Early identification of hearing loss due to otitis media: The utility of quality of life questions, patient history, and caregiver demographics in the assessment of hearing status

By

Arlene C. Molino PUBH 392 April 22, 2002

A Master's paper submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirement for the degree of Master of Public Health in the School of Public Health, Public Health Practice and Leadership Program.

Approved by

ABSTRACT

<u>Objective:</u> To identify questions that may be asked of caregivers to assess the likelihood of hearing loss in a child with a history of otitis media. <u>Methods:</u> This study utilized data collected from caregivers of children presenting to pediatric or otolaryngology practices. Primary analysis involved statistical comparison of selected characteristics based on history of otitis media and quality of life measures for children who were found to have hearing loss (pure-tone average (PTA) > 20dB HL of better hearing ear or soundfield) and children with normal hearing.

<u>Results:</u> Children whose caregivers reported a moderate to severe problem with physical suffering due to ear infections were more likely to have hearing loss than children whose caregivers reported less of a problem (p<0.05). A similar trend was found for caregivers who felt their children had a moderate to severe problem with hearing loss (p<0.05). Children felt to have spent more than 50 percent of the previous three months with ear infections or fluid were more likely to have hearing loss (p<0.05). Daycare attendance and age at first ear infection were not significantly associated with hearing loss. This result was not significant in bivariate analyses, and was only significant during logistic regression modeling. <u>Conclusions:</u> Caregiver assessment of physical suffering, hearing loss, and time spent with ear infections in the previous three months may be useful for early diagnosis of hearing loss and provision of appropriate care in children with otitis media.

INTRODUCTION

Otitis media (OM) is one of the most common childhood diseases. Twenty million non-hospital visits to physicians are made annually for OM with approximately half of these visits made by children less than three years old.¹ Treatment costs for otitis media have been estimated to be \$3.8 billion per year.² The incidence of the disease usually peaks before 18 months of age, and by six years of age 76 to 95 percent of children have had at least one episode of OM.³ Fluid remains in the middle ear from weeks to months after each episode of OM.⁴ This fluid is usually associated with a transient conductive hearing loss of with a median loss of about 25 decibels Hearing Level (dB HL).⁵ Chronic OM may result in more permanent conductive hearing loss.³

The most common cause of hearing loss in children is OM.⁶ Although this association has been described and confirmed in the literature, the potential sequelae of this hearing loss continues to be controversial. OM infection usually results in a mild to moderate hearing loss, in the range of 15 to 50 dB. This range is critical to speech perception and consequently may affect timely language development as well.⁷ A study by Holm and Kunze was one of the first to examine children with fluctuating hearing loss due to otitis media with effusion (OME) compared to a control group. They found significant differences in articulation of sounds, word comprehension, syntax, and grammar favoring the

control group.⁸ Furthermore, a study by the Greater Boston Otitis Media Study Group found that children who spent increasing amounts of time with middle ear effusion before age three were more likely to have lower scores on a standard verbal intelligence scale, as well as lower scores in mathematics and reading on a standard achievement test.9 However, Hubbard et al did not find such differences, and in fact found scores to be normal in both experimental and control groups.¹⁰ In addition to deficiencies in expressive language skills, the United States Agency for Health Care Policy and Research (AHCPR) found that children with hearing loss consequent to OM have shown poorer attention skills, a result supported by other studies.^{7,11} Impact on psychosocial and psychoeducational domains have also been shown, with one study showing evidence of compromised school performance and behavior.¹² The case also remains that even a transient mild degree of hearing loss may result in less obvious, but still significant, effects on family and social relationships and communication.¹¹ However, authors suggest that several studies that have both shown and refuted associations between otitis media and developmental impairments have had limitations, and consequently the issue still remains unresolved.

Despite the continued debate regarding the consequences of hearing loss due to OM, several groups have put forth recommendations regarding diagnosis of hearing impairment. The AHCPR recommends that hearing evaluation should be performed on all children who have had bilateral fluid for three months and remains optional for children who have had fluid for a shorter time period.⁷ The

American Academy of Pediatrics, American Academy of Audiology, and the American Academy of Otolaryngology have recommended monitoring infants with OME for hearing loss, although are not specific in the details of such monitoring.¹³ Daly *et al* have compiled information that they believe parents of children with recurrent otitis media should have regarding hearing loss.⁷ Their risk factors for hearing loss include: bilateral OME for 3 months or longer, or if two or more of the following characteristics are present: OME present for more than eight weeks, speech development slower than peers, speech less clear than previously, decreased talking, less responsive to name or other familiar sounds, saying "what" or "huh" frequently, sitting closer to TV or requiring louder volume, learning difficulties, being hyperactive or overly inattentive.

The most critical aspect of any screening program is early identification. A study by Yoshinagao-Itano *et al* showed that earlier identification of hearing losses decrease the likelihood of delayed language skills and personal-social abilities for all degrees of hearing loss.¹⁴ Fluid in the middle ear may be asymptomatic in children, and often the eardrum may be difficult to visualize, and may only have subtle findings even if examined.¹ Consequently, identifying other methods of detecting hearing loss in addition to a physical examination may be useful in the assessment of hearing status in children with OM.

The goal of this project is to identify standard questions that may be asked of caregivers to assess the likelihood that a child with otitis media or a history of otitis media has hearing loss using data collected through the Surgeons' Outcomes Research Cooperative (SOURCE). The questions will be drawn from the OM-6,

a 6-item, validated, quality-of-life survey for children with otitis media, as well as additional qualitative questions regarding the child's history of otitis media.¹⁵

The primary hypothesis of this study is that caregiver assessment of the child's difficulty with hearing, speech, emotions, and the time that the child has spent with ear infections or fluid in recent months will be strong predictors of the likelihood that a child will be diagnosed with hearing loss based on the findings by previous studies. In addition, a secondary goal of this project is to determine if certain factors that have been shown to increase the risk of recurrent OM infections also increase the likelihood that a child will be diagnosed with hearing loss. Frequent ear infections may increase the risk that a child may have hearing loss. ¹⁶ Factors such as early onset of first infection, passive smoke exposure, and daycare attendance have been found to be associated with increased risk for recurrent infections.¹⁷ This study will examine the relationship of these factors to hearing loss in children with a history of otitis media.

MATERIALS AND METHODS

This study utilized data collected through surveys completed by parents or caregivers of pediatric patients presenting to pediatric or otolaryngology practices at sixteen sites (11 academic centers and 5 private practice clinics) from July 1998 to August 1999. Practices were selected through the Surgeon's Outcomes Research Cooperative (SOURCE), a network of physicians collaborating in

quality of life studies in patients with ear, nose, and throat illnesses. Collection of data was either performed for a two-week period bi-annually or on an ongoing basis based on physician preference. Caregivers were asked to voluntarily complete a survey packet at the time of check-in for the child's appointment. Data were collected from 2,150 caregivers during this time period. Informed consent was implied if the caregiver read the letter regarding the study and chose to complete the surveys enclosed. The surveys were conducted anonymously to maintain patient confidentiality. The study was formally reviewed and approved by the Duke University Institutional Review Board and the University of North Carolina Institutional Review Board and granted an exemption based on utilization and analysis of an existing dataset.

The subject population for this study was restricted to patients with a primary diagnosis of OM based on the International Classification of Disease (ICD-9) coding (382.0, 382.03, 382.9, 381.0, 381.01, 381.3, 381.1, 382.3), which included patients with acute otitis media and variants and chronic otitis media and variants. Patients with a history of congenital deafness, craniofacial anomaly (including cleft palate), Downs syndrome, and mental retardation were excluded from this analysis.

The packet of surveys included the OM-6 with additional questions regarding the child's history of OM, and a demographic questionnaire (Figures 1 and 2). The OM-6 survey is a validated instrument for collecting quality of life measures for children with OM.¹⁵ The survey consists of six questions relating aspects of physical suffering, hearing loss, speech impairment, emotional distress, activity

limitations, and caregiver concern in the previous four weeks, with ear infections. As designed by Rosenfeld, responses to the questions were rated on the following scale: no problem, hardly a problem, somewhat of a problem, moderate problem, quite a bit of a problem, very much of a problem, extreme problem, with each response assigned a numerical value beginning with a value of 1 for no problem to a value of 7 for extreme problem. Responses to each of the 6 items on the OM-6 survey were categorized into two responses: no problem to mild problem, and moderate to severe problem. An overall survey score was calculated by adding the numerical values for the response to each of the domains and dividing by six.

Caregivers were also asked to assess the time that the child spent with ear infections or fluid in the ear in the previous month, three months, and twelve months. These responses were originally coded as: 0% to 25%, 26% to 50%, 51% to 75%, and 76% to 100%. For the purposes of this study, the responses were dichotomized into 0 to 50% of the time, and 51% to 100% of the time. Child age was recorded as a continuous variable. Caregiver smoking status was based on caregiver self-report (smoker vs. non-smoker). Daycare status was also dichotomized into the responses: no daycare, and in daycare full or part-time.

Trained medical staff assessed hearing status at the end of the child's visit. Hearing loss was defined as a pure-tone average (PTA) of greater than 20 dB HL of the better hearing ear or soundfield. Staff were allowed to rate the loss as not present, present, suspected or unknown. Hearing loss was generally classified as suspected when there is evidence of some degree of hearing loss, however the child has been uncooperative during portions of the test. For the purposes of this

study, hearing loss was categorized into "not present" and "present/suspected." Responses of "unknown" were classified as missing.

The STATA 6 statistical package was used to perform univariate, bivariate, and multivariate statistical analyses.¹⁸ A univariate analysis of the dataset was done to characterize the data, and examine the distribution of variables, taking note of significant numbers of missing values and skewed data.

To facilitate assessment of potential confounders during modeling, bivariate analysis was used to examine the relationship between hearing loss and each independent variable. Pearson's chi-square tests were used to examine the association between categorical variables and hearing loss.¹⁹ Student's t-tests were used to examine the association between continuous variables and hearing loss.²⁰ Separate bivariate analyses examined the relationship between responses to the questions and hearing status for children three years of age or younger and those older than three. This was done to determine if the association between survey responses and hearing status differed for children at different stages of development.

Multivariate statistical analysis was performed using logistic regression to generate a predictive model, using the presence or absence of documented/ suspected hearing loss as the response. The initial model included the primary outcome variable, hearing loss, and all other study variables in the previous bivariate analyses. The Wald test was used to examine whether groups of variables were not significant and could be dropped from the model.²¹ Adjusted proportions were calculated based on beta estimates from the logisitic regression

model adjusted for the other variables.²¹ Means are reported with their standard deviations. Proportions and their corresponding p-values are reported for the chi-square analyses, t-tests, and regression analyses. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 497 subjects met the inclusion/exclusion criteria for this study. A summary of patient characteristics is presented in Table 1. Age, race, age at first ear infection, daycare attendance, number of past ear infections, and percentage of time spent with ear infections were found to have some missing data, however the level was minimal and those cases were excluded from the analyses. The mean age of patients in this study was 3.2 years, with females comprising about 56 percent of the population. Eighty-four percent of the study population was White. Approximately 36 percent of the population studied had documented or suspected hearing loss at the time of their visit. The majority of the study population (97%) was seen in otolaryngology practices, with the remainder seen in pediatric practices. Otitis media with effusion (OME) was the most common diagnosis (33%).

Results of the bivariate analysis of the association between categorical independent variables and hearing loss are shown in Table 2. The mean age of about 3 years was similar for those with hearing loss and those without hearing loss (p=0.525). Child's mean age at the time of his or her first ear infection was

similar for those with no hearing loss and those with suspected or confirmed hearing loss (p=0.568).

Thirty-seven percent of children with non-smoking caregivers were found to have documented or suspected hearing loss compared to 30 percent of children with of smokers. This result was not statistically significant. Children in daycare at least part-time were slightly more likely to have documented or suspected hearing loss compared to those not in daycare (39% vs. 33%), however this result was not statistically significant. Children who were assessed by their parents to have spent more than 50 percent of the month previous to the visit with fluid in their ears or ear infections were almost twice as likely (53% vs. 29%) to be found to have documented or suspected hearing loss compared to children who were though to have spent less than 50 percent of the previous month with ear disease (p < 0.005). Similarly, a higher percentage of children assessed by their parents to have spent more than 50 percent of the past three months with fluid their ears or ear infections had documented or suspected hearing loss than those thought to have spent less time with ear infections. However, parental assessment of ear infection status for the previous twelve months was not significantly associated with hearing loss (p=0.434).

Bivariate associations between hearing loss and each of the six items on the OM-6 survey were examined and the results shown in Table 3. Caregivers who reported a moderate to severe problem with physical suffering related to ear infections were almost twice as likely to have a child with hearing loss (46% vs. 28%) than caregivers who gave a response of "no problem" to "mild problem."

Children whose caregivers felt that the child had a moderate to severe problem with hearing in the previous 4 weeks were more likely to have documented or suspected hearing loss (53% vs. 32%) than children of caregivers who felt that there was, at most, a mild problem (p<0.005). A reply of moderate to severe problem with emotional distress was also significantly associated with hearing loss. Caregivers who felt concerned or inconvenienced for at least some of the time due to ear infections or fluid in the previous four weeks were almost twice as likely to have a child with hearing loss (47% vs. 29%) than those caregivers that were rarely concerned or inconvenienced (p<0.005). Limitation in child activity and speech impairment were not significantly associated with hearing loss status.

There was also a statistically significant relationship between overall OM-6 survey score and hearing loss, with those with documented or suspected hearing loss having a mean total score of 2.7 and those with no hearing loss having a mean total score of 2.3. According to Rosenfeld *et al* a difference of 0.5 reflects a small level of clinical change, in this case clinical difference, and thus it is questionable whether or not this difference in score of 0.4 is clinically significant.¹⁵

A separate bivariate analysis compared the subgroups of children three years of age and younger and those older than three years to determine if the association between survey responses and hearing status differed for children at different stages of development. Patient demographics for each subgroup are shown in Table 4. Results from bivariate analyses are shown in Tables 5 and 6. Daycare attendance and caregiver smoking status were not significantly associated with

hearing status for either subgroup. Children three years of age or younger were more likely to have hearing loss if their caregivers felt that they had spent more than 50 percent of the previous month or three months with ear infections or fluid (p<0.005). There was no significant association between caregiver assessment of time spent with ear disease in the previous twelve months and hearing loss. A reply of "moderate" to "severe problem" to the questions on the OM-6 survey for the domains of physical suffering, hearing loss, speech impairment, and caregiver concern was significantly associated with documented or suspected hearing loss. Activity limitation and emotional distress did not appear to be statistically associated with hearing status.

For subjects older than three years of age caregiver assessment of time spent with ear infections or fluid in the previous month, three months or twelve months did not appear to be significantly associated with hearing loss. Caregiver responses of "moderate" to "severe" problem were associated with documented or suspected hearing loss in subjects older than three years of age for the OM-6 survey domains of physical suffering and hearing loss. Speech impairment, emotional distress, activity limitation, and caregiver concern did not appear to be significantly associated with hearing loss.

The initial logistic regression model included the following variables: child gender, caregiver gender, age, race, parental employment status, OM-6 physical suffering item, hearing loss item, speech impairment item, emotional distress item, activity limitation item, caregiver concern item, caregiver smoking status, age at first ear infections, daycare attendance, and time spent with fluid in past

one, three, and twelve months. The final model after removal of variables that did not appear to be related to the likelihood of hearing loss included the OM-6 physical suffering item, hearing loss item, speech impairment item, activity limitation item, caregiver smoking status, and time spent with fluid in past three and twelve months. These results are presented in Table 7. Children whose caregivers reported a moderate to severe problem with physical suffering in the past 4 weeks were more likely as children whose caregivers reported no problem to a mild problem to have a documented or suspected hearing loss, adjusted for the other variables in the final model (44% vs. 28%, p=0.001). Children whose caregivers reported that the child had a moderate to severe problem with hearing in the past 4 weeks are about 1.5 times as likely to have a suspected or documented hearing loss (49% vs. 32%) as children whose caregivers reported "no problem" to a "mild problem," adjusted for the other variables (p=0.009). After adjusting for the other variables, caregiver smoking status was statistically associated with hearing loss, with a higher proportion of children of caregivers who do not smoke found to have documented or suspected hearing loss compared to children of caregivers who smoke (38% vs. 24%, p=0.010). Children felt to have spent more than 50 percent of the previous three months with ear infections or fluid were more likely to have hearing loss (47% vs. 30%, p=0.002). Children whose caregivers reported that the child had spent more than 50 percent of the past 12 months with fluid in their ears or with ear infections were about 0.7 times as likely to have suspected or documented hearing loss than children whose

caregivers felt that they had spent 50% or less of the past 12 months with fluid in the ears or ear infections (p=0.042).

DISCUSSION

Otitis media has been shown by several studies to have an association with hearing loss.^{7,22} There continues to be debate as to the potential consequences that may result from fluctuating hearing loss associated with OM.^{4,8-10,22} Nevertheless, it may be of use to detect any hearing loss that may be present in a child, even if temporary, in order to address issues in the environment that may help to improve interactions, learning, and overall quality of life. Middle ear disease itself may present with acute, overt clinical symptoms, but may also be asymptomatic. Consequently, defining an efficient method of assessing a child's hearing may be a useful adjunct to a physical exam for the detection of hearing loss in children who may not be presenting with the usual symptoms. The goal of this study was to examine the association of documented hearing loss to responses to questions from the validated OM-6 survey, information regarding child history of OM, and select demographic information from the caregiver and child. The relationship between responses to the questions and hearing status was examined for the overall population as well as in subgroups of children three years of age or younger and those older than three. This was done to determine if the association between survey responses and hearing status differed for children at different stages of development.

Certain risk factors may put children at higher risk for OM and recurrent OM.^{3,23} Children who tend to develop otitis media with effusion (OME), and have subsequent recurrent disease have been shown to have their first infection before 18 months of age.¹¹ Daly et al found that children in day care were about 1.3 times more likely to have early onset acute OM than those children not in day care.¹⁷ They also found that having one smoker in the household was associated with early onset OM in bivariate analysis. However, this relationship did not persist in their multivariate analysis. A child at higher risk for middle ear disease or recurrence of such disease may be at higher risk for experiencing fluctuating hearing loss. The results presented here found no significant association between mean age at first ear infection or attendance at daycare and hearing status in the overall group or in the age group subsets. Reported smoking status by the caregiver was not significantly associated with documented or suspected hearing loss in children in the bivariate analyses for the overall group and the age subgroups. However caregiver non-smoking status and hearing loss were found to be associated after adjustment for other variables. This result is interesting considering the potential increased risk of recurrent OM infection conferred by passive smoke exposure as reported by Daly and other studies.¹⁷ This result may be affected by caregiver reluctance to admit to smoking, particularly if the child is very young. Caregivers who take their children to otolaryngologists may also be more educated about the risk factors for OM, and may also either be more reluctant to report smoking or have just recently guit smoking. In addition, the question asked does not allow insight into the child's immediate environment and

actual exposure to cigarette smoke. This situation may be clarified by asking questions specifically about the child's environment, including the presence of other smokers in the household, whether or not the caregiver used to smoke. In the case of caregivers who report smoking, it would be interesting to know if they smoke around the child. If they do not, simple report of smoking may not accurately represent exposure to passive smoke. The use of urine biomarkers to determine infant exposure to cigarette smoke may also provide a more accurate assessment.

Fluid may persist in the middle ear after an episode of OM for weeks to months, often accompanied by a transient conductive hearing loss.⁵ Chronic OM may damage the inner ear and result in a more permanent hearing loss.³ Consequently, amount of time spent with fluid in the ear or infections may be an important factor to consider when assessing the potential for hearing loss. This study found that a significantly higher percentage of children with caregivers who felt they had spent more than half of the previous three months with ear infections or fluid in the ears were found to have suspected or documented hearing loss. This relationship was significant in the bivariate analyses for the age group of three years and younger, but not for the older subset. In the final regression model, those felt to have spent more than 50 percent of the previous 12 months with ear infections or fluid were less likely to have hearing loss. This result was not significant in bivariate analyses, and was only borderline significant in the final model. Caregivers may be more reliable at assessing ear disease status for shorter intervals and intervals closer to the present time period. In addition, the

actual estimate of time spent with era disease may be more predictive of hearing loss in a more proximate time period.

The relationships between hearing status and questions from the OM-6, a validated survey measuring quality of life for children with otitis media, was also explored in this study.¹⁵ The six items on the survey represented the domains of physical suffering hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns. For the overall study population there was a significant relationship between a caregiver response of "moderate" to "severe problem" in the previous 4 weeks and documented or suspected hearing loss in the child for the domains of physical suffering, hearing loss, speech impairment, emotional distress, and caregiver concern. After adjustment for other variables, the strongest relationships were found between caregiver assessment of physical suffering and caregiver assessment of hearing loss and the presence of documented or suspected hearing loss.

In this study 50 percent of children whose caregivers felt that they had a moderate to severe problem with hearing were found to have documented or suspected hearing loss, the percentage rising to 60 percent in those children three years old or younger. A similar trend was observed in children older than three. These results are in accordance with previous studies that have looked at the ability of parents to assess their child's hearing status. A study in China examined the utility of a questionnaire to detect hearing loss in babies 6 to 8 months old.²⁴ They found that 34 percent of children whose parents had answered that their child has a difficulty hearing certain sounds or in certain situations had

some degree of hearing loss. Over fifty percent of parents in a study by Hovind and Parving were the first to notice that their child was experiencing difficulty with hearing.²⁵ A study by Watkins et al showed a similar result.²⁶ Thus, asking a parent specifically about a child's hearing, including increasing need for questions to be repeated, increased frequency of responses such as "what?", and louder volumes on the television or radio may be useful indicators of a child's hearing status. Although not done here, it is possible that further subgroup analysis of infants may find that this particular line of questioning may not be as useful. Newton et al found that questions asking parents to observe responses to sound in particular environments were useful, which may be better questions to ask the caregivers of young infants.²⁴

The presence of acute OM is often accompanied by ear pain, otorrhea, and local inflammation.²⁷ This study found the relationship between physical suffering and hearing status to be significant in the overall population, and in both age subgroups. Thus, increased severity of physical suffering experienced by the child due to OM may be associated with an increased likelihood that a child may also have hearing loss.

There continues to be debate over the relationship between speech and fluctuating hearing loss as a consequence of OM.^{3,4} This study found that a report of moderate to severe problems with speech, pronunciation, inability to clearly repeat words, or difficulty understanding the child was associated with suspected or documented hearing loss almost 50 percent of the time in the bivariate analyses for the overall population, with the relationship holding for children three and

younger. In the final model, the trend was evident, although was not statistically significant. It is possible that the relationship between speech and language development and transient hearing loss due to otitis media may be more pronounced in long-term evaluation, and thus using such questions to assess hearing difficulty that may have only been present in the previous four weeks may not be as helpful in facilitating diagnosis of hearing loss.

CONCLUSIONS

Hearing loss subsequent to otitis media may have important public health implications in the developmental progress of children in areas of speech, language, cognitive, and psychosocial constructs. Conductive hearing loss due to OME in young children may compromise auditory development.¹¹ Children may have difficulty in articulation of speech, vocabulary comprehension, and grammar.⁸ In addition, poorer school performance and increased attention and behavioral problems have also been associated with hearing loss due to otitis media.^{12,28} Undetected hearing loss may also contribute to strained caregiver-child relationships that could lead to less stimulating and responsive caregiving environments and social isolation.^{7,11} Early identification and intervention for children with all degrees of sensorineural hearing loss has been shown to positively impact normal child development.^{14,29} It is possible that such early

detection and intervention may reduce the risk of negative sequelae due to hearing loss subsequent to otitis media.

Currently, the Agency for Health Care Policy and Research (AHCPR) recommends hearing evaluation when otitis media with effusion persists for more than three months. If a bilateral hearing loss greater than 20dB HL is found, treatment including antibiotics, tympanostomy tube placement, and/or changes in the environment should be discussed.²⁸ However, in addition to the fact that the eardrums of infants and young children may be difficult to visualize, otitis media with effusion (OME) is often asymptomatic in young children. Screening all children who may potentially have otitis media or OME for hearing loss may not be efficient, and may be costly. Nevertheless, as discussed earlier, early detection of such loss may prevent future developmental delays. Thus, supplementing the traditional physical exam with questions that may be highly indicative of hearing loss may improve detection of hearing impairment in young children and infants and allow for timely intervention.

There are some limitations to this study that are worth further discussion. Hearing loss, measured as pure tone average greater than 20dB HL of better hearing ear or soundfield, was only documented as present, suspected, or absent. Thus we are unable to assess the ability of the independent predictors to predict hearing loss at different degrees of severity. Further subset analysis, in particular by type of OM, was limited by sample size. In some children, hearing loss may be present even without fluid in the middle ear and a normal tympanogram.¹¹ With this in mind, it would be interesting to compare the ability of the variables to

predict hearing loss in visits coded as "well-child" exams. It has been shown that children with hearing loss sequelae from OME may exhibit increased attentional problems as well as problematic school performance and behavior.^{11,12} Although this study could not address this issue it would be interesting to see if questions directed at such concerns should be important factors to consider in detecting hearing loss. The counterintuitive association between caregiver smoking status and hearing loss may have been a consequence of the question being too vague, and may need further clarification including frequency and amount of smoking and specific exposure of the infant to passive smoke, and adjustment for socioeconomic status.

Otitis media with effusion is the most common cause of transient conductive hearing loss in children.³ The consequences of such hearing loss continues to be debated. Such fluctuating hearing loss may potentially include speech impairment, difficulty in comprehension and learning, developmental delays, and behavior problems.¹⁰ However, early identification of moderate to severe hearing loss remains important to minimize negative impact.²⁹ This study used the OM-6 survey with additional caregiver demographic questions to determine the likelihood of hearing loss based on patient history and caregiver response. The strongest independent predictors of hearing loss (PTA >20dB better hearing ear or soundfield) in children with a history of otitis media were caregiver assessment of physical suffering and hearing loss in the previous four weeks and estimate of time spent with ear disease in the previous three months.

of documented or suspected hearing loss. A more detailed examination of the specific environment of the child may provide more insight into this finding. Using these questions physicians and medical staff may be able to suspect hearing loss in children with otitis media at an earlier stage. This will enable the appropriate and efficient use of further testing, treatment, and facilitate changes in the home and school environment to address the potential impact of hearing impairment on child development. Future studies should include well-child exams as fluid in the middle ear may be difficult to detect in infants and children and may be asymptomatic.

REFERENCES

¹Paradise JL. Otitis media and child development: should we worry? Pediatr Infect Dis J 1998 Nov; 17 (11):1076-83.

²Gates GA. Cost-effectiveness considerations in otitis media treatment. Otolaryngol Head Neck Surg 1996 Apr; 114 (4):525-30.

³Stach BA. Clinical audiology: an introduction. San Diego(CA): Singular Publishing; 1998.

⁴Roizen NJ. Etiology of hearing loss in children. Nongenetic causes. Pediatr Clin North Am 1999 Feb; 46 (1):49-64.

⁵Klein JO. Otitis media. In: Katz SL, Gershon AA, Hotez PJ, editors. Krugman's infectious diseases of children. 10th ed. St. Louis: Mosby, 1998.

⁶National Institute on Deafness and Other Communication Disorders (NIDCD). Health information: hearing and balance. Available at:

http://www.nidcd.nih.gov/health/hb.htm. Accessed March 16, 2002.

⁷Daly KA. Hunter LL. Giebnik GS. Chronic otitis media with effusion. Pediatr Rev 1999 Mar; 20 (3):85-94.

⁸Holm V, Kunze L. Effects of chronic otitis media on language and speech development. Pediatrics 1969 May; 43 (5):833-39.

⁹Teele DW, Klein JO, Chase C, Menyuk P, Rosner BA. Otitis media in infancy and intellectual ability, school achievement, speech, and language at age 7 years. Greater Boston Otitis Media Study Group. J Infect Dis 1990 Sep; 162 (3):685-94. ¹⁰Hubbard TW, Paradise JL, McWilliams BJ, Elster BA, Taylor FH.

Consequences of unremitting middle ear disease in early life: otologic, audiologic, and developmental findings in children with cleft palate. New Engl J Med 1985 Jun 13; 312 (24):1529-34.

¹¹Tharpe AM, Bess FH. Minimal, progressive, and fluctuating hearing losses in children: characteristics, identification, and management. Pediatr Clin North Am 1999 Feb; 46 (1): 65-78.

¹²Gravel JS, Wallace IF. Early otitis media, auditory abililities, and educational risk. Amercian Journal of Speech & Language Pathology 1995; 4 :89-94.
¹³Joint Committee on Infant Hearing. Year 2000 position statement: principles

and guidelines for early hearing detection and intervention programs. Pediatrics 2000 Oct ; 106 (4):798-817.

¹⁴Yoshinaga-Itano C. Early identification and intervention of hearing-impaired infants. Otolaryngol Clin North Am 1999 Dec; 32 (6):1089-1102.

¹⁵Rosenfeld RM, Goldsmith AJ, Tetlus L, Balzano A. Quality of life for children with otitis media. Arch Otolaryngol Head Neck Surg 1997 Oct; 123 (10):1049-54.

¹⁶Kidshealth. Hearing evaluation in children. Available at:

http://kidshealth.org/parent/system/medical/hear_p2.html. Accessed March 26, 2002.

¹⁷Daly KA, Brown JE, Lindgren BR, Meland MH, Le CT, Giebnik GS.
Epidemiology of otitis media onset by six months of age. Pediatrics 1999 Jun;
103 (6):1158-66.

¹⁸StataCorp. 1999 Stata statistical software. Release 6.0. College Station (TX): Stata Corporation; 1999.

¹⁹Elston RC, Johnson WD. Essentials of biostatistics. Philadelphia (PA): F.A. Davis Company, 1987.

²⁰Dawson-Saunders B, Trapp RG. Basic and clinical biostatistics.

London(England): Appleton & Lange, 1990.

²¹Kleinbaum DG. Logistic regression: A self-learning text. New York (NY):Springer-Verlag, 1994.

²²Roberts JE, Burchinal MR, Zeisel SA, Neebe EC, Hooper SR, Roush J, et al.
Otitis media, the caregiving environment, and language and cognitive outcomes at
2 years. Pediatrics 1998 Aug; 102 (2):346-54.

²³Daly KA, Selvius RE, Lindgren B. Knowledge and attitudes about otitis media risk: implications for prevention. Pediatrics 1997 Dec; 100 (6):931-6.

²⁴Newton VE, Liu X, Ke X, Xu L, Bamford JM. Evaluation of the use of questionnaire to detect hearing loss in babies in China. Int J Pediatr Otorhinolaryngol 1999 May 5; 48 (2):125-9.

²⁵Watkin PM, Baldwin M, Laoide S. Parental suspicion and identification of hearing impairment. Arch Dis Child 1990 Aug; 65 (8):846-50.

²⁶Hovind H, Parving A. Detection of hearing impairment in early childhood.Scand Audiol 1987; 16 (4):187-93.

²⁷McCracken GH. Diagnosis and management of acute otitis media in the urgent care setting. Ann Emerg Med 2002 Apr; 39 (4):413-421.

²⁸Roush J. Screening for hearing loss and otitis media: Basic principles. In:
Roush J, editors. Screening for hearing loss and otitis media in children. Canada:
Singular, 2001.

²⁹Downs MP, Yoshinaga-Itano C. The efficacy of early identification and intervention for children with hearing impairment. Pediatr Clin North Am 1999 Feb; 46 (1):79-87.

FIGURE 1:

Sample survey given to caregivers to collect demographic information.

DEMOGRAPHIC INFORMATION

Contion #4. Easte About Vour Obild
Section #1: Facts About Your Child
1.1 Child's Date of Birth: DD / DD / YY 1.2 Today's Date: DD / DD / YY
1.3 Was your child born: On the due date Before the due date After the due date
1.4 Is your child: Male Female
1.5 What is the highest grade of school your child has completed? (Check one box only)
Preschool5th grade11th gradeKindergarten6th grade12th grade1st grade7th gradeUngraded (If ungraded, how many years attended yrs2nd grade8th gradeyears attended yrs3rd grade9th gradeNot applicable4th grade10th grade
1.6 Have you ever been told by a teacher, school official, doctor, nurse or other health professional that your child
has any of the following conditions? Yes No A. Anxiety problems Yes No B. Asthma Epilepsy (seizure disorder) C. Attentional problems Hearing impairment or deafness D. Behavioral problems Hearing impairment or deafness E. Chronic allergies or sinus trouble Hearing impairment or deafness F. Chronic orthopaedic, bone or joint problems Seep disturbance G. Chronic respiratory, lung or breathing problems (NOT ASTHMA) Seep disturbance H. Chronic rheumatic disease Seep over child have any other chronic medical condition that is affecting what they do or how they feel? (Please describe below) J. Developmental delay or mental retardation No 1.7 Is your child a new patient to the practice (this is your FIRST visit) or an established patient (the child has been seen in this practice previously)?
Section #2: Facts About You
2.1 Are you: Male Female 2.2 What is your date of birth?
Not working due to Not working for Looking for work Full time Working full or part time my child's health "other" reasons outside the home homemaker (either outside the home or at a home-based business)
Continued on the back

SOURCE Network

. .

.

Pediatric QOL Demographics

	Sec	tion #2: Facts A	bout You (Continu	ied)		
2.4 Which of the follow	ving best describes	your relationship to	the child?		•	
Biological / Natural parent	Step parent	Foster parent	Adoptive parent	Guardian	Other (pleas	e describe)
2.5 What is the higher	st level of school th	at you have comple	ted or the highest de	gree you hav	e received?	
	ne high school, diploma	High school diploma	Some college no degree	College graduate	Post-gra degree	
2.6 Which of the follow	ving best describes	your racial backgro	ound?			
White Asian or P	acific Islander	Black Hispanic	American Ind	lian, Eskimo e specify)	·	
2.7 Do you or does an	yone in the child's	home environment :	smoke?	Yes	No	

۰.

٠

2

•

. .

FIGURE 2:

Sample otitis media quality of life survey given to caregivers that includes OM-6 items and additional information regarding child's history of otitis media.

OTITIS MEDIA QUALITY OF LIFE SURVEY

Instructions: Please help us understand the impact of ear infections on your child's quality of life by checking one box [x] for each question below. Thank You!

 <u>PHYSICAL SUFFERING</u>: Ear pain, ear discomfort, ear discharge, ruptured ear drum, high fever, or poor balance. How much of a problem for your child during the past 4 weeks?

Not present / no problem

Hardly a problem at all Somewhat of a problem Moderate problem

Q
V
F

uite a bit of a problem ery much of a problem Extreme problem

2. HEARING LOSS: Difficulty hearing, question must be repeated, frequently says "what," or television is excessively loud. How much of a problem for your child during the past 4 weeks?

Not present / no problem

Hardly a problem at all
Somewhat of a problem
Moderate problem

Q
Ve
Ex

uite a bit of a problem ery much of a problem xtreme problem

 <u>SPEECH IMPAIRMENT</u>: Delayed speech, poor pronunciation, difficult to understand, or unable to repeat words clearly. How much of a problem for your child during the past 4 weeks?

Not present / no problem

Hardly a problem at all Somewhat of a problem Moderate problem

	Quite a bit of a problem
Ĵ	Very much of a problem
	Extreme problem

4. EMOTIONAL DISTRESS: Irritable, frustrated, sad, restless, or poor appetite. How much of a problem for your child during the past 4 weeks as a result of ear infections or fluid?

Not present / no problem

Hardly a problem at all Somewhat of a problem Moderate problem

Quite
Very
Extre

e a bit of a problem much of a problem eme problem

5. ACTIVITY LIMITATIONS: Playing, sleeping, doing things with friends / family, attending school or day care. How limited have your child's activities been during the past 4 weeks because of ear infections or fluid?

Not present / no problem

Hardly a problem at all Somewhat of a problem Moderate problem

┛	1
\Box	,
	1

Quite a bit of a problem Very much of a problem Extreme problem

6. CAREGIVER CONCERNS: How often have you, as a caregiver, been worried, concerned, or inconvenienced because of your child's ear infections or fluid over the past 4 weeks?

Not present / no problem Quite a bit of a problem Hardly a problem at all Somewhat of a problem Very much of a problem Extreme problem Moderate problem 7. How old was your child at the time of his / her first ear infection? 0 - 6 months 7 - 12 months 13 - 18 months 19 - 24 months 2 vrs 3 yrs 4 yrs 5 yrs 6 yrs 8 - 12 yrs 7 vrs

Continued on the back

8.	How many	ear	infections	has	your	child h	ad:
----	----------	-----	------------	-----	------	---------	-----

a

A. Over the past 1 monthB. Over the past 3 monthsC. Over the past 12 months	$\begin{array}{c}0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\0\\$			8 9 10 or more
9. About what percent of time do	you think your child spe	ent with ear infect	ions or fluid in one	or both ears:
A. Over the past 1 month	0% - 25%	26% - 50%	51% - 75%	76% - 100%
B. Over the past 3 monthsC. Over the past 12 months				
10. How many sets of ear tubes	has your child had:	3		5 5
 11. Please tell us the approximation of ear tubes with the set of ear tubes with tubes with the set of ear tubes with tubes withubs with tubes with tubes withubs with tubes with tubes with tu	e date that your ere put in:			
12. Is your child in daycare?	No, not at all	🋄 Yes, pa	art-time	Yes, full-time
13. If your child IS in daycare who is a children0 - 6 children	hat is the total number of	_	nild's day care envir more children	onment?
14. Are there other children living	g at home with you and y	our child?	Yes	No
				·····

Characteristic	Mean (s.d.) or percent	Range
Age ^a	3.2 years (3.1)	0-18
% Male	44%	
% White ^b	84%	
% Black	11%	
% Hispanic	3%	
% with guardian(s) that smoke	24%	
Mean age at first ear infection ^c	1.8 years (1.5)	0-11
% in daycare at least part-time°	51%	
Mean number of ear infections in past ^c :		
1 month	0.79 (1.0)	0-10
3 months	1.7 (1.8)	0-10
12 months	4.3 (3.3)	0-10
% Guardian felt child spent > 50% time with		
fluid in ear(s) or with ear infections in past ^c :		
1 month	26%	
3 months	31%	
12 months	35%	
% with suspected or confirmed hearing loss ^d	36%	1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 - 1999 -
Types of otitis media		
Acute otitis media	22%	
Recurrent otitis media	26%	
Otitis media with effusion	33%	
Chronic otitis media	6%	
Chronic otitis media with effusion	14%	
Physician type		
Otolaryngologist	97%	
Pediatrician	3%	

TABLE 1 Patient characteristics (n=497)

^bn=477 ^cn=474

^dHearing loss defined as pure tone average (PTA) > 20dB in better hearing ear or soundfield); no hearing loss 64%, suspected hearing loss 18%, documented hearing loss 18%.

Characteristic	Ν	% documented/	P value	
		suspected hearing		
		loss, or mean (s.d.)		
Age – Pts. with hearing loss	173	3.0 years (3.1)		
Pts. without hearing loss	319	3.2 years (3.1)	0.525	
Gender				
Female	267	37%		
Male	213	35%	0.596	
Age at first ear infection				
Pts. with hearing loss	169	1.9 years (1.6)		
Pts. without hearing loss	305	1.8 years (1.5)	0.568	
Caregiver smoking status				
Non-smoker	377	37%		
Smoker	120	30%	0.140	
Daycare status				
none	231	33%		
part-time/full-time	243	39%	0.158	
Time spent with fluid in ear(s) or				
with ear infections in past:				
1 month		· · ·		
\leq 50%	350	29%		
> 50%	124	53%	<0.005	
3 months				
<u><</u> 50%	329	30%		
> 50%	145	48%	<0.005	
12 months				
<u><</u> 50%	306	37%		
> 50%	168	33%	0.434	

 TABLE 2

 Bivariate associations between patient characteristics and suspected/confirmed hearing loss

Characteristic	N	% documented/ suspected hearing loss, or mean (s.d.)	P value
Overall OM-6 survey score	147 PAANABAA AAssoo oo soosaa		
Pts. with hearing loss	169	2.7 (1.1)	
Pts. without hearing loss	305	2.3 (1.1)	<0.005
Otitis media survey (OM-6) Physical			
suffering measure			
No problem to mild problem	268	28%	
Moderate to severe problem	206	46%	< 0.005
Otitis media survey (OM-6) Hearing			
loss measure			
No problem to mild problem	391	32%	
Moderate to severe problem	83	53%	<0.005
Otitis media survey (OM-6) Speech			
impairment measure			
No problem to mild problem	416	34%	
Moderate to severe problem	58	47%	0.064
Otitis media survey (OM-6)			
Emotional distress measure			
No problem to mild problem	361	33%	
Moderate to severe problem	113	43%	0.050
Otitis media survey (OM-6) Activity			
limitation measure			
No problem to mild problem	393	35%	
Moderate to severe problem	81	41%	0.294
Ofitis media survey (OM-6) Caregiver			
concerns measure			
No problem to mild problem	297	29%	
Moderate to severe problem	177	47%	<0.005

TABLE 3 Bivariate associations between OM-6 Survey answers and documented/suspected hearing loss

TABLE 4	•
---------	---

Characteristic	\leq 3 years old	> 3 years old	
	(n=327)	(n=173)	
% male	47.0%	38.8%	
% White	80%	91%	
% Black	14%	6%	
% Hispanic	4%	3%	
Mean age at first ear infection	1.5 years (0.9)	2.4 years (0.2)	
% in daycare at least part-time	57%	38%	
Mean number of ear infections in past:			
1 month	0.9 (1.1)	0.6 (0.9)	
3 months	2.0 (1.8)	1.2 (1.6)	
12 months	4.8 (3.3)	3.4 (3.1)	
% guardian felt child spent >50% with fluid			
in ear(s) or with ear infections in past:			
1 month	29%	21%	
3 months	34%	24%	
12 months	39%	29%	
% with suspected or confirmed hearing loss ^a	38%	30%	
Types of otitis media			
Acute otitis media	22%	21%	
Recurrent otitis media	29%	20%	
Otitis media with effusion	38%	42%	
Chronic otitis media	7%	2%	
Chronic otitis media with effusion	14%	14%	

Patient characteristics for those three years of age and younger compared to those older than three years (Mean (s.d.) or percent)

^aHearing loss defined as pure tone average (PTA) > 20dB in better hearing ear or soundfield)

TABLE 5

Bivariate associations between OM-6 survey answers/patient characteristics and documented/suspected hearing loss for subjects three years of age or younger (n=327)

Characteristic	N	% documented/ suspected hearing loss	P value
Caregiver smoking status			
Non-smoker	253	40%	
Smoker	74	30%	0.111
Caregiver assessment of time spent with			
fluid in ear(s) or with ear infections in past: 1 month			·
$\leq 50\%$	223	30%	
> 50%	91	57%	< 0.005
3 months			
$\leq 50\%$	207	32%	
_ > 50%	107	50%	< 0.005
12 months			
< 50%	192	42%	0.084
	122	32%	•
Daycare status		Josef a de Série de	
none	134	33%	
at least part time	180	42%	0.196
Otitis media survey (OM-6) Physical			and the second
suffering measure	160	31%	
No problem to mild problem	154	45%	0.013
Moderate to severe problem			
Otitis media survey (OM-6) Hearing loss			
measure			
No problem to mild problem	278	35%	
Moderate to severe problem	36	58%	0.007
Otitis media survey (OM-6) Speech		an and a second s	
impairment measure			
No problem to mild problem	278	36%	
Moderate to severe problem	36	53%	0.050
Otitis media survey (OM-6) Emotional			The Configuration of the Confi
distress measure			
No problem to mild problem	224	36%	
Moderate to severe problem	90	42%	0.226
Otitis media survey (OM-6) Activity		nga 1910 - Ang Pengangan Ang Pang Pengangan Ang Pengangan Pengangan Pengangan Pengangan Pengangan Pengangan Pen Pengangan Pengangan P	an a state and the state of the state of the
limitation measure			
No problem to mild problem	254	37%	
Moderate to severe problem	60	40%	0.709
Otitis media survey (OM-6) Caregiver			
concerns measure			
None of the time to part of the time	177	31%	
Good part of the time to all of the time	137	47%	0.002

TABLE 6

Bivariate associations between OM-6 survey answers/patient characteristics and documented/suspected hearing loss for subjects older than three years of age (n=165)

Characteristic	N	% documented/ suspected hearing loss	P value
Caregiver smoking status			
Non-smoker	121	27%	
Smoker	44	31%	0.610
Caregiver assessment of time spent with fluid in			
ear(s) or with ear infections in past:			
1 month			
\leq 50%	123	27%	
- > 50%	33	42%	0.083
3 months			
< 50%	118	26%	
= > 50%	38	42%	0.064
12 months			
\leq 50%	111	28%	
> 50%	45	36%	0.347
Daycare status			
none	97	32%	
at least part time	59	27%	0.768
Otitis media survey (OM-6) Physical suffering	v		
measure			
No problem to mild problem	107	22%	
Moderate to severe problem	49	47%	0.002
Otitis media survey (OM-6) Hearing loss measure			
No problem to mild problem	109	22%	
Moderate to severe problem	47	49%	0.001
Otitis media survey (OM-6) Speech impairment	Contraction and Address of		And a second
measure			
No problem to mild problem	135	29%	
Moderate to severe problem	21	38%	0.392
Otitis media survey (OM-6) Emotional distress			
measure			
No problem to mild problem	134	28%	
Moderate to severe problem	22	45%	0.091
Otitis media survey (OM-6) Activity limitation		n a ta Cuinte na seconda na presenta da construction da construction de la construction da construction da cons En al seconda construction de la cons	
measure			
No problem to mild problem	136	29%	
Moderate to severe problem	20	40%	0.303
Otitis media survey (OM-6) Caregiver concerns			
measure			
No problem to mild problem	118	26%	
Moderate to severe problem	38	42%	0.064

documented/suspe	<u>cted heari</u>	ng loss	
Characteristics	N ^a	Adjusted % with documented/ suspected hearing loss	p value
Otitis media survey (OM-6) Physical suffering			
measure			
No problem to mild problem	268	28%	
Moderate to severe problem	206	44%	0.001
Otitis media survey (OM-6) Hearing loss measure	e		
No problem to mild problem	391	32%	
Moderate to severe problem	83	49%	0.009
Otitis media survey (OM-6) Speech impairment			
No problem to mild problem	416	33%	
Moderate to severe problem	58	43%	0.204
Otitis media survey (OM-6) Activity limitation		· · · · · · · · · · · · · · · · · · ·	
measure			
No problem to mild problem	393	37%	
Moderate to severe problem	81	25%	0.063
Caregiver smoking status			
Non-smoker	361	38%	
Smoker	113	24%	0.010
Time spent with fluid in ear(s) or with ear			
infections in past 3 months			
\leq 50%	329	30%	
> 50%	145	47%	0.002
Time spent with fluid in ear(s) or with ear			
infections in past 12 months			
\leq 50%	306	38%	
>50%	168	28%	0.042

TABLE 7
Adjusted* comparisons between OM-6 survey answers and
documented/suspected heaving loss

*Based on beta estimates from a logistic regression model adjusted for other variables in the model (OM-6 physical suffering measure, OM-6 hearing loss measure, OM-6 speech impairment measure, OM-6 activity limitation measure, caregiver smoking status, time spent with ear infections in past 3 months, time spent with ear infections in past 12 months).

^a limited by the variable with the lowest number of responses