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# Prevalence of hearing-loss among HAART-treated children in the Horn of Africa





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### ABSTRACT

*Objectives:* The prevalence of hearing loss (HL) in children infected with HIV/AIDS is not well studied. Even fewer studies focus on stable HIV-infected children treated with high-effective antiretroviral therapy (HAART). We aim to compare the prevalence of ear disease and HL in HAART-treated, HIV + children in Addis Ababa, Ethiopia with a well, similarly-aged elementary school population with unknown HIV status (HIVU).

*Methods:* Children underwent standard head and neck examination and cerumen removal by board certified otolaryngologists. Next, certified audiologists performed hearing screening with pure-tone audiometry using a circumaural headset but without an ambient noise reducing environment. Children failing audiometric screening underwent full behavioral audiometry including air and bone testing. The primary outcome parameter was HL > 25 dB with the audiologist accounting for background noise. A second endpoint was PTA >40 dB (500, 1000, 2000 Hz) without assessment of background noise.

*Results:* 107 HIV+ and 147 HIVU children met inclusion criteria. In the HIV + cohort 17.8% had evidence of TM perforations and 8.4% had otorrhea. In the HIVU group 2.7% had a TM perforation and 0% had otorrhea. Hearing was significantly worse in HIV + children. (Audiologist determination: 38.3% HL HIV+, 12.2% HIVU, Fisher's-Exact-Test OR: 4.5, 95% CI 2.4–8.3, p-value <0.0001; Worse-hearing-ear PTA > 40 dB: 19.6% HL HIV+, 6.1% HIVU, OR: 3.7, 95% CI 1.7–8.4, p-value <0.001).

Conclusions: Chronic OM, conductive and mixed hearing losses are significantly more common in HAART-treated HIV + children than in well, similarly-aged controls. Rates of SNHL are similar.

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### 1. Introduction

Several studies suggest an association between HIV infection and hearing loss in adults [1,2] and children [3–7]. Hearing losses in HIV + children with chronic otitis media are typically conductive, resulting from tympanic membrane perforations and chronic infection [8–10]. Some of these children also manifest sensorineural hearing loss of less certain cause.

Ethiopia has been profoundly affected by the HIV epidemic. 200,000 children aged 0–14 live with HIV according to a 2013 estimate [11]. The region of Addis Ababa has one of the highest rates of HIV infection (5.2%) in Ethiopia. Fortunately, many of these children have access to highly effective anti-retroviral agents (HAART) thanks to international programs fighting HIV infection in the developing world. The present study evaluates the prevalence of hearing loss in one such cohort of HAART-treated HIV + children in an orphanage in Addis Ababa, Ethiopia. A similarly-aged group of school children with no clinical evidence of HIV (HIV-unknown or HIVU) serves as a control population. The study also seeks to

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determine the prevalence of middle-ear disease in these cohorts through otoscopic evaluation and its relation to subject hearing status.

### 2. Methods and implementation

#### 2.1. Study design and population

This study reports the audiologic status of two groups of schoolage children in Addis Ababa, Ethiopia. These children were evaluated and treated as part of series of medical missions by Healing the Children, a United States based charity devoted to providing medical and surgical care to children in need around the world. The study was conducted at two different testing sites in Addis Ababa, Ethiopia over two, week-long visits in November 2015 and April 2016. HIV + HAART-treated children were recruited from an orphanage (HIV + cohort) and similarly-aged child subjects were recruited from a nearby public elementary school (HIVU cohort). No HIV testing of the HIVU group occurred as part of this study, however these subjects all demonstrated general good health and no apparent signs or symptoms of immunocompromise in the basic history and physical examination performed as part of the study. We therefore believe it is reasonable to assume that few, if any, of these subjects are HIV positive and are suitable to serve as control population.

### 2.2. Institutional study approval, consent for participation, study data handling

Evaluation and approval was obtained from the Institutional Review Boards at the University of Addis Ababa, Ethiopia; Temple University, Philadelphia, USA; and the University of Pittsburgh, Pittsburgh, USA. Prior to study participation, informed consent was obtained from the children's parents or legal guardians or from a designated child subject advocate for state ward subjects without a legal guardian. A translation of the consent form in Amharic was prepared by one of the authors (A.M.) and provided to all parents/ guardians. Assents for participation in the study was also confirmed with each child/subject (ages 7–20) prior to enrollment through a study team member fluent in both English and Amharic.

Any study subject and/or adult consenting on behalf of study subjects was given the opportunity to withdraw from the study at any time. Any child not wishing to participate was excluded from the study, but with continued access to all appropriate resources and medical care.

Both parental consent forms and subject assent forms were collected and kept in a secure location. Paper copies of subject-specific data were collected at the time of the study and identified only by a subject number. De-identified subject data were then transferred to electronic spreadsheet and evaluated using XLSTAT<sup>®</sup> (Addinsoft Inc, New York, NY) and MS Excel<sup>®</sup> (Microsoft Inc, Redmond, WA) [12,13].

### 2.3. Procedures

Each subject volunteered a general medical and otologic history which was obtained through an Amharic-English translator. The children then underwent standard pediatric ear, nose and throat examination using a portable otoscope and tongue blade by a board-certified otolaryngologist. Cerumen removal was attempted for subjects with obstructing ear wax prior to audiometric testing.

Hearing tests were performed by licensed audiologists from the United States and Germany with pure-tone audiometry. These Food and Drug Administration-approved audiometers were formally calibrated in the United States prior to the mission and then checked biologically each day by the audiologists on site. Children who failed audiometry screening underwent full behavioral audiometry including air and bone testing. Noise-protected environments were not available at either of the testing sites. Team audiologists deemed background noise to be excessive if a team member with established normal hearing could not hear 500 Hz air conduction tones at thresholds  $\leq$ 35 dB. Any audiometry testing performed during an elevated noise floor threshold were excluded from analysis and/or repeated after the elevated noise floor subsided.

### 2.4. Outcomes

The primary outcome measure for this study is presence or absence of hearing loss greater than 25 dB, accounting for background noise at the testing site. Hearing loss greater than 40 dB in the worse-hearing ear by air-conduction threshold measured at 500 Hz, 1 kHz, and 2 kHz (PTA3 > 40 dB) was chosen to represent "clinically significant" hearing loss. Also assessed were the type of hearing loss (sensorineural, mixed, or conductive); presence of ear disease on physical examination; and relation of hearing loss to HIV status.

### 3. Results and analysis

A total of 113 children were enrolled in the HIV + group and 172 children in the HIVU group. Five children in the HIV + group and five children in the HIVU group were excluded due to incomplete examinations. One HIV + subject and ten (10) HIVU subjects were excluded due to impacted wax that could not be removed without an operating microscope. Eighteen (18) HIVU subjects were excluded due to excessive noise during audiologic evaluation. One HIVU subject was excluded due to both impacted wax and excessive noise. There were a total 107 HIV + children and 147 HIVU children who completed both otologic examination and audiometric testing who were included in the data analysis (see Table 1).

The age of study participants ranged from 7 to 20 years (see Fig. 1), with a mean age of 13.6 in the HIV + cohort and 13.0 in the HIV unknown cohort. Median ages for the HIV+ and HIVU cohorts were 14 and 13 respectively. The gender distribution of study participants by cohort appears in Table 2.

CD4 counts of the HIV + subjects were also available through medical chart review. Among these subjects, the average CD4 count was 790 cells/mm [3] (range 185–1829 cells/mm<sup>3</sup>). Only one HIV + subject demonstrated CD4 count <200 cells/mm<sup>3.</sup>

In the HIV + cohort, 16.8% of the children reported a history of otologic complaints (otalgia, subjective hearing loss) with 5.3% having a history of otologic surgery (tympanoplasty or mastoidectomy). Among these subjects having prior otologic surgery, three patients who had undergone unsuccessful attempts at tympanoplasty demonstrated persistent perforation on examination. In the HIVU cohort, 19.04% reported a history of otologic complaints, but none reported any prior otologic surgery (See Table 3).

On examination of the HIV + cohort by otoscopy, 17.8% had tympanic perforations (either side or bilaterally), 8.4% had

### Table 1

Study enrollment and exclusion criteria by cohort.

	HIV+	HIVU
Initial enrollment	113	179
Incomplete examinations	5	5
Unremoved impacted wax	1	10
Noise	0	18
Final cohort number	107	147

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