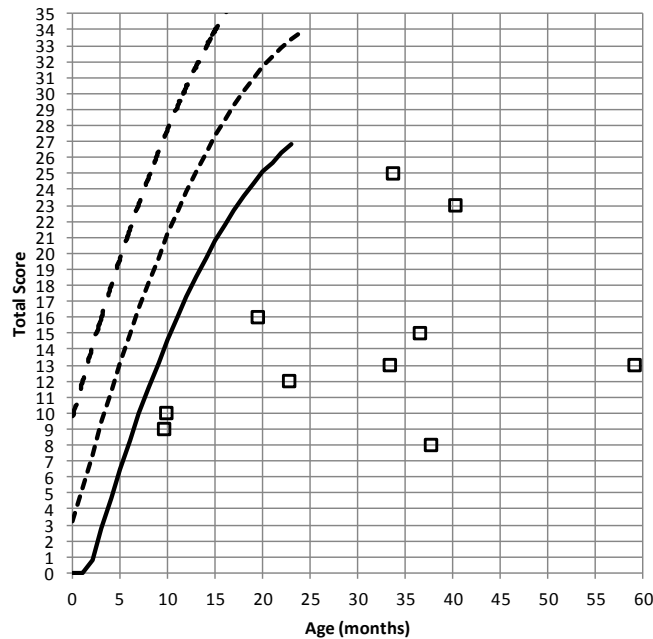


Figure 4-17: Updated LittEARS scores from children with hearing aids who were born full term and have severe comorbidities. The solid line indicates the minimum expected score, the small dashed line indicates the average expected score and the large dashed line indicates the maximum expected score from the German-derived norms. Open squares indicate LittEARS scores from children with PCHI who have severe comorbidities in this sample (n=10). Children with scores above the solid line are considered to be meeting auditory development milestones for their age and children with scores below the solid line are considered to not be meeting milestones.

4.7.3.2.1 Analysis 1

The LittEARS scores for the remainder of the children were grouped into the following categories prior to analyses: (a) typically developing, (b) mild to moderate comorbidities, and (c) complex factors. A regression analysis was conducted on the entire sample to characterize the cross-sectional trajectory of scores by age. An s-shaped curve provided a significant fit to the overall data ($R^2 = 0.44$; $F = 57.63$, $df = 75$, $p < 0.001$). With the

curvilinear effects of age removed, a univariate analysis of variance (ANOVA) was completed using the residuals to compare the effects of group (fixed factor) and PTA (covariate) on LittEARS scores (dependent variable). Results indicated a significant effect of group ($F(2, 76) = 8.26, p = 0.001, \eta^2 = 0.19$) and pure tone average ($F(1, 76) = 5.54, p = 0.021, \eta^2 = 0.07$). This provides a rationale for further analyses to be conducted on each group separately (i.e., typically developing, mild to moderate comorbidities, and complex factors).

4.7.3.2.2 Analysis 2

For all groups, an s-shaped function provided the best fit to the data (typically developing: $R^2 = 0.85; F = 155.02, df = 28, p < 0.001$; mild to moderate comorbidities: $R^2 = 0.90; F = 60.80, df = 8, p < 0.001$; complex factors: $R^2 = 0.60; F = 8.20, df = 13, p < 0.001$). Regression equations and curve fits can be found in Figure 4-18. Comparing the regression lines from each subgroup to each other as well as to the normative values (Figure 4-18) indicates that children who are typically developing are generally meeting auditory development milestones across age. In fact, 76.6% of the children (23 of 30) were considered to be meeting auditory development milestones for their age, as noted by the minimum normative values (Figure 4-18). Children with mild to moderate comorbidities appear to be performing in parallel, but have lower scores, compared to typically developing children. Finally, children with complex factors associated with hearing aid use show auditory development similar to the typically developing group up to about 12 months of age where their scores begin to decline compared to minimum normative data. This finding is somewhat comparable to the original analysis in the first phase, however, the trend for children with comorbidities in the current analysis mimics the trend for children with complex factors in the original analysis and vice versa.

Given the impact of PTA on scores noted in the ANOVA in Analysis 1, scores for children with a PTA of greater than 70 dB HL were removed from each subgroup. This cutoff was chosen as it approaches the hearing level candidacy criteria for cochlear implantation in children (Fitzpatrick, Olds, Durieux-Smith, McCrae, Schramm, & Gaboury, 2008). This left scores from children with a 70 dB HL or better PTA to be

further analyzed. Very few children in each subgroup had a PTA greater than 70 dB HL (e.g., four from the typically developing group), and the resulting curvilinear regression analyses were not significantly different compared to when those children were included.

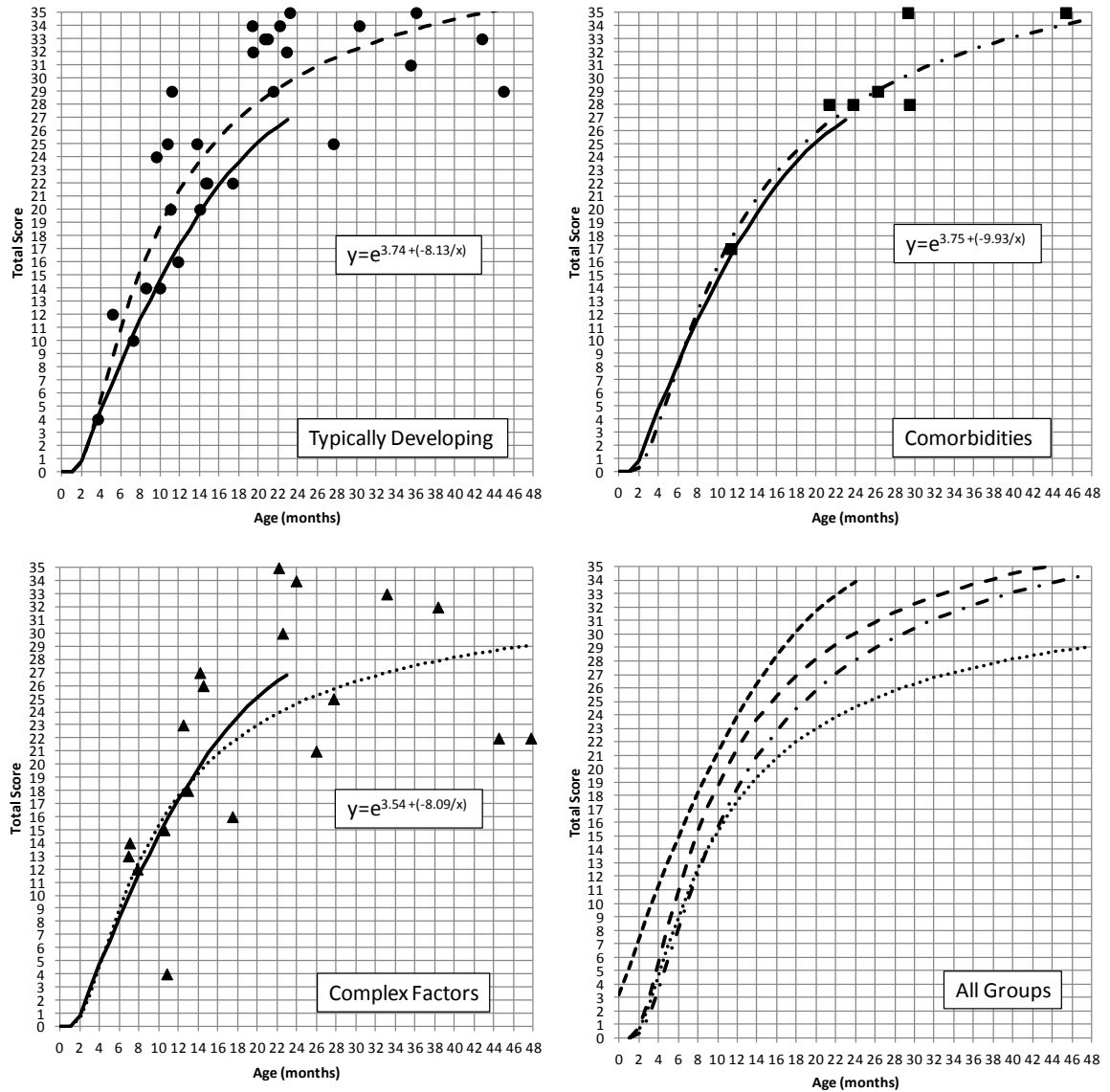


Figure 4-18: Updated LittleEARS scores (y-axis) by age (x-axis) and regression lines from children with hearing aids who: a) are typically developing and have no comorbidities or complex factors (filled circles; n=30); b) have mild to moderate comorbidities (filled squares; n=9); and c) have complex factors (filled triangles; n=27). The solid line represents the *minimum* normative values in each figure. The various lines indicate the regression for each set of data: a) large dashed, b) dotted-dashed, and c) dotted. Regression equations are noted within each figure. The fourth panel displays all regression lines on a single graph and compares them to the *average* normative values (small dashed).

4.7.3.3 Updated PEACH data from children with hearing loss who wear hearing aids

Eighty-six caregivers of children with PCHI who wear hearing aids (mean age = 44.0 months; age range = 11.2 to 107.1 months) were administered the PEACH a total of 188 times. Thirty-one children received a single administration, and 55 children received two to five repeated administrations of the PEACH. For children with repeated administrations, the result from the first administration has been included in the current analyses. As noted in the previous PEACH analysis, there was an age effect on overall PEACH scores for children younger than 24 months of age (Figure 4-9). This included only five children 24 months of age and younger who were included in the analysis. Therefore, the work was repeated with the new data set resulting in nine children who were 24 months of age and younger. Results were similar, with an age effect illustrated by an s-shaped curve ($R^2 = 0.19$; $F = 5.60$, $df = 25$, $p = 0.026$). When children older than 24 months of age were analyzed separately, a non-significant trend was noted, which further supports an effect of age on overall PEACH scores ($R^2 = 0.09$; $F = 1.57$, $df = 16$, $p = 0.229$). Regression equations are shown in Figure 4-19.

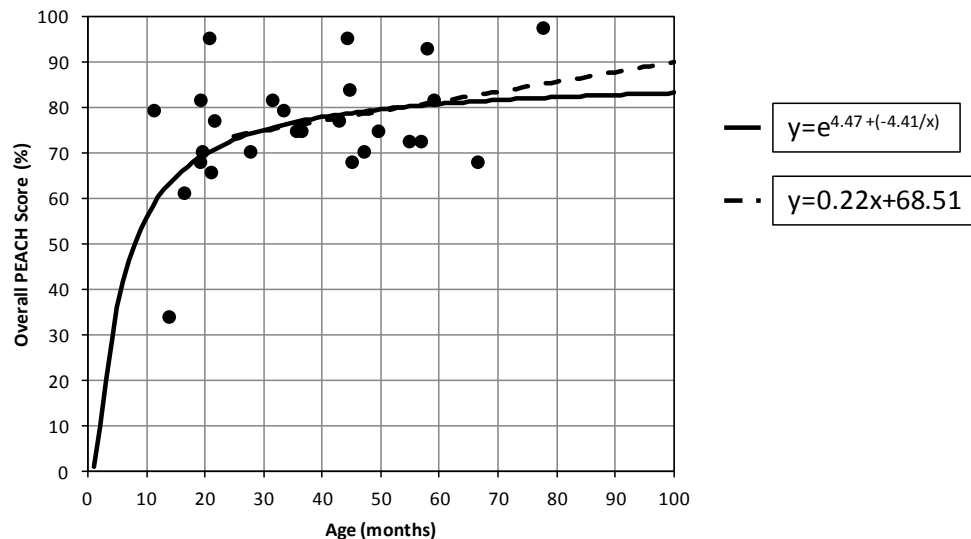


Figure 4-19: Updated PEACH scores (y-axis) by age (x-axis) and regression lines from typically developing children (filled circles; $n=28$) with hearing aids. The solid line is an s-shaped regression for typically developing children of all ages involved in this study. A nonsignificant linear regression is shown with the dashed line for typically developing children over the age of 24 months. Regression equations are noted in the

Due to this age effect, further analyses were completed with children older than 24 months of age. Of the children involved, 24.6% ($n = 16$) were born 37 weeks gestational age or earlier relative to a 40-week term and/or had other identified medical issues besides hearing loss (i.e., comorbidities). There were no children identified with severe comorbidities in this sample. In addition, 49.2% ($n = 32$) of the children were noted to have a complex factor related to amplification (i.e., inconsistent hearing aid use, delayed fitting due to late identification or other factors). The remaining 26.2% ($n = 17$) of children were full term, typically developing, early identified, enrolled early in programs of intervention, and did not have complex factors related to amplification.

Descriptive statistics are reported for children who are typically developing and older than 24 months of age (Figure 4-20). In addition, scores for children with comorbidities and complex factors are also included. The typically developing group had an average overall score of 78.7% ($SD = 9.26$) and average quiet and noise subscale scores of 81.4% ($SD = 11.70$) and 75.9% ($SD = 10.64$), respectively. These results were similar to previous analyses and indicate that children older than 24 months of age who were identified and fitted early with high-quality amplification and who are typically developing achieve high scores on the PEACH. In fact, the scores of children with hearing aids in this sample are approaching the high score of 90% achieved by normal hearing children by age three years. Children with comorbidities and complex factors demonstrated similar PEACH scores to each other, but both groups had lower scores and larger range of scores than children who were typically developing in this sample (Figure 4-20).

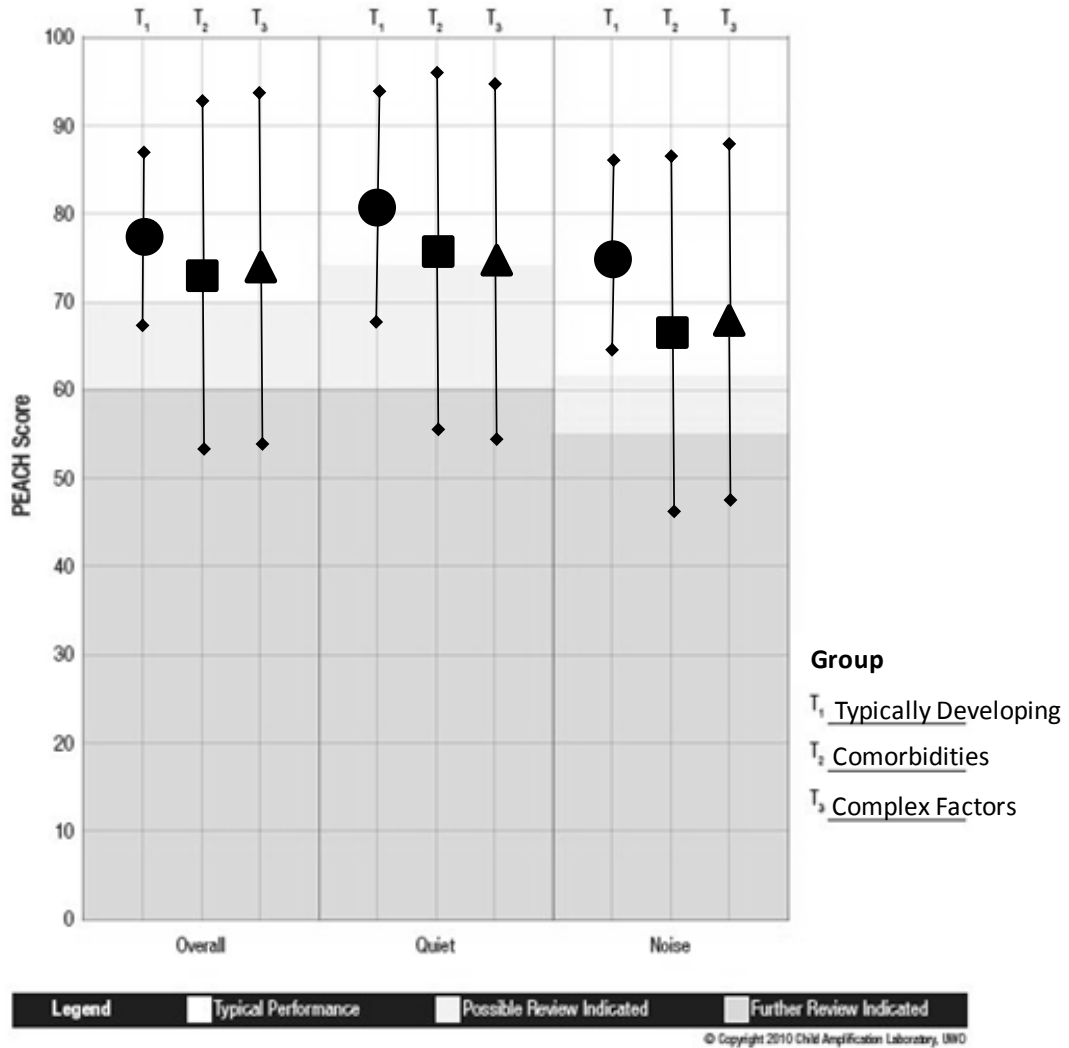


Figure 4-20: PEACH scores from the three subgroups: typically developing (circles; n=17), comorbidities (squares; n=16) and complex factors (triangles; n=32). Symbols represent average percentage scores for each subscale and vertical bars represent the standard deviation around the mean.

4.7.3.3.1 Analysis 1

A multivariate analysis of covariance (MANCOVA) was conducted to determine the impact of degree of hearing loss and complexity on the scores for the PEACH Quiet and Noise subscales. With complexity as a three-level independent variable (typically

developing, comorbidities, complex factors) and the degree of hearing loss as the covariate, results indicated that the multivariate effect of degree of hearing loss was significant, $F(2, 70) = 7.43, p < 0.05, \eta^2 = 0.179$, but complexity was not, $F(2, 70) = 0.37, p > 0.05, \eta^2 = 0.011$. Univariate effects confirmed that children who are typically developing or have complexities did not differ on their PEACH scores for either the Quiet, $F(2, 73) = 0.389, p > 0.05$ or the Noise, $F(2, 73) = 0.531, p > 0.05$, subscales. However, the degree of hearing loss was found to have a significant impact on PEACH scores for the Quiet, $F(1, 73) = 9.594, p < 0.05$, but not the Noise, $F(1, 73) = 1.027, p > 0.05$, subscales. This result is different from the previous analysis in that PTA does not have an impact on scores in the Noise subscale on the PEACH.

4.7.3.3.2 Analysis 2

Due to the impact of PTA on PEACH scores, a regression analysis was conducted on the entire sample to characterize scores by hearing loss level. This sample was not grouped by complexity (i.e., comorbidities or complex factors related to hearing aid use) because the previous analysis indicated no effect of group on PEACH scores. A linear regression provided the best fit to the data ($R^2 = 0.07; F = 4.99, df = 72, p = 0.029$), where the dependent variable was the overall PEACH score and the independent variable was PTA. The regression equation and the curve fit to the data can be found in Figure 4-21. It can be noted that overall PEACH scores decrease with increasing hearing loss and the lowest scores were obtained by children with comorbidities or complex factors.

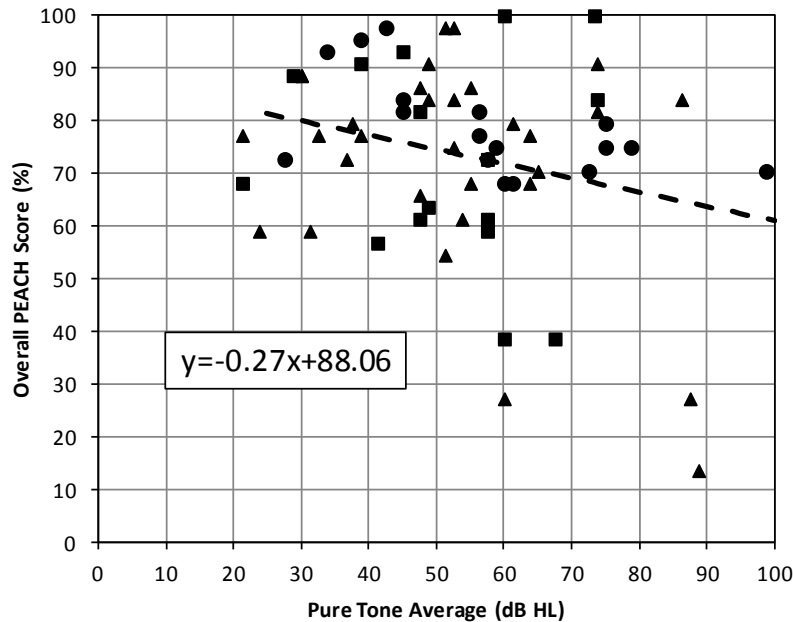


Figure 4-21: PEACH scores (y-axis) by PTA (x-axis) and regression line from typically developing children (circles; n=17), children with comorbidities (squares; n=16), and children with complex factors (triangles; n=32). The dashed line is the linear regression for all children older than 24 months of age involved in this study.

4.7.4 Discussion

This addendum further evaluated the pediatric outcome evaluation tools included in the UWO PedAMP. Following an additional six months of data collection, the total sample of children with hearing aids increased from 68 to 116. Further data collection was important because children involved in the study were divided into three subgroups for analyses: typically developing, other medical issues (comorbidities), or complex factors related to hearing aid use. Obtaining a larger overall sample size increased the number of children per subgroup. The complete data set included clinical process outcomes in the form of hearing aid fitting details as well as scores from functional outcomes obtained through caregiver report questionnaires (i.e., LittEARS and PEACH). The clinical process tools provided useful information for the interpretation of the functional outcomes measured by the LittEARS and the PEACH questionnaires. Variables such as

subgroup, age, and hearing loss level were investigated as potential predictors of outcome on each tool.

Similar to the previous data set, the majority of hearing aid fitting details were reported for the current sample. This reflects good adherence to hearing aid fitting protocols and provides evidence that the important elements of hearing aid verification (i.e., RECD, MPO, SII) were obtained. With the exception of a few outliers, the SII values fell within the typical range by degree of hearing loss. This information provides a glimpse of the quality of the hearing aid fitting, without the clinician needing to provide the exact fit to targets. This is unique compared to other studies of outcome of children with hearing aids where the *age* of hearing aid fitting was considered the important indicator of quality intervention, not *how well* the hearing aids were fitted. The clinician's judgment of the approximation of the output of the hearing aid to the prescribed target is considered a key component of hearing aid verification. The SII values offer a gross estimate of the audibility provided for pediatric hearing aid fittings and support the interpretation of scores on the functional outcome tools. By comparing the SII values of the fittings of the children involved in this study to normative values, the possibility of the impact of over- or under-amplification is removed as a variable impacting the child's functional outcome. Since the fittings in the current study are typical for the degree of hearing loss regardless of the presence of other medical issues or complex factors inherent to the child, good functional outcomes can be considered the result of good quality fittings. On the other hand, poorer scores displayed by children with comorbidities and complex factors are likely not due to a poor hearing aid fitting, but the impact of complicating factors related to the child. The reason for the outliers in the SII data is unknown, but it is possible that the children may have had middle ear dysfunction on the day of the fitting which prompted the clinician to apply a correction to prescriptive targets to account for a conductive overlay in the fitting (i.e., fluid in the middle ear space may result in increased hearing thresholds which requires an increase in hearing aid gain). The Aided SII Normative Values were derived from pediatric hearing aid fittings that did not have a conductive correction applied. Applying this correction results in increased prescribed gain compared to a pure sensorineural hearing aid fittings and therefore may increase the

SII values above the upper 95% confidence interval. Further work on the Aided SII Normative Values with different types of hearing aid fittings (i.e., conductive correction, frequency lowering technology), may result in different SII regions for different fitting situations.

Functional outcomes for the three subgroups were similar to the initial analyses. Children with severe comorbidities emerged again as subgroup within the comorbidities group. However, children with severe comorbidities had LittEARS data only; no children with PEACH data were identified as having severe comorbidities. This may be a result of the administration guidelines implemented for the questionnaires within the UWO PedAMP. Due to the infant-friendly items in the LittEARS and the fact that there is an age effect on PEACH scores for children younger than 24 months, it is recommended that the LittEARS be administered until a ceiling score is reached and the child is at least 24 months of age before administering the PEACH. Replicating the initial analysis, all children with severe comorbidities in this sample did not achieve the ceiling score of 27 or greater on the LittEARS. Therefore, the PEACH was not administered. It may be that some items on the LittEARS involve developmental milestones that children with severe comorbidities are not meeting, despite their having good auditory abilities (i.e., Does your child bring items when asked?). It may be appropriate to implement a maximum age cutoff for multiply-involved children given that they will be in more complex listening situations along with their typically developing peers (i.e., classroom settings). The PEACH includes questions about quiet and noisy environments which may provide useful information about different listening situations for children of a certain age, regardless of their developmental trajectory. Children with severe comorbidities are an intricate group and require further investigation to understand their patterns of auditory development and performance with hearing aids. Children with mild-to-moderate comorbidities appear to achieve lower overall scores on the LittEARS compared to typically developing children, but they progress in parallel to normative values. Further data collection to characterize the performance of children with less severe comorbidities remains a topic of future investigation.

Children with complex factors related to hearing aid use showed auditory development at the minimum normative range up until about 12 months of age when their scores began to decline. Further inspection of the raw data illustrates that there are two groups of children with complex factors: those who are meeting auditory development milestones and those who are not. Complex factors include situations such as inconsistent hearing aid use, delayed hearing loss identification, and delayed hearing aid fitting. Variation within each of these subgroups may have an effect on functional outcome. For instance, despite having a stated goal for when hearing aids should be fitted to children (i.e., by six months of age), it is unknown at what age the hearing aid fitting is considered to be *delayed*. Furthermore, the impact of degree of hearing loss on any of the above-mentioned factors could be significant. That is, inconsistent hearing aid use for a child with a severe hearing loss may have a more noteworthy impact on outcome in the early stages compared to a child who has a milder degree of hearing loss. Children identified as having complex factors related to hearing aid use are very common in the pediatric audiology population. This important subgroup warrants further study related to the variables associated within each unique complex factor.

When analyzing the different subgroups for the PEACH, once again the presence of a comorbidity or complex factor did not significantly impact PEACH scores. However, degree of hearing loss was shown to significantly affect scores on the Quiet subscale of the PEACH, but not the Noise subscale. This finding was different from the initial analysis which found hearing loss to significantly affect scores on both PEACH subscales. The larger sample size with the current analysis may have provided further information about the impact of noise on children involved in this study, regardless of whether or not they have another medical issue or complex hearing aid factor. An item analysis may provide further insight about the performance of children with different levels of hearing loss within the various listening situations included in the PEACH. This further work may help support clinicians' decisions about when to apply technologies to combat noise in the listening environment, for example.

Overall PEACH scores were impacted by degree of hearing loss: greater hearing loss meant poorer PEACH scores. A closer examination of the group data revealed that the poorest performers were children with comorbidities and complex factors and had a PTA of 60 dB HL or greater. As stated earlier, it may be that some complicating factors have more of an impact on outcome when hearing levels are worse. The current data set offers a small sample of these children and further investigation is required. An attempt to group children by degree of hearing loss for the LittleEARS data revealed very few children with a PTA greater than 70 dB HL. This cutoff was chosen due to its relevance to cochlear implant candidacy. However, given the finding from the PEACH data above, a cutoff around 50 or 60 dB HL warrants further investigation. The small number of children in the current sample with this degree of hearing loss may be a reflection of clinicians and/or caregivers referring for a cochlear implant evaluation based on degree of hearing loss. This requires further sampling of children with more severe hearing losses, given the sample size for these children in the current data set is small. Based on the results of the current analyses as well as the previous one, a sample of 20 to 30 children within each hearing loss category may allow for a more powerful analysis of scores by hearing loss level.

The current analysis replicated the age effect on overall PEACH scores, therefore the recommendation to administer to the LittleEARS until a ceiling score is reached and the child is older than 24 months of age before administering the PEACH is still supported. All children in this sample are being fitted with hearing aids following a systematic evidence-based protocol (Bagatto et al, 2010). The clinicians are implementing the protocol which is resulting in high-quality hearing aid fittings. As a result, the typically developing children are meeting auditory development milestones during the early stages of hearing aid use (i.e., LittleEARS) and displaying typical auditory performance as they get older (i.e., PEACH). These findings are significant in that they validate the previous stages of the hearing aid fitting process. Accounting for the child's auditory characteristics in an individualized and accurate way, selecting the appropriate hearing aid characteristics, and verifying the hearing aid's performance results in good auditory outcomes at both the early and later stages of hearing aid use. Although pediatric

audiologists see children with a variety of medical needs and complex external factors, a systematic way of evaluating their outcome is available through the UWO PedAMP. The guideline may be modified over time as new evidence develops so that objective outcome evaluation tools such as speech detection and discrimination tasks as well as early speech production measures (Moeller, 2011) can be included. Until then, clinicians have a systematic and evidence-based guideline with which to evaluate the auditory-related outcomes of the children they have fitted with hearing aids.

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Chapter 5

5 Validation of the Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Rating Scale⁷

5.1 Introduction

Outcome evaluation is a key component of the hearing aid fitting process for infants, toddlers, and preschool children. Tools for outcome evaluation should have characteristics such as good test-retest reliability, known normative properties, and should be feasible for use with a clinical population (Andresen, 2000; Cox, et al., 2000; Hyde, 2000). Recently, an outcome evaluation guideline for use with infants, toddlers, and preschool children up to six years of age was developed (Bagatto, Moodie, Malandrino, et al., 2011). The University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP) consists of clinical process outcomes (i.e., hearing aid verification information) as well as functional outcome measures in the form of caregiver report questionnaires. The development of the UWO PedAMP followed a knowledge-to-action process that evaluated the feasibility and utility of the guideline for clinical practice using interaction between developers, researchers, and clinicians. This supported the direct evaluation of its feasibility and utility in clinical practice (Graham, et al., 2006; Moodie, Bagatto, et al., 2011; Moodie, Kothari, et al., 2011). A critical review of existing pediatric subjective outcome evaluation tools was completed (Bagatto, Moodie, Seewald, Bartlett, & Scollie, 2011) and considered alongside clinician evaluations of each tool (Moodie, Bagatto, et al., 2011). Ultimately, two questionnaires were included in the guideline and are applied in a two-stage process by developmental level. The LittleEARS[®] Auditory Questionnaire (Tsiakpini, et al., 2004) is used for infants until a certain score and age criteria are met and the Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Rating Scale (Ching & Hill, 2005a) is used for toddlers and preschool children.

⁷ A version of this chapter was accepted for publication on March 8, 2012 (see Appendix I): Bagatto, M. P. & Scollie, S. D. (accepted March 8, 2012). Validation of the Parents' Evaluation of Aural/Oral Performance of Children (PEACH) Rating Scale, *Journal of the American Academy of Audiology*

The PEACH Rating Scale is based on the original Diary version (Ching & Hill, 2005b), which has published reliability and sensitivity data, normative values for normal hearing children, as well as normative and responsivity data for children with hearing loss who wear hearing aids (Ching & Hill, 2007; Ching, Hill, & Dillon, 2008; also see review in Bagatto, Moodie, Seewald et al, 2011). Limitations to the feasibility of the PEACH Diary version include challenges for caregivers to complete it at home and the time required to complete a follow-up clinical interview (Golding, et al., 2007; Moodie, Bagatto, et al., 2011). The PEACH Rating Scale is comprised of the same items as the Diary version, however, does not require the caregiver to systematically observe the child for a week nor is the clinician required to conduct the follow-up interview. The Rating Scale is designed to be completed by the caregiver during the clinical appointment and responses are obtained with a five point rating scale. Clinicians involved with the development of the UWO PedAMP preferred the Rating Scale version compared to the Diary version of the PEACH (Moodie, Bagatto, et al., 2011). Therefore, the PEACH Rating Scale was included in the UWO PedAMP due to its greater feasibility which supports clinical uptake. However, evaluation of age-related normative trends using the PEACH Rating Scale are not currently available.

Given the similarity of the items but differences in administrative format in the Diary and Rating Scale versions of the PEACH, we were interested in whether the normative data published for the Diary version would be replicated by the Rating Scale version. Therefore, the purpose of this study was to explore the use of existing PEACH Diary normative data relative to the PEACH Rating Scale for normal hearing children using a cross-sectional convergent validation research design. Additionally, it was of interest to examine the internal consistency of the PEACH Rating Scale to ensure that the items measure the same construct (i.e., functional auditory behaviours).

5.2 Method

5.2.1 Participants

The PEACH Rating Scale was administered to caregivers of normally hearing children recruited from the H.A. Leeper Speech and Hearing Clinic at the University of Western

Ontario in London, Ontario, Canada or the university daycare. Children recruited from the university daycare responded to an advertisement posted in the daycare. Children recruited from the clinic were either seen as part of a speech and language monitoring appointment or within a regular audiology assessment appointment. Children recruited from speech and language monitoring were not enrolled in formal speech/language therapy but had been assessed and discharged the year prior. Ethics approval for the study was obtained through the University of Western Ontario Office of Research Ethics for the H.A. Leeper Speech and Hearing Clinic and the university daycare and caregivers signed a consent form prior to participating in the study (see Appendix C).

A hearing screening was completed with the children from the daycare and those seen for speech and language monitoring (American Speech-Language-Hearing Association, 1997), and the children seen for audiology assessment had their hearing assessed using provincial protocols (Ontario Ministry of Children and Youth Services, 2008). If hearing status was normal in both ears, the caregiver of the child completed the PEACH Rating Scale during the same appointment with the audiologist present. The PEACH was administered to caregivers of 59 children aged two to 83 months (mean = 32.17 months). Clinicians followed the PEACH Rating Scale instructions by guiding the caregivers to think about their child's auditory behaviours over the past week related to the eleven items on the tool. The caregivers independently rated the frequency of the auditory behaviours using the scale provided. Figure 1 shows the distribution of age of the children. Of the children involved in this study, 34 were males and 25 were females. All of the children were born full term and were typically developing, according to caregiver report.

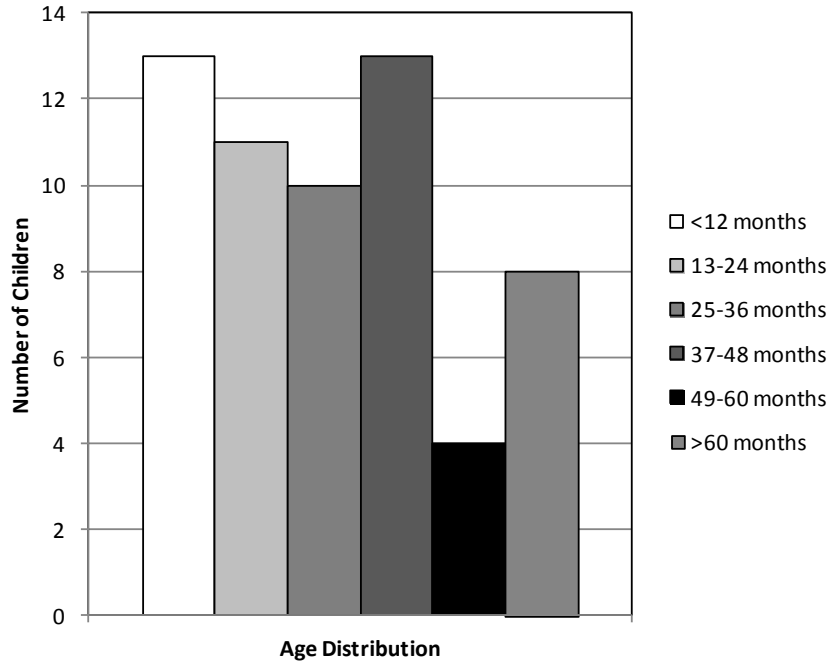


Figure 5-1: Age distribution of normal hearing children involved in this study.

5.2.2 Materials

The English version of the PEACH Rating Scale was administered in this study. The PEACH Rating Scale is comprised of 13 items designed to assess the child's auditory performance in both quiet and noisy listening situations. Each item is rated on a five point rating scale which has a value from zero to four assigned to it. Rating categories include both a word and a numeric value ranging from Never (0%) to Always (75-100%). The first two questions relate to the frequency of hearing aid use and whether the child displays discomfort to loud sounds while wearing his/her hearing aids. These items provide background about hearing aid use and are not included in scoring (Ching and Hill, 2005a). Given the children involved in this study did not wear hearing aids, the first two items were not completed by the caregivers involved in this study. Therefore, items three through 13 were completed by the caregiver who rated the frequency with which they observed their child's behaviour in a particular scenario over the past week. Items three through 13 are scored for an overall score, and also subscored into subscales for quiet (items 3, 4, 7, 8, 11 and 12) and noisy environments (items 5, 6, 9, 10 and 13).

Caregivers of young infants were asked to provide developmentally appropriate responses, given the age of the child and the question being asked. For instance, item 12 asks: “How often does your child successfully use a phone?” Successful telephone use will mean different things for different age groups, therefore, the caregivers were asked to rate it based on appropriate telephone behaviour for the developmental level of their child.

5.3 Results

The majority of the children (57 of 59) recruited for the study passed the hearing screening and the caregivers completed the PEACH Rating Scale following the screening. A total of two children initially had a refer result on the hearing screening in one ear. When this occurred, immittance measures were conducted in both ears. Results for both children indicated middle ear dysfunction in the ear that did not pass the pure tone screening. In this case, the caregiver did not complete the questionnaire and both children were rebooked in four to six weeks for a repeat screening. At the repeat screening, both children passed the pure tone screening in both ears and the caregiver completed the questionnaire. All 59 caregivers completed the entire PEACH questionnaire; no items were left unanswered.

Upon completion of the questionnaire, an overall score was calculated by adding together the scores associated with the rating category and dividing by the maximum total score possible (i.e., 44) to obtain an overall percentage score. Overall scores ranged from 0 to 100% with a mean score of 73.3%. Cronbach’s alpha equaled 0.78 which exceeds the 0.70 acceptable criteria for internal consistency. This is a measure of reliability indicating that questionnaire items measure the same overall construct (i.e., functional auditory behaviours). Further analyses of normative trends followed those used in the normative paper describing age-related scores for the PEACH Diary (Ching & Hill, 2007). Specifically, a logistic regression analysis was performed with age as the independent variable and the overall PEACH score as the dependent variable. The regression equation from these data is shown in Equation 1.

$$\text{Equation 1: } y = (\sin((2.395 * \exp(-0.85 + 0.18 * x)) / (2 * (1 + \exp(-0.85 + 0.18 * x))))^2;$$

where x = age and y = total score.

This logistic function accounted for 62% of the variance and forms a curvilinear relationship between age and overall PEACH score (Figure 2). Infants younger than about 20 months achieved low overall scores which rose to around 85% by about 30 months of age. The previous norms suggest a similar finding, where the logistic function reached asymptotic scores by 40 months of age (Ching & Hill, 2007). The logistic regression equation from the original normative curve was obtained (Ching, personal communication January 2012), allowing for a direct comparison of the original normative curve to the current curve. The correlation between the two curves was significant ($r = 0.98$, $p < 0.001$), indicating that the two curves were highly similar.

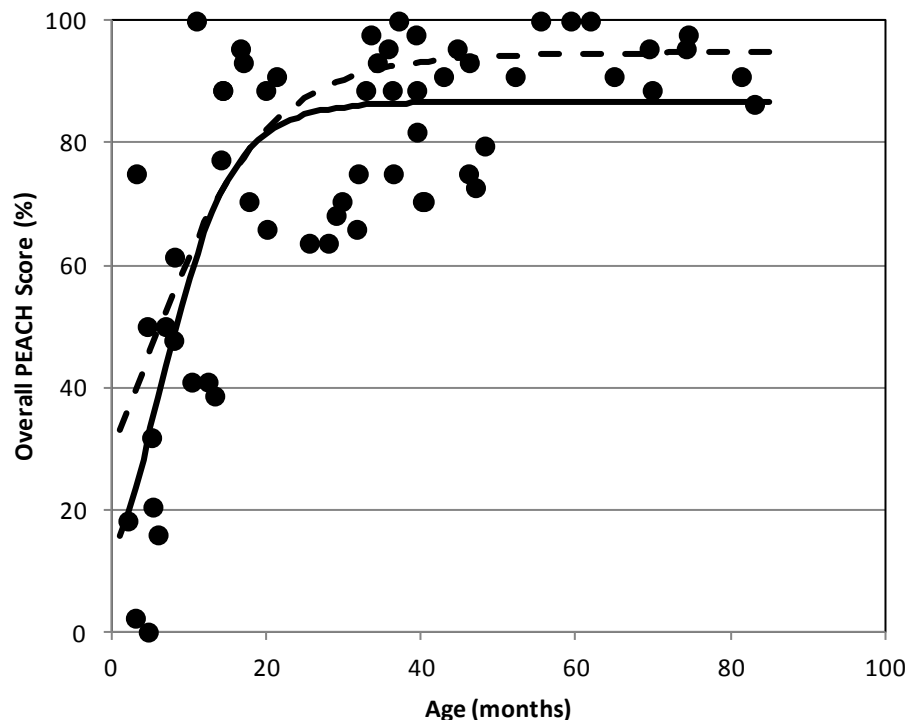


Figure 5-2: PEACH Rating Scale validation data from normal hearing children compared to the original normative data from Ching & Hill (2007). Filled circles are the overall PEACH percentage scores (y-axis) plotted by age in months (x-axis). The solid line represents the logistic regression curve developed from the current study (equation in text). The dashed line represents the original PEACH normative curve. When compared, the curves had a correlation coefficient of $r = 0.980$ ($p = 0.000$).

5.3.1 Effects of demographic variables: Age group and gender

Ching and Hill (2007) reported low scores on the PEACH below age 40 months. This finding was replicated in the current data set, with a visual analysis of Figure 2 indicating a change in scores approximately above and below 20 months of age. An independent samples t-test was conducted to evaluate scores between two groups of children: those 20 months of age and younger ($n = 23$) and those older than 20 months ($n = 36$). Between groups, the Levene's test of equality of variance was violated ($F = 32.436$, $df = 57$, $p < 0.001$). With equal variances not assumed, overall PEACH scores between age groups were significantly different ($t(26.129) = -4.597$, $p < 0.001$). Children in the younger group had significantly lower scores (mean = 54.8, $SD = 30.9$) than children in the older group (mean = 85.8, $SD = 11.8$).

The effects of gender were also evaluated. A two-tailed independent samples t-test was conducted and the Levene's test for equality of variances was violated ($F = 8.671$, $df = 57$, $p = 0.005$). With equal variances not assumed, no significant differences between scores obtained by females compared to males involved in this study were noted ($t(38.126) = 1.304$, $p = 0.200$).

5.4 Conclusions

The PEACH Rating Scale is a caregiver report questionnaire that evaluates real-world hearing performance in quiet and noisy listening situations. The Rating Scale version of the PEACH was previously found to have higher clinician-rated feasibility compared to the previously published Diary version, and was therefore selected for inclusion in the recently developed UWO PedAMP guideline (Bagatto, Moodie, Seewald, et al., 2011; Moodie, Bagatto, et al., 2011). This study evaluated the convergent validity of the PEACH Diary norms using the PEACH Rating Scale. Caregivers of 59 infants, toddlers, and preschool children with normal hearing completed the PEACH Rating Scale. Overall scores were plotted by age and a logistic regression was developed to describe the data. The resulting function was strongly associated to the previously published normative age trend obtained with the PEACH Diary version (Ching & Hill, 2007), with scores for children 20 months and younger being significantly lower compared to children older

than 20 months. High scores close to 85% were noted at around 30 months of age, which agrees closely with the previously published norms. The authors of the PEACH indicated that a score of 90% by three years of age is a reasonable goal when using this questionnaire. The current work supports this benchmark and the norms obtained with the PEACH Diary appear to be appropriate to apply when using the PEACH Rating Scale. Additionally, further analysis with the PEACH Rating Scale indicated that it has good internal consistency and scores are independent of the gender of the child.

The strong age-related trend in scores for both the PEACH Diary and Rating Scale versions has implications for use in clinical practice. The developers of the PEACH suggest computing age-corrected scores for younger children, which allows comparison of a younger child's score with the average normal hearing score for age-matched peers (Ching & Hill, 2007). An alternative strategy is used within the UWO PedAMP. Specifically, the PEACH Rating Scale is not administered until the child is older than 24 months of age (Bagatto, Moodie, Malandrino, et al., 2011). Prior to this age, the LittEARS questionnaire is used, as it was specifically designed for use within the zero to 24 month age range (Bagatto, Moodie, Malandrino, et al., 2011; Bagatto, Moodie, Seewald, et al., 2011). Either strategy allows age-appropriate interpretation of a child's scores against the age-related normative score for the PEACH. However, they have different advantages and disadvantages. Using age-corrected PEACH scores allows the clinician to use one tool across all ages, but requires item modification to ensure that items are described in a developmentally appropriate manner, and requires further calculations to perform the age corrections for scoring. Using the PEACH and LittEARS in combination avoids additional age correction in scoring and ensures use of developmentally appropriate questionnaire items, but does require using two different tools at different ages.

Recently, we evaluated the two-stage method of using the LittEARS and PEACH in combination (Bagatto, Moodie, Malandrino, et al., 2011) with children who have hearing loss who wear hearing aids. Children who reached the ceiling score on the LittEARS but were younger than 24 months of age performed poorly when the PEACH Rating Scale was administered. This is consistent with the age-related trend reported in the current

study and by Ching and Hill (2007). For a comprehensive review of the two-stage method see Chapter 4.

In summary, the validity of the PEACH Diary norms was confirmed using the PEACH Rating Scale in this study. The results of the present study further support the use of the PEACH Rating Scale within evidence-based outcome evaluation guidelines like the UWO PedAMP. Since the PEACH Rating Scale was rated more highly by clinicians (Moodie, Bagatto, et al., 2011) and provides similar normative properties to the PEACH Diary version, further evaluation and clinical use of the Rating Scale for children with hearing loss is warranted. Further study is needed to fully characterize performance on the PEACH Rating Scale considering severity of hearing loss and other medical issues. Recent data have begun to describe the early evaluation of its use in children who have hearing loss, including those who are typically developing, have other medical issues besides hearing loss, and who have known complex factors related to hearing aid use (Bagatto, Moodie, Malandrino, et al., 2011).

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Chapter 6

6 Summary, implications, limitations, and future directions of the current work

6.1 Summary

This work involved the development and evaluation of an outcome evaluation guideline for infants, toddlers, and preschool children with permanent childhood hearing impairment (PCHI). Although outcome evaluation tools exist for this population, some lacked well-developed norms, validation data, or were not part of a systematic clinical guideline. The work presented here described a procedure for selecting subjective outcome evaluation tools for infants, toddlers, and preschool children who have hearing loss (Chapter 2), offered validation data for the chosen tools (Chapters 3 and 5), as well as characterization data for children with hearing loss who wear hearing aids (Chapter 4). Through this repeated measures longitudinal observational study, a guideline known as the University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP) was developed and implemented with a naturally-occurring population of children with hearing loss. This fostered clinical data collection by experienced pediatric audiologists with children who were typically developing as well as those who had other medical issues besides hearing loss. This unique attribute led to a description of auditory development and performance for the children who are usually seen in audiology clinics. Additionally, an understanding of clinical process outcomes related to hearing aid verification was gathered through the use of a newly developed tool included in the UWO PedAMP (i.e., Aided Speech Intelligibility Index [SII] Normative Values Worksheet). Systematically gathering hearing aid fitting details provided information about the quality of the hearing aid fitting in order to support the interpretation of the functional outcomes measured with the subjective questionnaires.

The development of the UWO PedAMP, and its subsequent evaluation, has provided further evidence for the use of the LittleEARS and Parents' Evaluation of Aural/Oral Performance of Children (PEACH) questionnaires with a clinical pediatric audiology population as well as highlighted the importance of gathering hearing aid fitting details.

Through the course of this work, visual tools to permit rapid scoring of the questionnaires and hearing aid fitting characteristics fostered the clinical implementation of the UWO PedAMP in pediatric audiology clinics. It is hoped that through the research evidence provided in addition to the accompanying practical tools, the UWO PedAMP may facilitate the routine use of outcome measurement by pediatric audiologists.

6.2 Research aims

The purpose of the current work was to identify appropriate subjective outcome evaluation tools for inclusion in an outcome evaluation guideline for infants, toddlers, and preschool children who wear hearing aids and to subsequently evaluate the chosen tools to determine their usefulness for the population of interest. Specifically, Chapter 2 aimed to discover auditory-related subjective outcome evaluation tools for infants, toddlers, and preschool children and determine which ones were of good quality. Good psychometric properties as well as clinical feasibility were considered important elements when choosing the tools (Andresen, 2000). Following this task, Chapters 3 and 5 sought to validate whether the existing norms for the chosen questionnaires were appropriate for use with Canadian English-speaking normal hearing children. This work further contributed to the statistical properties of the chosen tools. Chapter 4 provided a description of the UWO PedAMP, how it was used to collect clinical data with children who wear hearing aids, and their performance on the questionnaires. Additionally, the performance of children with comorbidities and complex factors related to hearing aid use was studied.

6.3 Summary of findings

Overall, the results of this investigation reveal two caregiver report questionnaires that were suitable to include in an outcome evaluation guideline for infants, toddlers, and preschool children with hearing loss who wear hearing aids (Chapter 2). The LittleEARS Auditory Questionnaire (Tsiakpini, et al., 2004) assesses auditory development in the early years of life. The PEACH Rating Scale (Ching & Hill, 2005) assesses auditory performance and is suitable for children older than 24 months of age. Both questionnaires were deemed to be feasible for clinical use (Moodie, et al., 2011) and are supported by

good statistical properties. The normative values for both the LittleEARS and the PEACH were validated in the current work and were found to be appropriate for use with the Canadian English-speaking normal hearing population (Chapters 3 and 5). The questionnaires were included in the UWO PedAMP to measure functional outcomes and were supported by process outcomes in the form of hearing aid fitting details. With the use of the UWO PedAMP in a clinical setting, outcomes of children with hearing loss who wear hearing aids were investigated (Chapter 4). Results indicated children who are typically developing and have been fitted with hearing aids using evidence-based protocols displayed typical auditory development and performance when compared to their normal hearing peers. Furthermore, children with comorbidities displayed borderline normal auditory development through the LittleEARS, which showed a parallel progression as they got older. Children with complex factors related to hearing aid use displayed a similar pattern to children with comorbidities up to the age of 12 months where their auditory development began to decline. The impact of comorbidities and complex factors were not significant when assessing auditory performance with the PEACH, however, degree of hearing loss was significant for the overall group: as hearing loss increased, scores on the PEACH decreased. In addition, there was an age effect on scores for the PEACH which supports the recommendation to administer it when a certain score on the LittleEARS is obtained *and* when the child is at least 24 months of age. Further results of this work demonstrate that the UWO PedAMP can be used in a clinical setting to evaluate the outcome of hearing aid fitting to infants, toddlers, and preschool children. This is a necessary contribution to the field since outcome evaluation guidelines for this population are lacking.

6.4 Clinical implications

Evidence from this study suggests that typically developing children who wear hearing aids fitted using an evidence-based protocol demonstrate auditory development and performance similar to their normal hearing peers. This is a significant finding as it supports the clinical procedures that pediatric audiologists have been implementing for almost three decades. The Desired Sensation Level (DSL) Method has been researched and refined for clinical implementation over the past 30 years (Bagatto, et al., 2005;

Scollie, et al., 2005; Seewald, Moodie, Scollie, & Bagatto, 2005). Clinicians worldwide follow evidence-based protocols based on the DSL Method to fit hearing aids to children who have hearing loss. The DSL Method has supported three of the four stages of the hearing aid fitting process: the integration of infant hearing assessment procedures (i.e., auditory brainstem response [ABR], real-ear-to-coupler difference [RECD]) for hearing aid fitting, the selection of pediatric-friendly hearing aid features, prescriptive targets to maximize the child's ability to hear speech comfortably, and clinical procedures to verify that the hearing aid output is meeting the targets. The current work with the UWO PedAMP provides the clinician with a systematic and evidence-based way of evaluating the outcome of the first three stages of hearing aid fitting process. The children in this study were fitted with hearing aids using a provincial protocol (Bagatto, Scollie, Hyde, & Seewald, 2010) based on the DSL Method. The results of the current work have essentially validated the impact of this protocol for a clinical population. This further supports the work that clinicians do with their young patients who wear hearing aids.

The findings from this work also enhance our understanding of how children with comorbidities and complex factors related to hearing aid use perform with hearing aids. In the current study, children in these groups wore hearing aids fitted using the same provincial protocol as typically developing children (Bagatto, et al., 2010). Modifications to the output of the hearing aid were not required when a child had cerebral palsy, for example. Therefore, the hearing aid intervention for any given child was provided based on the child's degree of hearing loss, and the output (i.e., SII) was not modified based on comorbidities or complex factors. This means that every child involved in this study had access to speech through the use of high-quality hearing aid fittings. However, the children identified with comorbidities or complex factors did not perform as well as typically developing children in the early stages of auditory development, despite their good quality hearing aid fittings. Children with comorbidities displayed an overall delay in auditory development that progressed with time, but remained on the borderline of normal. Children with complex factors demonstrated a ceiling score around 12 months of age that did not resolve with time. These findings have implications for how clinicians counsel caregivers of children who are not typically developing. For example, consistent hearing aid use may have an impact on the child's outcome with hearing aids (Moeller,

Hoover, Peterson, & Stelmachowicz, 2009). Knowing how these children perform can provide the clinician with some evidence to support their counseling efforts with the child's caregiver, which may lead to more consistent hearing aid use and ultimately more favourable outcomes for the child. This work has significant clinical implications for the children that are often seen in audiology clinics.

Another important clinical implication is that the nature of the UWO PedAMP supports its use with a naturally-occurring clinical pediatric audiology population. This is significant because 25 to 40% of the children seen in audiology clinics have other medical issues besides hearing loss (Tharpe, Fino-Szumski, & Bess, 2001). This was also reflected in the overall participant pool gathered in the current study (see Chapter 4). The introduction of a guideline that is both supported by evidence and clinically feasible to implement are important characteristics of an outcome evaluation guideline (Andresen, 2000). The companion study to this work examined the use of the UWO PedAMP by a network of pediatric audiologists in Canada (Moodie, et al., 2011). Using an integrated knowledge translation approach (Graham, et al., 2006), pediatric audiologists were engaged in the development and refinement of the guideline from its inception. This helped foster clinical feasibility and uptake of the guideline (Moodie, et al., 2011). This unique aspect of the UWO PedAMP advanced the implementation of the guideline within the Ontario Infant Hearing Program, as well as other jurisdictions in North America, Europe, the United Kingdom, and New Zealand. Due to its scientific rigor and clinical feasibility, the UWO PedAMP may be included in future hearing aid fitting guidelines as a model for outcome evaluation for infants, toddlers, and preschool children in Early Hearing Detection and Intervention (EHDI) programs around the world. The UWO PedAMP completes the hearing aid fitting process by systematically evaluating the outcome of the previous three stages of the process. Outcomes can be examined at the child level and at the program level using the UWO PedAMP. Although tracking the performance of an individual child is important for the family as well as the clinician, examining outcomes of the EHDI program overall may support areas such as the refinement of existing protocols, attainment of future funding, and reporting of outcomes for the program as a whole.

Another noteworthy clinical contribution of this work is related to the caregivers of the children with hearing loss. Given that the tools included in the UWO PedAMP are subjective in nature, the caregiver is the respondent. This requires the caregiver to observe and reflect on their child's auditory behaviours on a regular basis. As a result, the caregiver may become a skilled observer of their child's auditory performance in real life and across developmental stages. Activities such as this include the caregivers in a meaningful way in their child's intervention services (Harrison & Dannhardt, 1996). A shared language may be developed between the clinician and the caregiver, which may further build rapport with the family. Caregiver engagement may be enhanced as a result, which is known to be important for the consistent use of hearing aids in children (Harrison & Dannhardt, 1996). A guideline such as the UWO PedAMP which includes outcome evaluation tools that are low in respondent burden is an important characteristic of outcome evaluation (Andresen, 2000).

6.5 Scientific implications

In addition to the clinical implications of this work, the empirical findings provide a new understanding of the outcome evaluation tools themselves. Prior to this investigation, a critical review of outcome evaluation tools for infants, toddlers, and preschool children was not available. The work in Chapter 2 provided a detailed evaluation of the available tools in order to provide evidence to support their inclusion in a guideline. This part of the investigation eliminated the immediate need to develop a new functional outcome evaluation tool and supported the use of two existing high quality tools (i.e., LittLEARS and PEACH) within the UWO PedAMP. It also provided a framework with which clinicians can critically evaluate other outcome evaluation tools that are available (i.e., for school-age children).

Once the outcome evaluation tools were chosen, the norms for the LittLEARS and PEACH were validated with Canadian English-speaking normal hearing children. Validation of normative data is an important characteristic of outcome evaluation tools (Andresen, 2000). Chapters 3 and 5 provided validation data for the chosen subjective outcome evaluation tools included in the UWO PedAMP. This contributes to our knowledge of the psychometric properties of the LittLEARS and PEACH and provides

support for their use within the UWO PedAMP for normal hearing children from English-speaking families.

A further scientific contribution of this work relates to the auditory development and performance data from children with hearing aids. Although data using the PEACH with children who wear hearing aids are available (Ching & Hill, 2007; Ching, Hill, & Dillon, 2008; Ching, Crowe, et al., 2010; Ching, Scollie, et al., 2010; Golding, et al., 2007), the work in Chapter 4 provided further validation that the children involved in the current study were demonstrating typical auditory performance. Additionally through this work, a score sheet for the PEACH was developed for the UWO PedAMP to support clinical feasibility of the tool. The performance regions on the score sheet were developed using existing data from children who wear hearing aids and may be further refined following future work.

This investigation also provided unique information about the performance of a clinical sample of children who wear hearing aids. Children who were typically developing demonstrated that they were meeting auditory development milestones for their age according to the LittleEARS. Furthermore, children with comorbidities and complex factors were studied as two separate groups and showed borderline normal auditory development which progressed in different ways. Prior to this investigation, data using the LittleEARS with children who wear hearing aids were not available. This work provides new evidence to support the use of the LittleEARS with children who wear hearing aids and also describes auditory development trends for children who are not typically developing or have complex factors related to hearing aid use. Although group results for the PEACH indicated that there was no significant impact of comorbidity or complex factor, degree of hearing loss impacted PEACH scores. Further data collection with each group may reveal an interaction between degree of hearing loss and group, however more data is required. This type of characterization of scores with an atypical population supports the quality of the normative data acquired which is an essential attribute for clinical outcome measures (Andresen, 2000).

Large-scale outcome studies could also benefit from the current work. Many of the recent investigations reporting outcomes of children involved in EHDI programs have included detailed outcome measure test batteries, many of which are too lengthy to be completed clinically or require another professional for administration, scoring, and interpretation (eg., Sininger, Grimes, & Christensen, 2010). As a result of the current work, an evidence-based outcome evaluation guideline that is clinically feasible for pediatric audiologists is available. It has been implemented in a world-class EHDI program (i.e., Ontario Infant Hearing Program) where provincial data is being examined and the clinicians are involved in its future development. With this example, investigators embarking on large-scale studies of the outcomes of children who wear hearing aids may wish to include the UWO PedAMP as part of their study materials. This will add consistency to the way outcomes are collected, reported, and interpreted in future research studies, which will contribute significantly to the research of this notable population.

6.6 Limitations of the current work

A number of limitations within the current investigation need to be considered. Data from children who wear hearing aids in this study contribute significantly to the understanding of the auditory-related outcomes of this population. Although further data collection and analyses were completed and included in Chapter 4, the sample size limited the analyses in some ways. Of the 116 children who wore hearing aids in this study, 15 had a bilateral severe hearing loss and two had a profound hearing loss (see Table 4-1). These numbers were slightly lower depending on the outcome evaluation tool (i.e., LittleEARS, PEACH) being investigated. An explanation for this occurrence may be the fact that to be considered a candidate for a cochlear implant, a child under two years of age must have a hearing loss in the severe to profound range (Fitzpatrick, Olds, Durieux-Smith, McCrae, Schramm, & Gaboury, 2008; Kim, Jeong, Lee, & Kim, 2010;). Because the participating clinics were not cochlear implant centres, children who were considered candidates for cochlear implants were transferred to appropriate centres for evaluation. The resulting small sample size in the more significant hearing loss regions prevented characterization of scores by degree of hearing loss for the individual outcome evaluation tools. Further,

the children who wore hearing aids in this work were divided into three groups based on whether they were typically developing, had comorbidities, or complex factors related to hearing aid use. This is a vital consideration when working with children with various hearing loss profiles because there is a need for a better understanding of the impact of degree of hearing loss on outcome for each of these three groups. Characterizing the impact of hearing loss per subgroup would also provide clinically relevant information for intervention and referral decisions for children who are being considered for cochlear implantation (Fitzpatrick, et al., 2008). In addition, characterizing scores for each outcome evaluation tool by degree of hearing loss will provide clinicians with benchmarks for the auditory development and performance of their young patients. Based on the data presented in Chapter 4, a sample size of 20 to 30 in each hearing loss category, for each group of children, may provide the needed data to properly characterize scores on the outcome evaluation tools with this level of detail.

A further limitation of this work is that objective measures were not included in the UWO PedAMP. Subjective outcome evaluation tools were chosen for the initial version of the UWO PedAMP due to the complexity of the population seen in pediatric audiology clinics and the ease of clinical implementation. Very young infants or children with developmental issues are often unable to perform objective behavioural tasks reliably. Interestingly, these are the children for whom outcome measures are needed the most. Utilizing subjective caregiver report questionnaires was a good first step in developing an outcome evaluation guideline. However, objective outcome measures such as speech detection and discrimination tasks may potentially be useful for clinicians who provide habilitation services to their young patients. In the meantime, clinicians who fit children with hearing aids have been provided with recommended outcome evaluation tools to measure the impact of the hearing aid fitting on the child's auditory development and performance. There is the potential to modify the UWO PedAMP to include objective tasks in future versions in order to support the need to observe auditory behaviours in children who wear hearing aids.

An additional limiting factor of this work is that children involved in the study were categorized as having other medical issues (i.e., comorbidities) based on clinician report.

The investigators did not require a developmental quotient as many large pediatric centers routinely require, especially as part of a cochlear implant evaluation (e.g., Wiley, Meitzen-Derr, & Choo, 2008). Obtaining a developmental quotient using a standardized scale would provide information about gross motor skills, fine motor skills, adaptive skills, language, and personal-social skills. These data would provide more meaningful descriptions of the child's developmental skills in order to better categorize them for the purposes of evaluating auditory-related outcomes.

Further issues that were not addressed in this study relate to the caregivers' participation in completing the outcome evaluation tools. Information regarding the educational, socio-economic, and caregiver engagement status are just a few of the potential factors that may impact the responses on the questionnaires from an individual caregiver. Although literacy issues were dealt with at the time of the appointment (i.e., administered interview-style, an interpreter was used), it is not known how these factors impacted the scores obtained in this study. In addition, the validity of caregiver report was not examined. Research in the area of gross motor function has indicated that caregivers provide dependable reports of gross motor milestones such as sitting, crawling, and walking when compared to therapists' observations (Bodnarchuk & Eaton, 2004). Similar findings have been reported for caregivers of Chinese children with hearing impairment (Lee, Chiu, van Hasselt, & Tong, 2009). The investigators found that caregivers were more accurate reporters of vocabulary knowledge when the vocabulary was easier; education level, occupation, and household income were not significant predictors of the accuracy of caregiver report (Lee, et al., 2009). On the other hand, a study examining the accuracy of caregiver ratings of hearing ability for children with otitis media indicated poor predictability of hearing levels or changes in hearing status from caregiver report (Rosenfeld, Goldsmith, & Madell, 1998). One caveat of the Rosenfeld and colleagues (1998) findings was that the caregiver report was based on a single question about hearing ability within a larger quality-of-life scale. It is possible that with a dedicated auditory development or performance questionnaire like the ones used in the current study, the accuracy of caregiver report will be realized, as it was in the gross motor function work. Nevertheless, examining caregiver characteristics and the accuracy of

their reports is an important limitation of the current work that requires further examination.

An added limitation of this study related to the cross-sectional nature of the data analyses. An imperative consideration when collecting normative data is whether the sampling is from many individuals at the same point in time or by observing the same group of individuals over time. There are both practical and statistical advantages and disadvantages to cross-sectional and longitudinal data collection strategies for collecting normative data. While large amounts of data can be collected in a relatively short period of time with a cross-sectional strategy, measures of change as well as cause and effect cannot truly be examined (Yee & Niemeier, 1996). In addition, large variability is often noted that cannot be explained by the variables being studied at one point in time. Obtaining a more in-depth look into a population is especially important when studying development. While longitudinal data collection has practical limitations such as subject attrition and lengthy data collection phases, it allows researchers to observe trends and measure change in a population over time (Yee & Niemeier, 1996). Therefore, future work should consider the data analysis process when developing normative data because different strategies will provide a different perspective of the population. It is therefore important to strive to analyze the longitudinal data that exists in the current data set. This may provide a more generalizable normative data set that will help with prognosis and clinical management of a child with hearing loss who wears hearing aids.

6.7 Recommendations for future work

6.7.1 Impact of degree of hearing loss

This research has resulted in many questions in need of further investigation. One relates to the impact of degree of hearing loss on auditory development and performance in children. While there is currently a hearing loss classification system in widespread use by audiologists, it is based on the softest detectable level of sound, measured in decibels, for various frequencies in each ear. Decibel threshold ranges are categorized as normal, mild, moderate, moderately-severe, severe, and profound. The current classification system, however, does not describe the patient's specific communicative function or

disability for a given level of hearing impairment (World Health Organization, 2009). So, there is the potential to reclassify hearing impairment for children based on the International Classification of Functioning. As a result of the current project, a systematic, evidence-based outcome evaluation guideline exists for infants, toddlers, and preschool children who wear hearing aids. This allows clinicians and researchers to measure the developing auditory behaviours of children who wear hearing aids. This population has varying degrees of hearing loss and their progress needs to be tracked in a meaningful way so that appropriate intervention decisions can be made. Future work could include developing a classification of auditory functioning based on the level of the child's hearing loss.

6.7.2 Children with hearing loss who do not wear hearing aids

Another future goal of this work may be to examine the auditory development and performance of children who have permanent hearing loss and do not wear hearing aids. These children often have minimal/mild bilateral sensorineural hearing loss (i.e., < 40 decibel [dB] hearing level [HL]), unilateral sensorineural hearing loss, or auditory neuropathy spectrum disorder (ANSD). For families of many of these children, a strong recommendation for the use of hearing aids cannot be made due to the lack of evidence. Therefore, these children are often monitored closely by their audiologist to track hearing thresholds over time. Little evidence for providing hearing aids to these children is available in part because of the lack of understanding of their auditory development and performance beyond measuring hearing thresholds. This may lead to clinical uncertainty about management which results in practice variation (e.g., Fitzpatrick, Durieux-Smith, & Whittingham, 2010). Implementing the UWO PedAMP with these children provides a more comprehensive way of monitoring the auditory development and performance of these children at various ages. Results from the LittleEARS or the PEACH for children who do not wear hearing aids but have been identified with a hearing loss can support individual audiological monitoring as well as subsequent intervention decisions for the family. In addition, gathering group data for this population will provide evidence for how children with minimal/mild bilateral hearing loss, unilateral hearing loss, and ANSD perform without hearing aids. Comparison to a group of children with the same type of

hearing loss whose families chose to intervene with hearing aids could be accomplished. This future work could provide vital insight into the management decisions of these children whose auditory development and performance are not yet well-understood.

6.7.3 Longitudinal data analysis

Similar to the current work, many projects that aim to gather normative data, validate it, and characterize it with different sub-groups employ cross-sectional data analysis strategies in the initial stages (e.g., Palisano, et al., 2000). Later work usually involves a longitudinal data collection and analysis strategy to further understand the population (e.g., Hanna, et al., 2009; Wood & Rosenbaum, 2000). Ultimately, a longitudinal cohort study of auditory development and performance among children with hearing loss who wear hearing aids is required in order to contribute significantly to the understanding of this population. In the current project, the caregivers of some children were seen multiple times in the audiology clinic. Therefore, the outcome measures were completed repeatedly for some of the children involved in this study. These data provide an opportunity to understand the developmental patterns of children with hearing aids using a longitudinal approach to data analysis. While cross-sectional data allows for a more immediate look at the population at a given point in time, longitudinal data provide a better understanding of trends and changes in the population over time.

In the current work for example, multiple scores from the LittleEARS questionnaire can be examined for a given child to track auditory development with hearing aids over time. This can be done by implementing a latent growth modeling approach to longitudinal data analysis (Meredith & Tisak, 1990). An exploratory analysis is a way to visualize how each child's auditory development changes over time (McArdle & Epstein, 1987). This can be done in absolute terms by comparing the scores against the LittleEARS overall score or in relative terms by comparing scores of individuals to other sample participants. Both strategies allow the investigator to identify cases that are outliers prior to analysis. To illustrate these issues, a sample case is provided below, illustrating a child's auditory development over time in comparison to the trajectory of LittleEARS scores determined in the addendum in Chapter 4 for typically developing children who wear hearing aids. This provides an initial look at longitudinal data for one child involved in this study.

In this example, the child was born full term and identified as having a moderate bilateral sensorineural hearing loss (pure tone average = 52.5 dB HL) in early infancy. He was reportedly typically developing and does not have complex factors related to hearing aid use. He was fitted with hearing aids in both ears when he was approximately six months of age. The speech intelligibility index (SII) values were typical for his degree of hearing loss and other hearing aid fitting details (i.e., RECD, maximum power output) were measured. Thus, clinical process outcomes for the provision of hearing aids were consistent with preferred practices. The LittleEARS was administered to his caregiver a total of five times in the aided condition between the ages of approximately seven months to 16 months. His functional auditory development outcomes over time are presented in Figure 6-1. It can be noted that during the first four months of hearing aid use, this child's auditory development was not within the typical range for normal hearing children. Reasons for this may be that the child needed time to attach meaning to the new sounds he was hearing before displaying typical auditory development. In addition, the clinician noted that during the second hearing aid follow-up appointment (i.e., approximately 10 months of age), middle ear dysfunction was revealed which may have dampened the input through the hearing aids. As such, the caregiver's observations may reflect the child's poor hearing at this time. The main point in this example is that over time this child's LittleEARS scores (i.e., auditory development) improved and were similar to scores characterized by typically developing children who wear hearing aids involved in this study. Latent growth modeling such as this could be examined for other children involved in this study who have multiple administrations of the outcome measures to describe auditory development patterns over time for children who wear hearing aids.

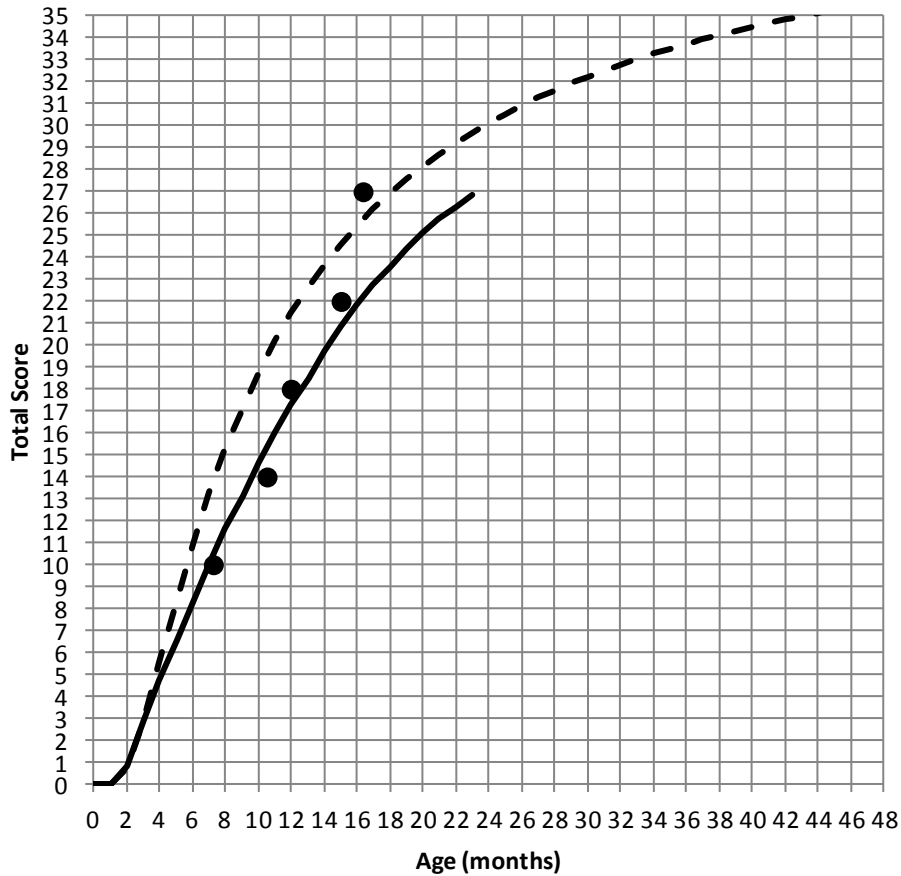


Figure 6-1: Example of LittleEARS scores over time for one child involved in this study. The dashed line represents the trajectory of LittleEARS scores for typically developing children who wear hearing aids involved in this study. The solid line represents the *minimum* expected score for normal hearing children. The circles represent the current child's LittleEARS scores (y-axis) at various ages (x-axis).

6.7.4 Percentile ranks

In addition to longitudinal data analysis, the use of percentile ranks is a common way to interpret an individual's relative standing compared to the norms. Reference percentiles are constructed so that an individual's rank represents the percentage of individuals from the normative sample that he/she outperforms. This is useful because while variability exists in the normative sample, there is also variability in the individual being measured as well as in the measurements themselves. That is, there will be times when a child with

a certain degree of hearing loss will achieve a LittleEARS score that does not fall in line with the average auditory development curve. In this situation, clinicians and researchers need a clear statistical way of understanding if this is a significant deviation from average and if the child's performance will remain at this level over time. Percentile ranks provide a more informative way of using normative data by providing information about an individual's variability with reference to the average at a given point in time, as well as a meaningful way to track performance over time.

6.7.5 Guideline evolution

The UWO PedAMP will evolve as a result of the development and application of research evidence and clinical tools. As the outcomes of children with various audiometric and medical profiles become better understood, performance ranges and benchmarks for these clinical subpopulations may be applied to the existing outcome evaluation tools within the guideline. Furthermore, additional outcome evaluation tools may be considered for the UWO PedAMP to provide a multi-dimensional assessment of outcome. Objective outcome evaluation tools such as speech recognition tasks and cortical evoked potentials are available and would provide valuable information to support the subjective measures included in the current guideline. Moreover, subjective measures of early verbal and vocal development have recently been suggested and may be a useful addition to future versions of the UWO PedAMP (Moeller, 2011). As the guideline evolves, an integrated knowledge translation approach will continue to be implemented to support clinical uptake of additional outcome evaluation tools.

6.8 Concluding statements

This observational study developed and evaluated an audiological outcome evaluation guideline for use with infants, toddlers, and preschool children who wear hearing aids. This work is valuable because a systematic, evidence-based outcome evaluation guideline that is clinically feasible has not been available for this population. Through a critical review, subjective outcome evaluation tools were chosen to be included in a guideline. The normative values for the chosen tools were subsequently validated for use with English-speaking families in Ontario. In addition, characterization of scores for children

who wear hearing aids were obtained in order to describe their outcomes with intervention. Outcomes of children with hearing aids who were typically developing were described as well as those with other medical issues and complex factors related to hearing aid use. This unique aspect of the current investigation supports the challenging work that pediatric audiologists do with all of their patients. Overall, typically developing children who wear hearing aids displayed appropriate auditory development and performance when their hearing aids were fitted using an evidence-based protocol. The current study validates the necessary work that pediatric audiologists do with children who have hearing loss. Future work will provide further information about the impact of degree of hearing loss, children's performance with hearing aids over time, and support intervention decisions for families of children with hearing loss who do not have hearing aids. The current work has provided significant information about the positive outcomes of children who wear hearing aids and are managed by pediatric audiologists in Ontario.

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Appendices

Appendix A: Sample of LittleEARS Auditory Questionnaire Items

Item	Auditory Response	Answer	Example
1	Does your child respond to a familiar voice?	<input type="checkbox"/> yes <input type="checkbox"/> no	Smiles; looks toward source; talks animatedly
12	Does your child react to his/her name?	<input type="checkbox"/> yes <input type="checkbox"/> no	
21	Does your child imitate sounds when asked?	<input type="checkbox"/> yes <input type="checkbox"/> no	“Aaa”, “ooo”, “iii”
34	Does your child follow complex commands?	<input type="checkbox"/> yes <input type="checkbox"/> no	“Take your shoes off and come here.”

Appendix B: PEACH Rating Scale: Page 1



**Parents' Evaluation of Aural/Oral
Performance of Children
(P.E.A.C.H.)**

Developed by Teresa Ching & Mandy Hill

Child's Name:		Your Name:	
D.O.B:		Interviewer:	
Number & Interval:		Date:	

Appendix B: PEACH Rating Scale: Page 2



Parents' Evaluation of Aural/Oral Performance of Children (P.E.A.C.H.)

Developed by Teresa Ching & Mandy Hill

What is the PEACH?

- The PEACH (Parents' Evaluation of Aural/oral performance of Children) is a questionnaire designed to record how your child is hearing and communicating with others when using his/her hearing aids and/or cochlear implant. We ask you to observe your child's listening behaviour in everyday life and give a rating in relation to a range of hearing and communication scenarios.

The PEACH is not a test. Remember even normal hearing people have some difficulty hearing in some situations. Children's listening skills improve as they grow and develop and as they get more listening practice.

Why use the PEACH?

- The PEACH is used to evaluate the effectiveness of your child's hearing aids and/or cochlear implant. Your PEACH ratings will be used to build a picture of your child's functional performance in everyday life situations. The results can be used by your child's audiologists to tailor audiological intervention to address the specific difficulties experienced by your child. The PEACH scores collected at several intervals over time can also be used to monitor your child's progress with intervention.

How do I do it?

- Think about your child's behaviour over the past week in relation to each question.
- Give a rating, based on the estimated percentage of time that your child displays the described behaviour.

What happens next?

- After you return a completed PEACH, a researcher may contact you to talk through your ratings. The researcher may ask you further questions to make sure they have a thorough understanding of the abilities and needs of your child.

Results from the PEACH will be used to monitor your child's progress. The information will also be passed onto your child's audiologist to guide intervention.

Pre-Rating Checklist

	Yes	No
Has the child been wearing his/her hearing aids and/or cochlear implant?		
Has the child been well/healthy?		
Have the child's hearing aids and/or cochlear implant been working properly?		

If the PEACH is used to assess performance when aided, it should only be completed when the answer to all of the above items is YES.

Appendix B: PEACH Rating Scale: Page 3

Please reflect on your child's listening behaviour over the past week and circle the appropriate number

	Question	Never 0%	Seldom 1 - 25%	Sometimes 26 - 50%	Often 51 - 75%	Always 75-100%
1.	How often has your child worn his/her hearing aids and/or cochlear implant?	0	1	2	3	4
2.	How often has your child complained or been upset by loud sounds?	4	3	2	1	0
3.	When you call, does your child respond to his/her name in a quiet situation?	0	1	2	3	4
4.	When asked, does your child follow simple instructions or do a simple task in a quiet situation?	0	1	2	3	4
5.	When you call does your child respond to his/her name in a noisy situation when he/she can't see your face? (examples of responses include looks up, turns, answers verbally)	0	1	2	3	4
6.	When asked, does your child follow simple instructions or do a simple task in a noisy situation?	0	1	2	3	4
7.	When you are in a quiet place reading with your child, how often does he/she pay close attention to what you are saying? OR if your child is listening to stories/songs on the TV or CD when there is no other background noise how often can he/she follow what is being said?	0	1	2	3	4
8.	How often does your child initiate/ participate in conversation in a quiet situation?	0	1	2	3	4
9.	How often does your child initiate/ participate in conversation in a noisy situation?	0	1	2	3	4
10.	How often does your child understand what you say in the car/bus/train?	0	1	2	3	4
11.	How often does your child recognise peoples' voices without seeing who was talking?	0	1	2	3	4
12.	How often does your child successfully use a phone?	0	1	2	3	4
13.	How often does your child respond to sounds other than voices?	0	1	2	3	4

Appendix B: PEACH Rating Scale: Page 4



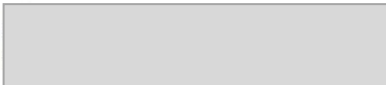
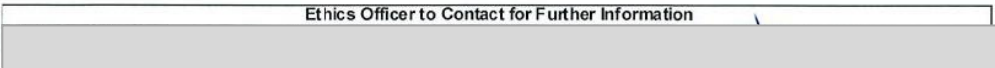
Please provide comments regarding any of the above items:



Scoring: To be completed by professional

		RAW Score	% Score
QUIET	(Q's 3+4+7+8+11+12) A		(A/24) x 100
NOISE	(Q's 5+6+9+10+13) B		(B/20) x 100
OVERALL	(A + B) C		(C/44) x 100

Appendix C: Ethics approval notice

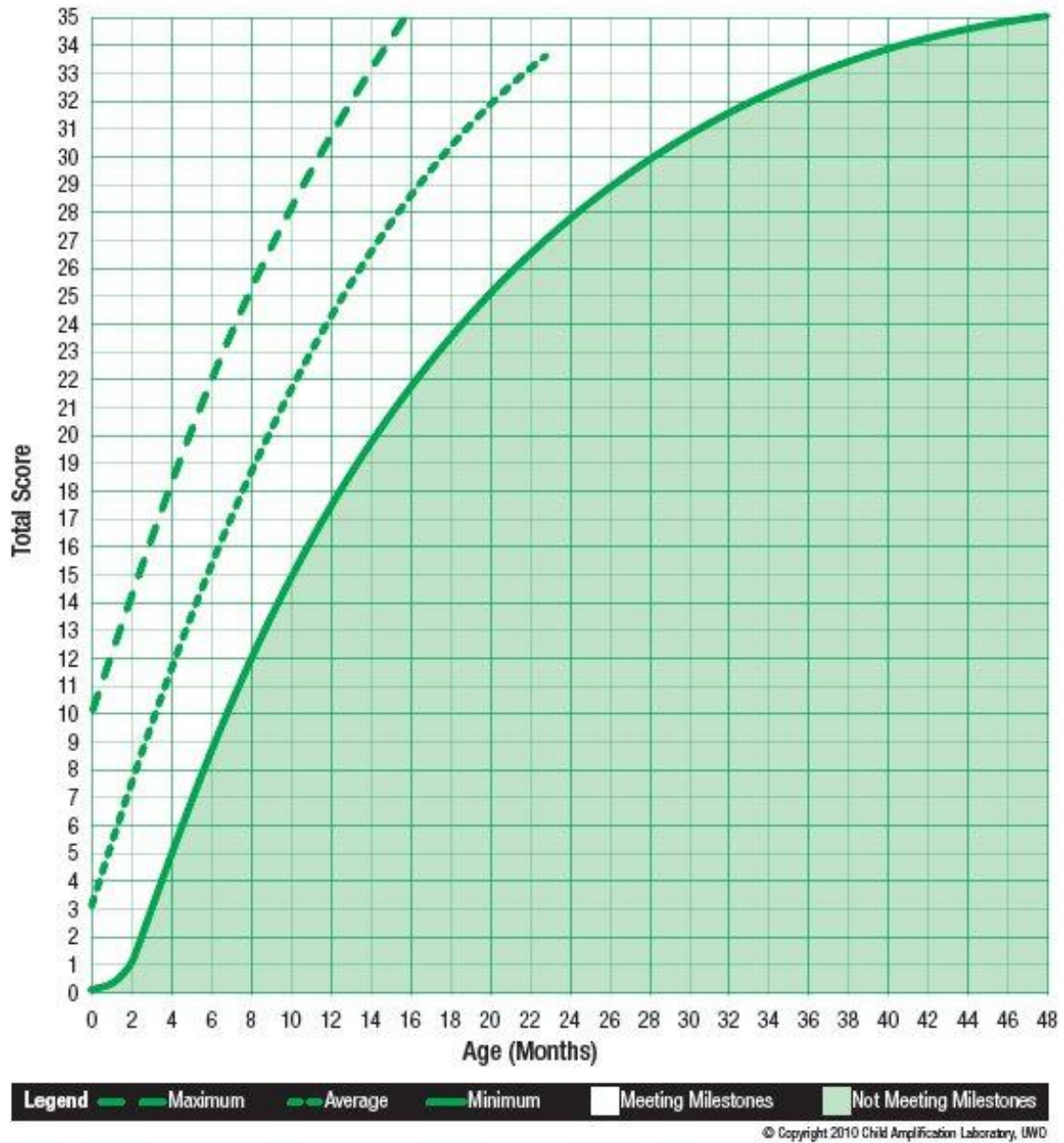
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<hr/>	
Principal Investigator: Dr. S.D. Scollie Review Number: 16924E Review Date: March 05, 2010 Protocol Title: Development and Evaluation of a Pediatric Audiological Monitoring Protocol Department and Institution: Communication Sciences & Disorders, University of Western Ontario Sponsor: Ethics Approval Date: May 13, 2010	Review Level: Expedited Approved Local # of Participants: 100 Expiry Date: May 31, 2015
Documents Reviewed and Approved: UWO Protocol Documents Received for Information:	
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Appendix D: Availability of Questionnaires

Questionnaire / Outcome Tool	Location
Aided Speech Intelligibility Index (SII) Normative Values	www.dslio.com
Hearing Aid Fitting Summary	www.dslio.com
LittleEARS Auditory Questionnaire	http://www.earfoundation.org.uk/shop/items/98 Other languages direct from MED-EL. Tel: +44 (0) 1226 242 874
PEACH Diary	http://www.nal.gov.au/outcome-measures_tab_peach.shtml
PEACH Rating Scale	http://www.outcomes.nal.gov.au/LOCHI%20assessments.html

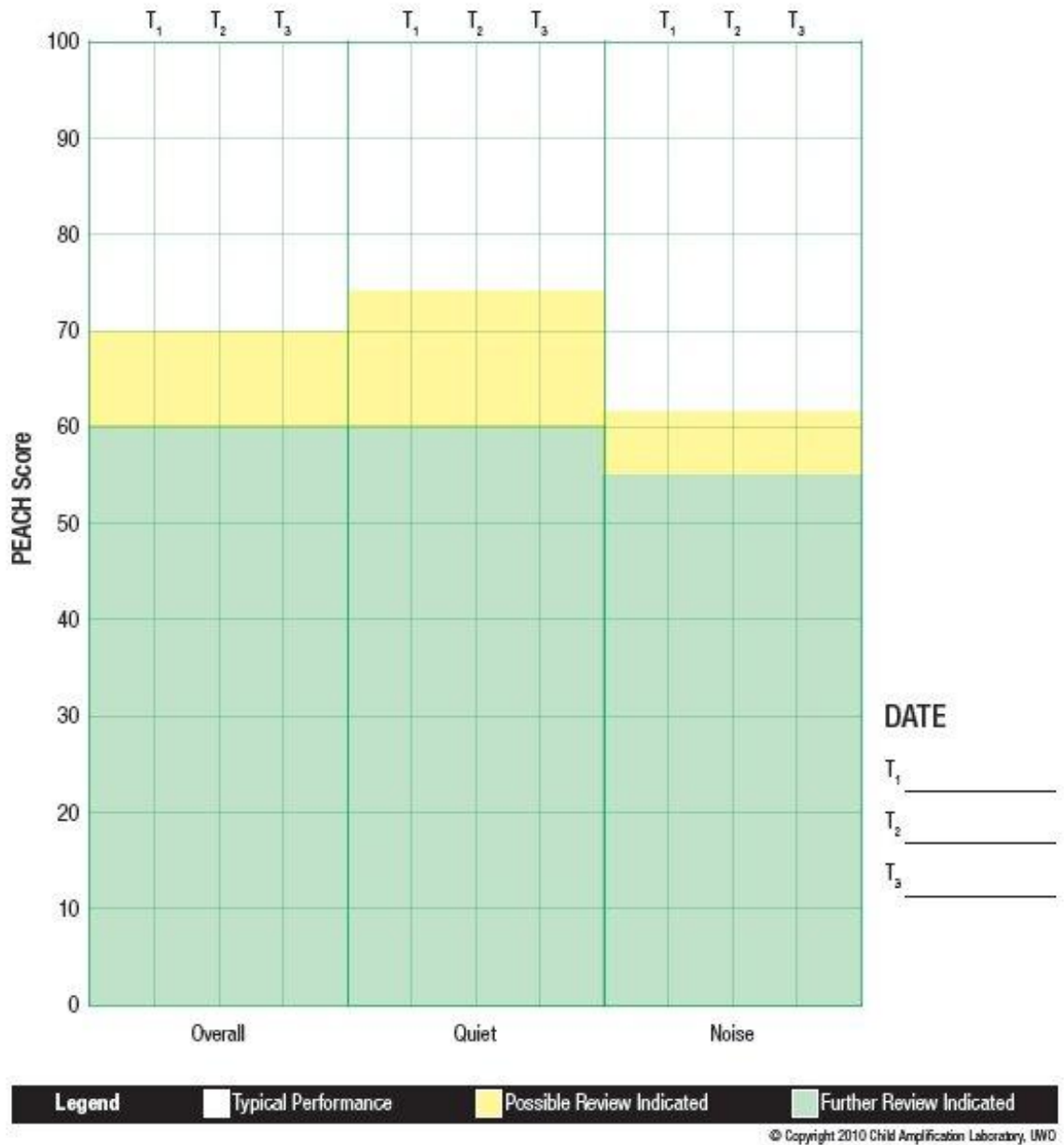
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Appendix E: LittleARS Score Sheet



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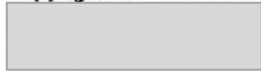
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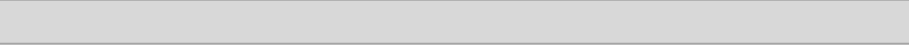
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Vanderbilt Bill Wilkerson Center for Otolaryngology and Communication Sciences

[REDACTED]

Curriculum Vitae

Name	Marlene Patricia Bagatto
Post-secondary Education and Degrees	<p>The University of Western Ontario London, Ontario, Canada 1992-1996 B.A.(Hons.)</p> <p>The University of Western Ontario London, Ontario, Canada 1996-1999 M.Cl.Sc.</p> <p>Central Michigan/Vanderbilt University Mt. Pleasant, MI, USA 2003-2005 Au.D.</p> <p>The University of Western Ontario London, ON, Canada 2008-Present Ph.D. Candidate</p>
Honours and Awards	<p>Networks of Centres of Excellence Young Innovators Award 2006</p> <p>Vanier Canada Graduate Scholarship Doctoral Research Award: Canadian Institutes of Health Research 2009-2012</p>
Related Work Experience	<p>Research Associate Child Amplification Laboratory National Centre for Audiology The University of Western Ontario London, ON, Canada 1999-Present</p> <p>Clinical Pediatric Audiologist Ontario Infant Hearing Program H.A. Leeper Speech and Hearing Clinic The University of Western Ontario London, ON, Canada 2003-Present</p>

Related Publications

Bagatto, MP, Moodie, ST, Scollie, SD, Seewald, RC, Moodie, KS, Pumford, JM & Liu, KR. (2005) Clinical protocols for hearing instrument fitting in the Desired Sensation Level Method, *Trends in Amplification*, 9(4): 199-226.

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- Bagatto, MP, Seewald, RC, Scollie, SD & Tharpe, AM.** (2006) Evaluation of a probe-tube insertion technique for measuring the real-ear-to-coupler difference (RECD) in young infants, *Journal of the American Academy of Audiology*, 17:573-581.
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Bagatto, MP. (2010) Beyond Matching Targets: An Approach to Outcome Evaluation in Pediatric Hearing Aid Fitting. *Sound Foundation Through Early Amplification*, 5th International Conference, Chicago, IL.

Bagatto, MP. (2011) An Approach to Outcome Evaluation for Infants and Children Who Wear Hearing Aids. *Canadian Academy of Audiology Conference*, Victoria, BC.

Bagatto, MP. (2011) Evaluating the Impact of Hearing Aid Intervention. *Fourth European Pediatric Amplification Conference*, Phonak AG, Istanbul, Turkey.

Bagatto, MP. (2012) The University of Western Ontario Pediatric Audiological Monitoring Protocol (UWO PedAMP). *Eleventh Annual Early Hearing Detection and Intervention Conference*, St. Louis, MO.