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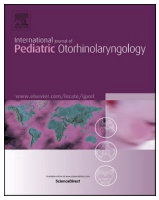

# The use of hearing tests to assess otitis media with effusion in children with Down syndrome

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ABSTRACT

*Background:* Down syndrome is associated with an increased risk for otitis media with effusion (OME), a childhood condition in which fluid accumulates in the middle ear, potentially leading to hearing loss. The American Academy of Pediatrics Down syndrome guidelines and the American Academy of Otolaryngology – Head and Neck Surgery OME guidelines recommend hearing testing to assess the hearing status of children with Down syndrome diagnosed with OME.

*Methods:* Through an Institutional Review Board approved retrospective chart review at Children's Mercy, this project assessed how clinical factors affect the frequency in which children with Down syndrome receive hearing testing after diagnosis of OME. The study included data from all children with Down syndrome between 1 and 8 years old diagnosed with OME in the Down syndrome, general pediatrics, and otolaryngology clinics between 2018 and 2020. Demographics and clinical factors, including clinic setting, were collected.

*Results:* Of the 124 patients identified, 91.1 % were diagnosed with OME in the otolaryngology clinic and 33.1 % received hearing testing. While most diagnoses occurred in the otolaryngology clinic, a higher proportion of hearing testing at the time of diagnosis occurred in the Down syndrome clinic. This could be explained by the fact that the Down syndrome clinic is a multidisciplinary clinic, where yearly visits include hearing screening. Bivariate analysis using chi-square or Fisher's tests showed that clinic setting had a significant association (p-value $<0.001$) with hearing testing. However, logistic regression depicted all clinical factors had an insignificant effect on hearing testing at 5 % significance.

*Conclusion:* While results indicate hearing testing is largely not performed to assess OME early in otolaryngology clinics, they may be used to assess intervention efficacy post-diagnosis. Results point to the importance of Down syndrome clinics in early diagnosis of hearing loss leading to timely referrals to otolaryngology clinics which diagnose and manage OME in children with Down syndrome.

## 1. Introduction

Down syndrome, also known as Trisomy 21, is a complex genetic disorder with a prevalence of 6.7 per 10,000 individuals in the United States [1]. Given its genetic complexity and effect on several body systems, Down syndrome presents risks to individuals for several comorbid conditions throughout their lifetime including otitis media with effusion (OME). OME is a condition in which fluid accumulates in the middle ear without the presence of infection; it is the most common cause of hearing loss in children with Down syndrome [2]. Given the association of hearing loss with impaired language abilities in children with Down syndrome, the management of OME as prevention for hearing loss is increasingly important in this population [3]. Children with Down syndrome have an increased incidence of stenotic or narrowed external auditory canals [4]. This can lead to issues with cerumen impaction or difficulty with visualizing the tympanic membrane and diagnosing OME [4]. Additionally, children with Down syndrome also have an increased frequency of mixed or sensorineural hearing loss [4]. Secondary to these factors, the appropriate and timely diagnosis and treatment of OME in children with Down syndrome is incorporated into guidelines developed by the American Academy of Pediatrics (AAP) and the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS). AAO-HNS OME guidelines recommend the assessment for OME include pneumatic otoscopy and tympanometry for diagnostic accuracy [4].

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Additionally, they suggest that children at risk for developmental difficulties, including Down syndrome, should receive a hearing test for OME of any duration rather than wait 3 months after diagnosis [4]. AAP Down syndrome guidelines recommend clinicians review the risk of OME in children with Down syndrome and use hearing tests to assess whether a child should be referred to an otolaryngologist for further evaluation [5]. Both AAO-HNS and AAP guidelines recommend the use of hearing tests to evaluate progression of OME and subsequent hearing loss [4,5].

Down syndrome clinics provide a unique opportunity for patients to receive hearing testing in accordance with AAP guidelines. At Children's Mercy, patients with Down syndrome are seen in the multidisciplinary Down syndrome clinic once a year. At this clinic visit, each patient is seen by a pediatric audiologist, speech pathologist, occupational therapist, psychologist, nutritionist, and a social worker. Health screening, including annual hearing screening, is offered at every visit as per the AAP Down syndrome guidelines [5]. In the Down Syndrome Clinic, full hearing evaluations and tympanograms are performed on children that can perform behavioral hearing exams. In cases where the children may not need a full audiogram because they have had one recently or they are not able to perform behaviorally, Otoacoustic Emissions are performed. If the patient fails the hearing screening at the visit, a referral to the otolaryngology clinic is made by the audiologist to assess the reason for the failed hearing test. In cases of OME, the patient is considered for pressure equalization tubes (PET) or other management options as indicated per AAO-HNS guidelines [4,6]. The referral process for children with Down syndrome is depicted in Fig. 1

AAO-HNS guidelines for OME and PET placement are informed by research detailing the potential complications of chronic OME [4,6]. A review by Jung, Alper, Hellstrom, Hunter, Casselbrant, Groth et al. showed bilateral and unilateral OME can negatively impact language development [7]. Surgical interventions recommended by the AAO-HNS include pressure equalization tubes (PET) and possibly adenoid removal [6]. Guidelines recommend PET placement in children with bilateral OME for 3 months, or unilateral OME for 6 months [6]. Modifying factors that may make surgeons consider PET sooner could be developmental delays such as speech delay, hearing loss, or even vision impairment if children are more reliant upon their hearing [6]. Additionally, for chronic OME with hearing difficulties, or recurrent acute

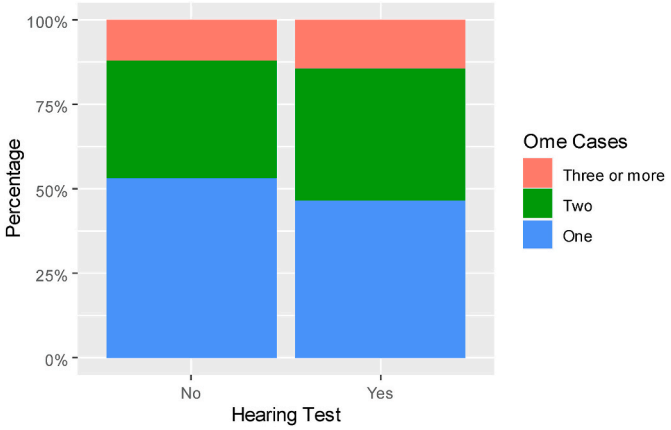


**Fig. 2.** Stacked bar chart of hearing test by categorical OME cases.

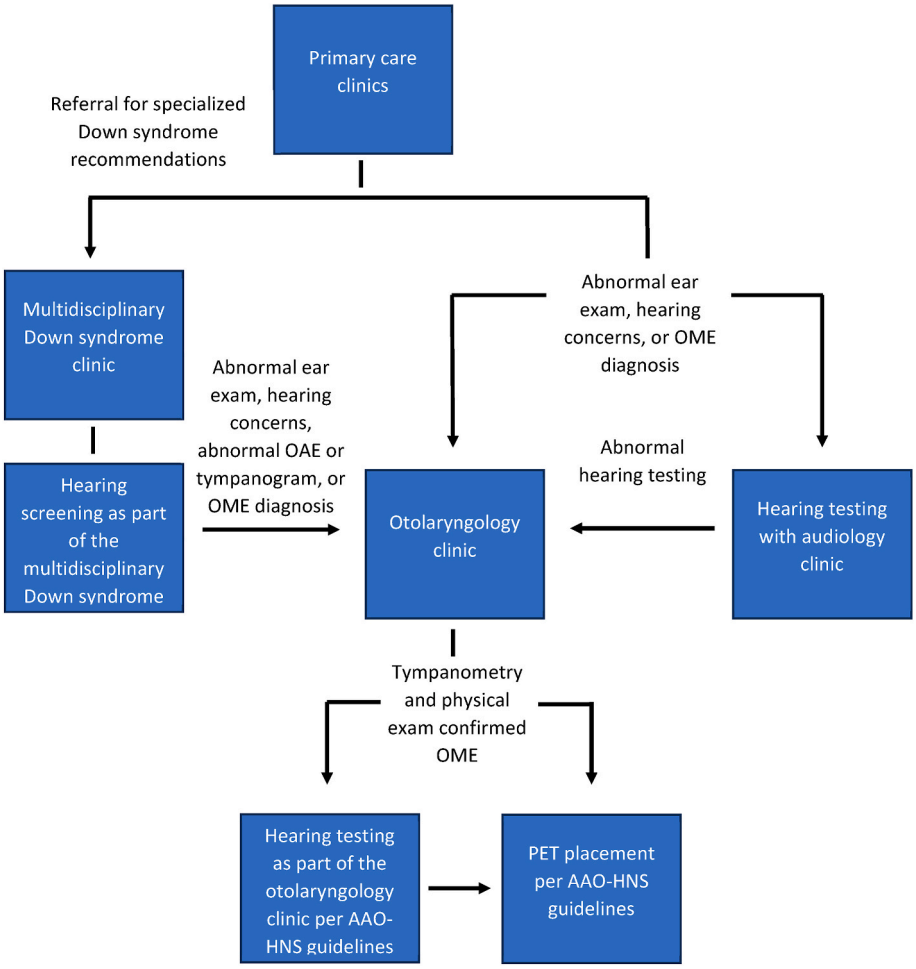


**Fig. 1.** Flow chart for evaluation of OME in children with down syndrome.

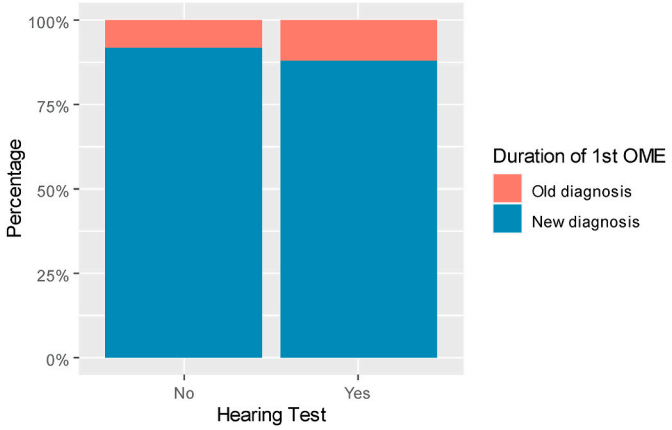


**Fig. 3.** Stacked bar chart of hearing test by categorical duration of 1st OME diagnosis.

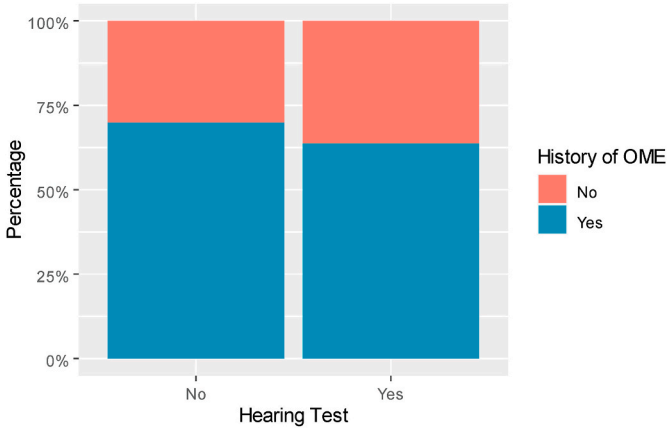


**Fig. 4.** Stacked bar chart of hearing test by history of OME

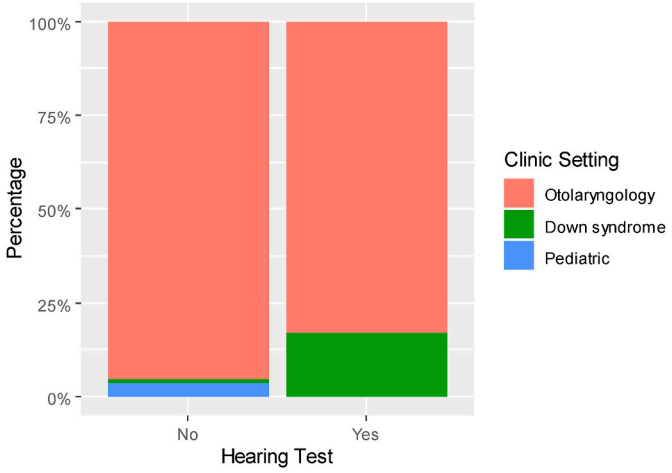


**Fig. 5.** Stacked bar chart of hearing test by clinic setting.

otitis media with OME, bilateral PET placement is recommended after 3 months [4]. However, the duration surgeons should wait before considering PET in children at risk for developmental delay, such as those with Down syndrome, is not specified [6].

A longitudinal research study conducted with the Children's Hospital Medical Center in Ohio found that frequent evaluation by an otolaryngologist every 6 months and rigorous treatments, such as PET placement

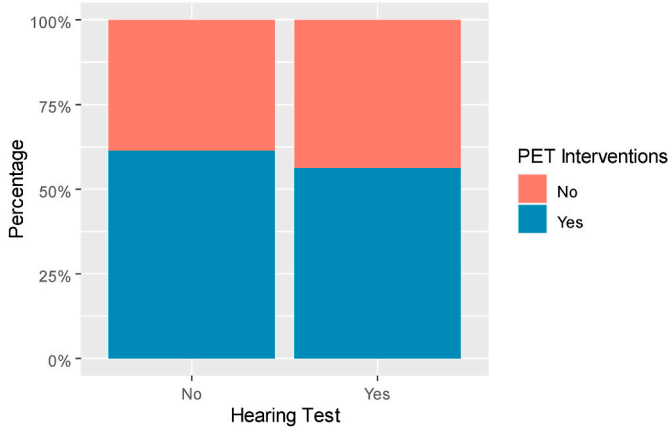


**Fig. 6.** Stacked bar chart of hearing test by PET intervention.

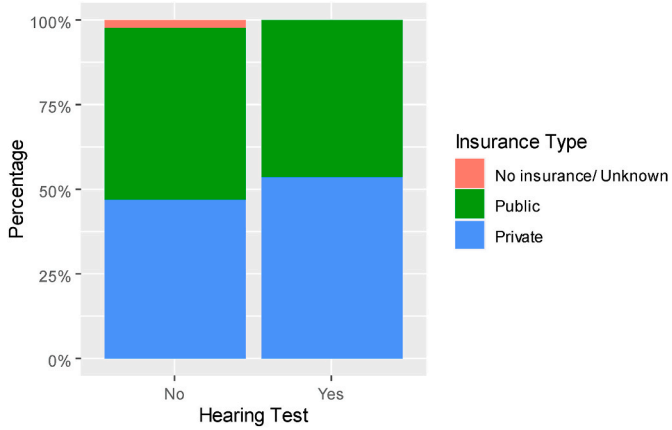


**Fig. 7.** Stacked bar chart of hearing test by insurance type of patients.

for OME, can reduce the prevalence of temporary hearing loss among children with Down syndrome [8]. More recently, a prospective study conducted by the Oregon Health and Science University in 2016 assessed quality of life improvement after PET [9]. The researchers discovered that PET placement as management for OME improved hearing and speech among children with Down syndrome [9]. While the use of PET has been proven to prevent conductive hearing loss in children with Down syndrome, there exists uncertainty surrounding the use of such interventions in children at risk for developmental difficulties including Down syndrome.

A research study conducted by Fortnum, Leighton, Smith, Brown, Jones, Benton et al., in 2014 addressed this uncertainty through surveying parents of children with Down syndrome as well as clinicians [10]. Their findings demonstrated that both parents and physicians viewed OME as a challenging condition to treat with a wide variety of management options dependent on the physician [10]. With an effort to further investigate interventions for OME in children with Down syndrome, a mixed method study was conducted in 2019 by researchers affiliated with Ashton University [11]. The study discovered significant variance in treatment strategies of OME across England [11]. Corroborating the findings of Fortnum, Leighton, Smith, Brown, Jones, Benton et al. they determined that parents felt uncertainty about the efficacy of a wide variety of managements for OME [10,11]. Parental and clinician uncertainty around effective OME management strategies, particularly for children with Down syndrome, points to the need for a tool such as hearing testing to establish the efficacy of treatments.

Given the uncertainty surrounding management of OME in children with Down syndrome, this study seeks to analyze how clinicians adhere

to clinical guidelines to aid in management. The aim of this study is to specifically examine adherence to clinical recommendations for hearing testing after the diagnosis of OME in children with Down syndrome at Children's Mercy Hospital. The results of this project will contribute to the growing need for research studies assessing OME in children with Down syndrome. It will shed light on how clinicians in pediatric and otolaryngology clinics assess and manage OME in children with Down syndrome and illuminate gaps in knowledge with the goal of motivating other researchers to investigate this area of study as well.

## 2. Methods

The study was conducted by extracting information on 124 children from a retrospective medical chart review of Children's Mercy Hospitals. These children were included in the study if they had a diagnosis of Down syndrome, were between 1 and 8 years of age at diagnosis of OME, and were diagnosed with OME between January 1, 2018, and January 1, 2020. Institutional Review Board ethics approval was obtained through Children's Mercy Hospital.

The primary outcome variable of this study was a hearing test after diagnosis of OME in children with Down syndrome (Yes, No). Two types of explanatory variables, demographic and OME-related factors, were considered in this study. Demographic factors included biological sex, ethnicity, age at first OME diagnosis, and type of healthcare insurance. Moreover, the number of OME cases, duration of first OME diagnosis, history of OME, clinic setting, otolaryngology referral after diagnosis with OME, evaluation for PET, newborn hearing screening, and history of PET interventions were considered as clinically related exposures of this study. For duration of first OME diagnosis, 0 months was categorized as new diagnosis whereas greater than 0 months was considered as an old diagnosis.

For descriptive analysis, this study presented the distribution of each explanatory variable in the 2nd column of Table 1. It also displays the distribution of hearing test after the first OME diagnosis by each of the exposures in the 3rd and 4th column of Table 1 including the frequency with column percentage for each categorical variable and mean with standard deviation or median with interquartile range for each quantitative variable.

Statistical analysis was performed to determine if there was any significant association between the response and explanatory variables. Chi-square test (or Fischer's exact test when appropriate) for categorial exposures and one-way Analysis of Variance test for continuous exposure were performed in bivariate analysis. The p-values obtained from these tests are reported in the last column of Table 1. We performed a stepwise model selection procedure based on Akaike Information Criterion value to select the best logistic regression model. The results obtained from the selected best logistic regression model in the adjusted analysis are reported in Table 2.

## 3. Results

In this study, 33.1 % of patients had a hearing test after the first OME diagnosis. The 2nd column in Table 1 depicts that most patients during the time period had only one OME diagnosis (50.8 %), had a new diagnosis (90.3), had a history of OME (67.7 %), were diagnosed in the otolaryngology clinic setting (91.1 %), did not receive otolaryngology referral (97.6 %), did not receive evaluation for PET (50.8 %), passed newborn hearing test (60.5 %), and had history of PET interventions (59.7 %). Moreover, most of them were male (59.7 %) and not Hispanic or Latine (81.5 %). The average age of these patients at their first OME during the time period studied was 3.57 years with 2.22 years standard deviation. The percentage of patients having private and public healthcare insurance was equal (49.2 % each).

The reported p-values of bivariate analysis using chi-square test (or Fisher's exact test when appropriate) for categorical exposures and one-way Analysis of Variance test for continuous exposure showed that only

**Table 1**
Distribution of hearing test after 1st OME diagnosis by clinically related exposures and demographic exposures.

| Variable | All N = 124 | Hearing Test after 1st OME Diagnosis | | p-value |
|---|---|---|---|---|
| | | No, N = 83 (Column %) | Yes, N = 41 (Column %) | |
| **Number of OME Cases** | | | | 0.775 |
| One, N (%) | 63 (50.8) | 44 (53.0) | 19 (46.3) | |
| Two, N (%) | 45 (36.3) | 29 (34.9) | 16 (39.0) | |
| Three or more, N (%) | 16 (12.9) | 10 (12.0) | 6 (14.6) | |
| **Duration of 1st OME (Months) Diagnosis** | | | | 0.529 |
| New diagnosis (0 Month), N (%) | 112 (90.3) | 76 (91.6) | 36 (87.8) | |
| Old diagnosis (Other than 0 Month), N (%) | 12 (9.7) | 7 (8.4) | 5 (12.2) | |
| **Code Used at 1st OME** | | | | 0.664 |
| ICD10 Only, N (%) | 72 (58.1) | 50 (60.2) | 22 (53.7) | |
| SNOMED Only, N (%) | 22 (17.7) | 13 (15.7) | 9 (22.0) | |
| Both, N (%) | 30 (24.2) | 20 (24.1) | 10 (24.4) | |
| **Patient History of OME** | | | | 0.603 |
| Yes, N (%) | 84 (67.7) | 58 (69.9) | 26 (63.4) | |
| No, N (%) | 40 (32.3) | 25 (30.1) | 15 (36.6) | |
| **Clinic Setting** | | | | 0.001 |
| Pediatric clinic, N (%) | 3 (2.4) | 3 (3.6) | 0 (0.0) | |
| Down syndrome clinic, N (%) | 8 (6.5) | 1 (1.2) | 7 (17.1) | |
| Otolaryngology clinic, N (%) | 113 (91.1) | 79 (95.2) | 34 (82.9) | |
| **Received an Otolaryngology Referral after Diagnosis with OME** | | | | 0.550 |
| Yes, N (%) | 3 (2.4) | 3 (3.6) | 0 (0.0) | |
| No, N (%) | 121 (97.6) | 80 (96.4) | 41 (100.0) | |
| **Evaluation for PET** | | | | 0.524 |
| Yes, N (%) | 61 (49.2) | 43 (51.8) | 18 (43.9) | |
| No, N (%) | 63 (50.8) | 40 (48.2) | 23 (56.1) | |
| **Newborn Hearing** | | | | 0.991 |
| Pass, N (%) | 75 (60.5) | 50 (60.2) | 25 (61.0) | |
| Fail, N (%) | 27 (21.8) | 18 (21.7) | 9 (22.0) | |
| Unknown, N (%) | 22 (17.7) | 15 (18.1) | 7 (17.1) | |
| **History of PET Interventions** | | | | 0.706 |
| Yes, N (%) | 74 (59.7) | 51 (61.4) | 23 (56.1) | |
| No, N (%) | 50 (40.3) | 32 (38.6) | 18 (43.9) | |
| **Sex** | | | | 0.706 |
| Male, N (%) | 74 (59.7) | 51 (61.4) | 23 (56.1) | |
| Female, N (%) | 50 (40.3) | 32 (38.6) | 18 (43.9) | |
| **Ethnicity** | | | | 0.958 |
| Hispanic or Latine, N (%) | 23 (18.5) | 16 (19.3) | 7 (17.1) | |
| Not Hispanic or Latine, N (%) | 101 (81.5) | 67 (80.7) | 34 (82.9) | |
| **Age at 1st OME (years)** | | | | 0.660 |
| Mean (Standard Deviation) | 3.57 (2.22) | 3.63 (2.23) | 3.44 (2.23) | |
| Median (Interquartile Range) | 3 (2, 5) | 3 (2, 5) | 3 (1, 5) | |

(*continued on next page*)

**Table 1** (*continued*)

| Variable | All N = 124 | Hearing Test after 1st OME Diagnosis | | p-value |
|---|---|---|---|---|
| | | No, N = 83 (Column %) | Yes, N = 41 (Column %) | |
| **Insurance Type** | | | | 0.672 |
| Private, N (%) | 61 (49.2) | 39 (47.0) | 22 (53.7) | |
| Public, N (%) | 61 (49.2) | 42 (50.6) | 19 (46.3) | |
| No insurance/Unknown, N (%) | 2 (1.6) | 2 (2.4) | 0 (0.0) | |

**Table 2**
Results obtained from logistic regression model of adjusted analysis.

| Coefficients | Coefficients | Standard error | p-value |
|---|---|---|---|
| **Intercept** | −0.843 | 0.205 | <0.001 |
| **Clinic Setting** | | | |
| Pediatric clinic | −15.993 | 2746.703 | 0.995 |
| Down syndrome clinic | 18.973 | 1981.736 | 0.992 |
| Otolaryngology clinic (Reference) | – | – | – |
| **Received an otolaryngology referral after diagnosis with OME** | | | |
| Yes | −34.966 | 3386.983 | 0.992 |
| No (Reference) | – | – | – |

clinic setting had a significant association (p-value <0.001) with the hearing test after diagnosis at 5 % level of significance (see Figs. 2-7). Thus, for patients with a diagnosis OME, the distribution of clinic setting was found to be significantly different among those who received hearing testing compared to those who did not receive testing.

The stepwise model selection procedure resulted in a reduced model which included only two explanatory variables: clinic setting and otolaryngology referral after diagnosis with OME. The results of adjusted analysis using logistic regression model depicted that the two exposures included in the model were not found to have significant effect on receiving the hearing test after first OME diagnosis of children with Down syndrome at the 5 % significance level.

## 4. Discussion

In the unadjusted bivariate analysis, only 31.1 % of patients had a hearing test after an OME diagnosis, indicating that hearing tests were largely not used to inform diagnosis or management at the time of diagnosis. Additionally, no factors had a significant effect on whether a patient received a hearing test at the time of diagnosis in the adjusted analysis, including whether the child received the diagnosis in the otolaryngology clinic, Down syndrome clinic, or pediatrics clinic.

A systematic review conducted by Sait, Alamoudi, and Zawawi also compared guideline recommendations to how clinicians manage OME in children with Down syndrome [12]. They discovered similarly that there was considerable variation in how clinicians treated children with Down syndrome who were diagnosed with OME, and that the results of interventions such as PET varied by study [12]. Although the systematic review did not assess how many patients received hearing testing at diagnosis, they did comment on the fact that the Commission for the Early Detection of Deafness included in their guidelines that certain hearing thresholds were indicators for surgery [12]. This suggests that there is support from the guidelines that hearing testing could help inform management.

Another study demonstrated how audiologic testing can assess the severity of an effusion before and after diagnosis. Al-Salim, Tempero, Johnson, and Merchant examined the audiologic profiles of children with OME and found that children with larger or longer lasting effusions had more significant hearing impairments at the time of diagnosis and that the hearing impairments persisted post-operatively [13]. Additionally, this study proposed that future research studies could examine how pre- and post-operative hearing testing for OME could contribute to clinician decision-making [13]. Thus, while our study indicated that only 31.1 % of patients received hearing testing at the time of diagnosis, hearing testing could potentially be a valuable tool to allow clinicians to stratify patients before and after surgical management.

Although clinic setting did not ultimately have a significant correlation on whether hearing testing was performed, after logistic regression, our study showed that Down syndrome clinics consistently offered hearing testing (p-value of 00.001). While the Down syndrome clinic was less likely to formally diagnosis OME compared to the otolaryngology clinic (6.5 % in the Down syndrome clinic v. 91.1 % in the otolaryngology clinic), it was able to consistently monitor the hearing status of children in accordance with yearly audiologic screening recommended by the AAP Down syndrome guidelines [5]. This finding is corroborated by a study conducted in Dublin that established that implementing a multidisciplinary Down syndrome clinic showed greater adherence to guidelines [14]. Another study by Skotko, Davidson, and Weintraub also found that Down syndrome clinics consistently provided audiologic evaluations and allowed for collaborations between various specialties including audiology [15]. This study demonstrates the consistency with which Down syndrome clinics check hearing status, and thus reinforces how critical Down syndrome clinics are for monitoring the hearing of children with Down syndrome [15].

Children with Down syndrome provide unique challenges in the diagnosis and monitoring of OME and their hearing. As previously written, children with Down syndrome are more likely to have narrowed external auditory canals, cerumen impaction, and hearing loss not related to OME [4]. Small canals and cerumen can lead to challenges in diagnosing OME [4]. This supports the value of routine hearing testing via audiogram and tympanometry that is done in the Down syndrome clinic.

Both the otolaryngology clinic and the Down syndrome clinic at Children's Mercy work with multidisciplinary teams including audiologists. Thus, diagnoses in the otolaryngology and the Down syndrome clinic can be corroborated with audiologic evaluation if needed. This is in comparison to general pediatrics clinics, which often do not work directly with audiologists. If audiology evaluations are performed in the primary care clinic at Children's Mercy, only Otoacoustic Emission testing is available. While only 3 cases of OME were diagnosed in the general pediatrics clinic, none of them resulted in audiologic evaluation. This finding points to the importance of multidisciplinary clinics which can utilize resources provided by various healthcare professionals. Multidisciplinary clinics have been shown to improve quality of life among patients [16]. A research study examining head and neck cancer care demonstrated that professionals working on an integrated team resulted in better treatment outcomes [16]. Additionally, multidisciplinary care was more positively viewed by patients [16]. Further research studies could explore whether multidisciplinary clinics such as Down syndrome clinics and otolaryngology clinics improve the quality of life of children with Down syndrome.

There are several limitations to this study. Firstly, this is a retrospective study. Additionally, this study has a small sample size and was conducted at a tertiary care facility and its' findings may not be generalizable to all settings that take care of children with Down syndrome, such as community clinics. Lastly, this study did not examine whether parental knowledge about guidelines influenced whether the child received a hearing test.

## 5. Conclusion

Only 33.1 % of patients with Down syndrome received hearing testing at diagnosis of OME, and factors chosen for analysis did not have a significant effect on whether children received hearing testing. This suggests that practitioners do not consistently use hearing testing to

assist in diagnosis or management of OME. Down syndrome clinics like that at Children's Mercy offer the opportunity for children with Down syndrome to consistently receive hearing testing at regular intervals. Future studies could examine whether the use of hearing testing can inform surgical management of OME in children with Down syndrome.

## Ethical approval

Not required.

## Funding

Children's Miracle Network.

## CRediT authorship contribution statement

**Mackenzie O'Donnell:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Nasrin Sultana:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Nasreen Talib:** Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization. **Jason May:** Writing – review & editing, Supervision, Resources. **Michael Slogic:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization.

## Declaration of competing interest

None declared.

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