Otitis Media and Speech and Language: A Meta-analysis of Prospective Studies

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ABSTRACT. *Objective.* **Considerable controversy surrounds whether a history of otitis media with effusion (OME) in early childhood causes later speech and language problems. We conducted a meta-analysis of prospective studies to determine: 1) whether a history of OME in early childhood is related to receptive language, expressive language, vocabulary, syntax, or speech development in children 1 to 5 years old and 2) whether hearing loss caused by otitis media in early childhood is related to children's receptive language or expressive language through 2 years of age.**

Methods. **We searched online databases and bibliographies of OME studies and reviews for prospective or randomized clinical trials published between January 1966 and October 2002 that examined the relationship of OME or OME-associated hearing loss in early childhood to children's later speech and language development. The original search identified 38 studies, of which 14 had data suitable for calculating a pooled correlation coefficient (correlational studies) or standard difference between parallel groups (group studies). Random-effects meta-analysis was used to pool data when at least 3 studies had usable data for a particular outcome.**

Results. **We performed 11 meta-analyses. There were no significant findings for the analyses of OME during early childhood versus receptive or expressive language during the preschool years in the correlation studies. Similarly, there were no significant findings for OME versus vocabulary, syntax, or speech during the preschool years. Conversely, there was a significant negative association between OME and preschoolers' receptive and expressive language (lower language) (0.24 and 0.25 standard difference, respectively) in the group studies. Additionally, hearing was also related to receptive and expressive language in infancy (3%–9% of variance).**

Conclusions. **Our results indicate no to very small negative associations of OME and associated hearing loss to children's later speech and language development. These findings may overestimate the impact of OME on outcomes, because most studies did not adjust for known confounding variables (such as socioeconomic status) and excluded data not suitable for statistical pooling, especially from methodologically sound studies. Although some OME language differences were detectable by meta-analysis due to increased statistical power, the clinical relevance for otherwise healthy children is**

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There continues to be considerable debate over whether a history of otitis media (OM) with effusion (OME) during the first few years of life, a critical period for learning language, causes later speech and language difficulties.[1–3] When a child has OME, a mild to moderate fluctuating hearing loss generally occurs that has been hypothesized to interfere with rapid language processing, causing a child to encode information inefficiently, incompletely, or inaccurately into the database from which language develops.[3] If OME and the associated hearing loss persists or recurs during the formative years of language and learning, it has been hypothesized to delay language development, possibly affecting vocabulary or grammar.

During the past 3 decades, >100 original studies have examined whether a history of OM (including OME and acute OM) is related to later speech and language development. Children with a history of OME scored lower on measures of speech and language development in some studies,[4–6] compared with children who infrequently experienced OME, whereas other studies did not find such a linkage between OME and children's speech and language development.[7–9] Although earlier studies[10,11] of the OME-language learning relationship had many methodologic problems, studies in the past 2 decades avoided many of these problems by following children prospectively[7,12,13] or using randomized clinical trials (RCTs) in which children with persistent OME were randomized to have tympanostomy tubes inserted promptly or at a later point while monitoring language development.[6,8,9]

Two recent systematic reviews[14,15] examined how OME relates to children's later speech and language development. The Agency for Healthcare Research and Quality (AHRQ)[14] examined associations between a history of OME and standardized measures

TABLE 1. Characteristics of Final Data Set for Meta-Analysis

Author (Year) and Location	Description of Study Sample: Source; Ethnicity; SES	OME and Hearing Documentation	Meta-Analyses Using Study Data (Test Used, Child Age at Testing)
Teele et al[46] (1984) Boston, MA	Neighborhood health centers and private practice; ethnicity unknown; SES: middle and lower	Otoscopy, age 0–3 y (well and sick office visits)	Correlational analyses: Rec language 3 y vs OME (PLS, 3 y) Exp language 3 y vs OME (PLS, 3 y) Vocabulary 3 y vs OME (PPVT, 3 y) OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (PLS, 3 y) Exp language 2–5 y vs OME (PLS, 3 y) Vocabulary 3 y vs OME (PPVT, 3 y)
Pearce et al[42] (1988) Alberta, Canada	Hospital, <37 weeks' gestation and 1500 g or complicated ventilation; IQ >70; OM⁺ had tubes before age 3.5 y or abnormal tymp twice; OM⁻ had normal tymp; 88% white; SES: unknown	Tymp at 0, 4, 8, 12, 18, and 36 mo	OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (SICD, 2–4 y)
Rach et al[43] (1988) Nijmegen, Netherlands	Community birth cohort, matched sample; OM⁺ had OME >6 mo; OM⁻ was normal; SES: unknown; Dutch speaking	Tymp every 3 mo, age 2–4 y	OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (RDLS, 31–36 mo) Exp language 2–5 y vs OME (RDLS, 31–36 mo)
Wallace et al[47] (1988) New York, NY	Hospital, high-risk and full-term infants; 52% Hispanic, 44% black; SES: mostly low; English speaking	Otoscopy, age 0–1 y (mean 8–9 visits); ABR at 0, 3, 6, 9, and 12 mo	Correlational analyses: Rec language 1–2 y vs hearing (SICD, 1 y) Exp language 1–2 y vs hearing (SICD, 1 y)
Friel-Patti and Finitzo[40] (1990) Dallas, TX	Private pediatric practice, typically developing; ethnicity unknown; SES middle-high; English speaking	Otoscopy, tymp every ≤6 weeks, age 6–18 mo, then every 12 weeks	Correlational analyses: Rec language 1–2 y vs hearing (SICD, 18 mo) Exp language 1–2 y vs hearing (SICD, 18 mo)
Roberts et al[44] (1991) North Carolina ABC Study	University-based childcare; 60% black, 38% white; SES: 52% low, 48% middle	Otoscopy, tymp every 2–4 weeks, age 0–3 y	Correlational analyses: Vocabulary 3–5 y vs OME (NDW, 54 mo) Syntax 3–5 y vs OME (MLU, 54 mo)
Gravel and Wallace[41] (1992) New York, NY	Hospital, 61% high risk, 39% full term infants; 52% black, 39% Hispanic; SES: low; English speaking	Otoscopy, 0–1 y (10 routine visits plus illness visits)	OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (SICD, 4 y) Exp language 2–5 y vs OME (SICD, 4 y)
Roberts et al[45] (1998) North Carolina COMP Study	Child care centers; 100% black; SES: mostly low	Otoscopy, tymp every 2–4 weeks, age 6–24 mo	Correlational analyses: Rec language 1–2 y vs hearing (SICD-R, 2 y) Exp language 1–2 y vs hearing (SICD-R, 2 y)
Maw et al[6] (1999) Bristol, United Kingdom	Otolaryngology clinic; if bilateral chronic OME randomized to no tubes (OM⁺) vs tubes (OM⁻); 96% white; SES: unknown	Otoscopy, tymp; bilateral OME documented ≥3 mo	OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (RDLS, 3.8–4.5 y) Exp language 2–5 y vs OME (RDLS, 3.8–4.5 y)
Paradise et al[7] (2000) Pittsburgh, PA	Urban hospitals or private practice; 83% white, 16% black; SES: 32% low, 66% private insurance	Otoscopy, tymp at least monthly, age 0–3 y	Correlational analyses: Vocabulary 3 y vs OME (PPVT-R, 3 y) Vocabulary 3–5 y vs OME (NDW, 3 y) Syntax 3 y vs OME (MLU, 3 y) OM⁺ group vs OM⁻ group analyses: Vocabulary 3 y vs OME (PPVT-R, 3 y) Speech 3 y vs OME (PCC, 3 y)
Roberts et al[12] (2000) North Carolina COMP Study	Child care centers; 100% black; SES: mostly low	Otoscopy, tymp every 2–4 weeks, age 6–48 mo	Correlational analyses: Rec language 3 y vs OME (SICD-R, 3 y) Exp language 3 y vs OME (SICD-R, 3 y) Vocabulary 3 y vs OME (PPVT, 3 y) Vocabulary 3–5 y vs OME (NDW, 3 y) Syntax vs 3–5 y OME (MLU, 3–5 y)
Rovers et al[9] (2000) Utrecht, Netherlands	Birth cohort failed hearing screen age 9 mo; if OME 4–6 mo randomized to no tubes (OM⁺) vs tubes (OM⁻); SES: unknown	Otoscopy, tymp, audiogram every 3 mo, age 9–19 mo	OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (RDLS, 2.5 y) Exp language 2–5 y vs OME (RDLS, 2.5 y)

Author (Year) and Location	Description of Study Sample: Source; Ethnicity; SES	OME and Hearing Documentation	Meta-Analyses Using Study Data (Test Used, Child Age at Testing)
Shriberg et al[14] (2000) Dallas, TX	Private practice, typically developing; ethnicity unknown; SES: 100% middle-high; English speaking	Otoscopy, tymp every ≤6 weeks, age 6–18 mo, then every ≤12 weeks; ABR at 6 mo; VRA at 12 and 18	Correlational analyses: Rec language 3 y vs OME (SICD, 3 y) Exp language 3 y vs OME (SICD, 3 y) Vocabulary 3 y vs OME (PPVT, 3 y) OM⁺ group vs OM⁻ group analyses: Rec language 2–5 y vs OME (SICD, 3 y) Exp language 2–5 y vs OME (SICD, 3 y) Vocabulary 3 y vs OME (PPVT, 3 y) Speech 3 y vs OME (PCC, 3 y)
Paradise et al[8] (2001) Pittsburgh, PA	Urban hospitals or private practice; if OME threshold, randomized to late tubes (OM⁺) vs early tubes (OM⁻); 60% white, 40% nonwhite; SES: 65% low, 35% private insurance	Otoscopy, tymp at least monthly age 0–3 y	OM⁺ group vs OM⁻ group analyses: Vocabulary 3 y vs OME (PPVT, 3 y) Speech 3 y vs OME (PCC, 3 y)

ABR, indicates auditory brainstem response; Exp, expressive; IQ, intelligence quotient; Rec, receptive; SICD, SICD-Revised; tymp, tympanometry; VRA, visual response audiometry.

of receptive and expressive language in 6 cohorts of children and concluded that they could neither support nor refute the possible effect of OME on children's language development. Casby[15] analyzed 22 studies of the association of OME to children's receptive and expressive language, combining multiple outcomes from single-cohort, group, and correlation studies, different ages, and specific and overall measures of language. He reported the magnitude of an association of OME to language to be markedly low. OME-related hearing loss was not used as a predictor in either of these meta-analyses. The conclusions and the meta-analyses, however, may have limited validity because of issues concerning study selection, data pooling, and choice of outcome measures.

To address the methodologic limitations of earlier systematic reviews, we conducted a meta-analysis to test whether a history of OME in early childhood is related to children's later speech and language skills. We included only prospective studies and RCTs because they provide the highest scientific rigor for clinical recommendations.[16] We examined the following speech and language outcomes separately in children tested between 1 and 5 years of age: 1) receptive language or language comprehension; 2) expressive language or language production; 3) speech production or how the individual sounds are said; and 4) 2 commonly studied language domains (vocabulary and grammar). We initially included studies of children through the age of 12 years but found insufficient combinable data to complete analyses after age 5 years. We also examined OME-related hearing loss as a predictor of language outcomes when there was sufficient data for the analysis.

METHODS

Study Selection

First, we searched Medline, the Cochrane Library, and PsycInfo, the bibliographies of OME original data studies, and OME language reviews for articles published between January 1966 and October 2002 examining how OME in early childhood relates to later speech and language skills. The MeSH search terms and keywords used in our computerized search strategy were: otitis media/otitis media with effusion/ear infections; infant, preschool, child, adolescent; and speech/language development/disorder, child language/development, speech perception/production, language comprehension/production, receptive/expressive language, and communication/disorders. Manual searches included the bibliographies of original OME data studies and review articles.

Two investigators independently examined the listings obtained for original research studies that 1) used a prospective or RCT study design, 2) measured outcomes of receptive language, expressive language, vocabulary, syntax, language use, and speech, and 3) documented OME or associated hearing loss before the age of 5 years. We did not include studies on children with biological or genetic conditions that increased the risk for OME such as Down syndrome, cleft palate, or other craniofacial anomalies. We also did not include case reports, letters to the editor, review articles, book chapters, and conference or symposium proceedings.

Two investigators independently reviewed 38 articles meeting the criteria for inclusion and abstracted descriptive information and quantitative data. Any disagreements were settled by consensus after reexamining the article. We then eliminated articles in several steps. First, we excluded studies that included the same children in multiple studies,[17–22] only including 1 study in each age grouping for the multiple studies using the criteria as described below. Second, we excluded studies that used parent

report to document speech or language instead of standard means of assessing speech and language.[23,24] Third, we excluded studies without usable data for the meta-analysis,[13,25–32] including correlation studies that did not report a correlation coefficient or R^2 and group comparison studies that did not report means and standard deviations (SDs), standard or mean group differences, T values, or P values.

Next, we grouped studies by design (correlational versus independent group comparisons), independent variable in early childhood (OME versus direct measure of hearing), and the age of the speech or language outcome assessment (infancy [1–2 years], preschool [2–5 years], or school age [5–8 years]). The categorization into correlational versus group studies was due to data-pooling issues, because the 2 types of data are not interchangeable. In the correlational studies, an independent variable (OM or hearing) is examined for its association with ≥1 outcomes. Group studies compared outcomes in ≥2 independent and parallel groups of children with differing levels of OM based on historical experience or randomization to tympanostomy tubes versus watchful waiting.

Several a priori decisions were made in grouping and pooling the data. For each age grouping, a study could contribute data from a given cohort of children only once to maintain statistical independence. For infants, we used the oldest outcome age if a study reported multiple outcomes (eg, ages 1 and 2 years). For preschoolers, we used outcome data from 3 years old, if available, because 3 years was the most frequent test age and permitted consistency. For studies in a preschool grouping that did not include test results at 3 years old, we again included the oldest test age reported (eg, 5 years old for a study of outcomes at ages 4 and 5 years). Thus, it was possible for the same cohort of children who were followed longitudinally with different measures to participate in >1 meta-analysis; however, the same group of children could only be part of 1 meta-analysis.

A final criterion for meta-analysis for each age group was that data be available from ≥3 studies to justify statistical pooling. Thus, we excluded studies[5,33–38] in meta-analyses that were in an age grouping that would contain data from only 1 or 2 cohorts (eg, only 2 correlation studies examined OME and receptive language in infancy). Eleven age groupings remained with at least 3 studies on a particular outcome and were available for meta-analyses: 1) infancy: receptive language versus hearing loss (correlation studies); 2) infancy: expressive language versus hearing loss (correlation studies); 3) preschool: receptive language versus OME (correlation studies); 4) preschool: receptive language versus OME (group studies); 5) preschool: expressive language versus OME (correlation studies); 6) preschool: expressive language versus OME (group studies); 7) preschool: vocabulary comprehension (Peabody Picture Vocabulary Test [PPVT])[39] versus OME (correlation studies); 8) preschool: vocabulary comprehension (PPVT)[39] versus OME (group studies); 9) preschool: expressive vocabulary (number of different words [NDW]) versus OME (correlation studies); 10) preschool: expressive syntax (mean length of utterance [MLU]) versus OME (correlation studies); and 11) preschool: speech versus OME (group studies).

Fourteen studies were included in the final data set.[4,6,7–9,12,40–47] Table 1 lists the study population, procedures for documenting OME, speech and language tests administered, age of children when tested, and to which specific meta-analyses the study contributed data for each of these included studies.

Statistical Methods

Data from individual studies were combined (pooled) by using a random-effects model of meta-analysis,[48] which assumes a population (distribution) of true effect sizes with each source article representing 1 member of this population. Under this model, results are expected to vary from study to study, with differences caused by experimental error and differences in populations (between-study variability). Because of this additional variability, the 95% confidence interval (CI) for the pooled result is wider (less precise) than for a fixed-effect model. Therefore, the random-effects model gives a more conservative estimate of association.

For correlation studies, data were pooled by using the Pearson correlation coefficients (R) and sample sizes from source articles. Adjusted coefficients were used whenever available to account for the impact of modifying factors on effect size (eg, maternal education and socioeconomic status [SES]). If a study gave separate

coefficients for low- versus middle-income families, we used the middle-income data as a more-conservative estimate. The combined R is statistically significant ($P < .05$) if the 95% CI does not contain zero; negative values indicate poorer outcomes with OM. A statistically significant $R < 0.25$ suggests little or no relationship, 0.25 to 0.49 suggests a fair relationship, 0.50 to 0.74 suggests a moderate relationship, and ≥0.75 suggests a good relationship. The coefficient of variation (R^2) gives the variability in effect size that is explained by changes in the independent variable (OME or hearing levels).

For studies comparing independent groups (randomized or observational) with different levels of OM, data were pooled by using the P values or group means and SDs from source articles. If >2 groups were available, we designated the group with the least OM as "OM⁻" and the one with the most OM as "OM⁺" (data from intermediate groups were not used). Effect sizes for individual and combined studies were calculated by using the standard difference (d), defined as the mean difference between the OM⁺ versus OM⁻ groups divided by the common within-group SD. This allows comparison between studies, because the metric of comparison is the number of SD units that the groups differ. The d is statistically significant ($P < .05$) if the 95% CI does not contain zero; negative values indicate poorer outcomes with OM. A statistically significant $d < 0.20$ suggests little or no effect, 0.20 to 0.49 suggests a small effect, 0.50 to −0.79 suggests a moderate effect, and ≥0.80 suggests a large effect. Analysis of variance (ANOVA) was used whenever possible to assess the impact of study design (randomized versus observational) on outcomes.

Statistical analysis was performed by using comprehensive meta-analysis,[49] which weights study results with the inverse of variance and calculates a random-effects estimate of the combined effect and 95% CI. A test of heterogeneity is performed by using the Q statistic to evaluate whether the pooled studies represent a homogeneous distribution of effect sizes. Significant heterogeneity beyond random fluctuation exists if $P < .05$, although the test has low power and important variations may be present even with a nonsignificant result. For this reason, the random-effects model is used regardless of the test of heterogeneity, because this model assumes a population of true effect sizes (not 1 size) with broader confidence limits adjusted for heterogeneity between studies.

All meta-analyses with statistically significant results include a graphic display of results to aid interpretation. The forest plot is a widely used form of presentation that plots point estimates (black squares) from different studies along with their error bars (horizontal lines).[50] Because the eye is drawn to longer error bars, data from smaller studies have a relatively greater visual effect. To compensate for this distortion, boxes are drawn proportional to study-sample size. The combined result is depicted below the studies with a black diamond spanning the 95% CI. When most or all of the individual studies' 95% CIs contain the combined rate difference (center of the black squares), the studies are relatively homogeneous.

RESULTS

Receptive Language Versus OME and Hearing Loss

Three correlation studies[4,12,46] (Table 2) examined whether OME was associated with receptive language at 3 years old using the Preschool Language Scale (PLS)[51] or Sequenced Inventory of Communication Development (SICD).[52] Meta-analysis showed no association between OME and receptive language, and the combined 95% CI does suggest adequate statistical power.

Seven parallel group studies[4,6,9,41–43,46] (Table 3) examined whether OME was associated with receptive language at age 2 to 5 years by using the PLS, SICD, or Reynell Development Language Scales (RDLS).[53] Two studies were randomized,[6,9] and 5 were prospective cohorts.[4,41–43,46] Meta-analysis showed a significant negative association between OME and receptive language during the preschool years (Fig. 1), with a d of −0.25 (95% CI: −0.41,

TABLE 2. Correlation Meta-Analysis of Receptive and Expressive Language at Age 3 Years Versus OME

Author (Year)	Test (age, y)	Receptive Language			Expressive Language		
		N	Dir*	R (95% CI)†	N	Dir*	R (95% CI)†
Teele et al[46] (1984)	PLS (3)	205	E	−0.14 (−0.27, 0)	201	E	−0.14 (−0.27, 0)
Roberts et al[12] (2000)	SICD (3)	79	E	−0.15 (−0.36, 0.07)‡	79	E	−0.13 (−0.34, 0.09)‡
Shriberg et al[4] (2000)	SICD (3)	67	R	.23 (−0.01, 0.45)	67	R	0.11 (−0.13, 0.34)
Combined	Various (3)	351	E	−0.03 (−0.27, 0.22)§	347	E	−0.07 (−0.22, 0.08)¶

* Direction of effect: expected (E) or reverse (R).
† Pearson correlation coefficient: $P < .05$ if 95% CI does not contain zero.
‡ Adjusted correlation coefficient.
§ Random effects (receptive) combined $P = .811$; test of heterogeneity: $Q = 7.44$, degrees of freedom (df) = 2, $P = .024$.
¶ Random effects (expressive) combined $P = .350$; test of heterogeneity: $Q = 3.21$, df = 2, $P = .201$.

−0.09). All studies were homogeneous ($P = .564$). The magnitude of relationship suggests a small effect, but the 95% CI cannot exclude a trivial (−0.09) or almost good (−0.41) effect. There was a smaller d in the 2 randomized studies (−0.22) than in the observational studies (−0.28), but sensitivity analysis showed no impact of randomization on outcomes (ANOVA: $P = .729$).

Three correlation studies[40,45,47] (Table 4) examined whether hearing loss from OME was associated with receptive language at age 1 to 2 years by using the SICD. Meta-analysis showed a statistically significant negative association between hearing loss and receptive language during infancy (Fig. 2), with an R value of −0.17 (95% CI: −0.29, −0.05). All studies were homogeneous ($P = .516$). Although the magnitude of relationship is small (explains 2.9% of variance), the 95% CI cannot exclude a trivial (−0.05) or fair (−0.29 correlation) effect.

Expressive Language Versus OME and Hearing Loss

Three correlation studies[4,12,46] (Table 2) examined whether OME was associated with expressive language at 3 years old by using the PLS[51] or SICD[52] at 3 years old. Meta-analysis showed no association between OME and expressive language, and the combined 95% CI does suggest adequate statistical power.

Six parallel group studies[4,6,9,41,43,46] (Table 3) examined whether OME was associated with expressive language at ages 2 to 5 years by using the PLS,[51] SICD,[52] or RDLS.[53] Two studies were randomized,[6,9] and 4 were prospective cohorts.[4,41,43,46] Meta-analysis showed a significant negative association between OME and expressive language (Fig. 3), with a d of −0.24 (95% CI: −0.41, −0.07). All studies were homogeneous ($P = .432$). The magnitude of relationship suggests a small effect, but the 95% CI cannot exclude a trivial (−0.07) or almost good (−0.41) effect. There was a smaller d in the 2 randomized studies (−0.23) than in the observational studies (−0.25), but sensitivity analysis showed no impact of randomization on outcomes (ANOVA: $P = .908$).

Three correlation studies[40,45,47] (Table 4) examined whether hearing loss from OME was associated with expressive language at age 1 to 2 years by using the SICD.[52] Meta-analysis showed a statistically significant negative association between hearing loss and expressive language during infancy (Fig. 4), with an R value of −0.30 (95% CI: −0.43, −0.16). All studies

were homogeneous ($P = .295$). Although the magnitude of relationship is fair (explains 9.0% of variance), the 95% CI cannot exclude a trivial (−0.16) or almost good (−0.43) correlation. Sensitivity analysis showed no change in the combined result when a small study[47] with low birth weight children and a larger effect size ($R = −0.55$) was excluded.

Vocabulary, Syntax, and Speech Versus OME

Four correlation studies[4,7,12,46] (Table 5) examined whether OME was associated with receptive vocabulary at 3 years old by using the PPVT.[39] Meta-analysis showed no association between OME and receptive vocabulary, and the combined 95% CI does suggest adequate statistical power.

Four parallel group studies[4,7,8,46] (Table 6) examined whether OME was associated with receptive vocabulary at 3 years old by using the PPVT. One study was randomized,[8] and 3 were prospective cohorts.[4,7,46] Meta-analysis showed no association between OME and receptive vocabulary during the preschool years, but the combined 95% CI suggests adequate statistical power, because the upper limit ($d = −0.37$) cannot exclude a fair to good effect size.

Three correlation studies[7,12,44] (Table 7) examined whether OME was associated with expressive vocabulary at age 3 to 5 years by using NDW on a language sample. Meta-analysis showed no association between OME and NDW, and the combined 95% CI does suggest adequate statistical power.

Three correlation studies[7,12,44] (Table 7) examined whether OME was associated with expressive syntax at age 3 to 5 years by using MLU on a language sample. Meta-analysis showed no association between OME and MLU, and the combined 95% CI does suggest adequate statistical power.

Three parallel group studies[4,7,8] (Table 8) examined whether OME was associated with speech development at 3 years old. One study was randomized,[8] and 2 were prospective cohorts.[4,7] Meta-analysis showed no association between OME and speech development at 3 years old, but the combined 95% CI suggests adequate statistical power, because the upper limit ($d = −0.32$) cannot exclude a fair effect size and the lower limit (0.01) just missed statistical significance.

DISCUSSION

Our findings suggest that OME and the related hearing loss children experienced during early child-

TABLE 3. Group Data Meta-Analysis of Receptive and Expressive Language at Age 2 to 5 Years Versus OME

Author (Year)	Test (Age, y)	Receptive Language					Expressive Language				
		OM+ Group: N; Mean (SD)	OM− Group: N; Mean (SD)	P Value	Dir*	d (95% CI)†	OM+ Group: N; Mean (SD)	OM− Group: N; Mean (SD)	P Value	Dir*	d (95% CI)†
Teele et al[46] (1984)	PLS (3)	88; 119.9 (18.6)	54; 123.4 (21.7)	.30	E	−0.18 (−0.52, 0.16)	86; 116.0 (24.6)	53; 120.6 (23.7)	.28	E	−0.19 (−0.54, 0.16)
Pearce et al[42] (1988)	SICD (2–4)	23; 17.8	20; 26.0	.02	E	−0.73 (−01.37, −0.09)	—	—	—		—
Rach et al[43] (1988)	RDLS (2.5–3)	36; −0.13	13; 0.23	.13	E	−0.49 (−01.15, 0.17)	35; −00.76	13; −0.14	.02	E	−0.77 (−01.44, −0.10)
Gravel and Wallace[41] (1992)	SICD (4)	8; 35.5 (5.4)	13; 37.8 (5.3)	.342	E	−0.42 (−01.37, 0.53)	8; 36.0 (6.2)	12; 39.0 (6.2)	.274	E	−0.49 (−01.47, 0.48)
Maw et al[6] (1999)‡	RDLS (4.5)	71; 0.13	81; 0.39	.14	E	−0.25 (−0.58, 0.09)	71; −0.38	81; −0.07	.11	E	−0.26 (−0.58, 0.06)
Rovers et al[9] (2000)‡	RDLS (2.5)	86	87	.18	E	−0.20 (−0.51, 0.10)	86	87	.18	R	−0.20 (−0.51, 0.10)
Shriberg et al[4] (2000)	SICD (3)	8; 43.0 (4.1)	59; 42.0 (4.3)	.534	R	.23 (−0.52, 0.99)	8; 42.0 (3.0)	59; 43.1 (4.4)	.452	R	.28 (−0.47, 1.04)
Combined	Various (2–4.5)	320	327	.003	E	−0.25 (−0.41, −0.09)§	294	295	.006	E	−0.24 (−0.41, −0.07)¶

* Direction of effect: expected (E) or reverse (R).
† Standardized difference between groups: $P < .05$ if 95% CI does not contain zero.
‡ Groups differentiated by random assignment to tympanostomy tubes.
§ Test of heterogeneity (receptive): $Q = 4.84$, degrees of freedom (df) = 6, $P = .564$.
¶ Test of heterogeneity (expressive): $Q = 4.87$, df = 5, $P = .908$.

hood explain none to a very small amount of the observed variation in children's language skills. Although 4 of the 11 analyses revealed small but statistically significant associations, our results may overestimate the true impact of OME on speech and language outcomes. Most of the data were not adjusted for known confounding variables (eg, maternal education, SES, and childcare environment) that have been shown to explain a considerably larger portion of children's language development than OM. Additionally, results were sensitive to study design in that significant differences could be found only in some analyses for parallel group contrasts and not for the gradations in exposure in correlation studies. The negligible association of OME with developmental outcomes suggests that differences in otherwise healthy children are detectable only by large studies or meta-analysis to increase statistical power.

Meta-analysis is an invaluable tool to integrate prior research, illuminate research gaps, and define priorities for future research. To maximize validity, we focused on the associations of OME in early childhood to speech and language during the preschool years and the association of hearing loss to language during infancy. We used an a priori meta-analysis protocol that included explicit criteria for study selection, data abstraction, and data pooling. A random-effects model was used to pool the data and adjust 95% CIs for potential heterogeneity in the design, conduct, or reporting of individual study results. All included studies were prospective controlled cohorts[4,7,12,40−47] or RCTs,[6,8,9] which prevented methodologically flawed (eg, uncontrolled or retrospective) studies from influencing results. We ensured the consistency of results by only combining studies with similar data formats (correlational versus group statistics), similar speech or language outcomes, similar speech or language assessment age ranges, and a consistent predictor (OME or hearing loss).

These results for OME are generally consistent with 2 recent meta-analyses[14,15] of the OME-language linkage. However, OME-related hearing loss was not a predictor in either of these meta-analyses. The present meta-analysis included 1 study that was also reviewed in the meta-analysis of the AHRQ[14] and 9 studies from the Casby meta-analyses.[15] The AHRQ[14] found no associations for receptive or expressive language as measured by standardized tests in 6 cohorts of children. They reported that the heterogeneity and wide 95% CIs among the studies could not exclude that an effect was missed (low power). Yet, the AHRQ report[14] concluded that they could neither support nor refute the possible effect of OME on children's language development. Casby[15] reported the magnitude of an effect of OME to be markedly low based on his meta-analysis of 22 studies of the association of OME to children's receptive and expressive language through the elementary school years. Children with histories of early OME scored an average of 0.16 d below their peers without OME histories in receptive language (95% CI: −0.23, −0.10) and −0.23 d lower in expressive language

Fig 1. Meta-analysis of receptive language at age 2 to 5 years versus OME for group studies. Effect size is expressed as standard difference (*d*).
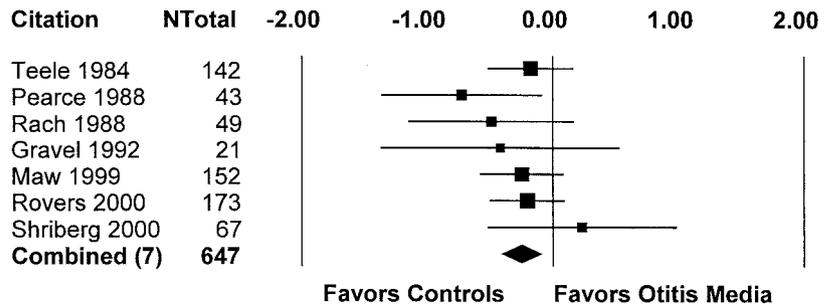
Citation	NTotal
Teele 1984	142
Pearce 1988	43
Rach 1988	49
Gravel 1992	21
Maw 1999	152
Rovers 2000	173
Shriberg 2000	67
Combined (7)	647

Favors Controls   Favors Otitis Media

TABLE 4. Correlation Meta-Analysis of Receptive and Expressive Language at Age 1 to 2 Years Versus Hearing

Author (Year)	Receptive Language				Expressive Language			
	N	Dir*	Test (Age, y)	R (95% CI)†	N	Dir*	Test (Age, y)	R (95% CI)†
Wallace et al[47] (1988)	25	E	SICD (1)	−0.03 (−0.42, 0.37)	25	E	SICD (1)	−0.55 (−0.78, −0.20)
Friel-Patti and Finitzo[40] (1990)	151	E	SICD (2)	−0.23 (−0.38, −0.07)	151	E	SICD (2)	−0.26 (−0.40, −0.11)
Roberts et al[45] (1998)	85	E	SICD (2)	−0.11 (−0.32, 0.11)	85	E	SICD (2)	−0.27 (−0.46, −0.06)
Combined	261	E	SICD (1–2)	−0.17 (−0.29, −0.05)‡	261	E	SICD (1–2)	−0.30 (−0.43, −0.16)§

* Direction of effect: expected (E) or reverse (R).
† Pearson correlation coefficient: $P < .05$ if 95% CI does not contain zero.
‡ Random effects (receptive) combined $P = .005$; test of heterogeneity: $Q = 1.32$, degrees of freedom (df) = 2, $P = .516$.
§ Random effects (expressive) combined $P < .001$; test of heterogeneity: $Q = 0.24$, df = 2, $P = .295$.

Fig 2. Meta-analysis of receptive language at age 1 to 2 years versus hearing for correlation studies. Effect size is expressed as Pearson correlation coefficient.
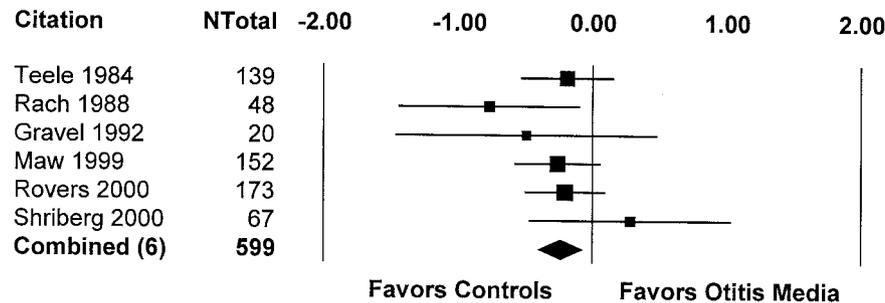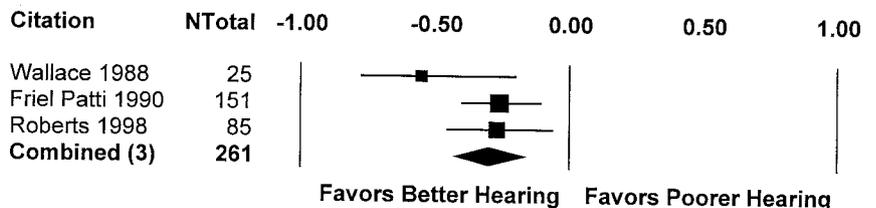
Citation	NTotal
Wallace 1988	25
Friel Patti 1990	151
Roberts 1998	85
Combined (3)	261

Favors Better Hearing   Favors Poorer Hearing

Citation	NTotal
Teele 1984	139
Rach 1988	48
Gravel 1992	20
Maw 1999	152
Rovers 2000	173
Shriberg 2000	67
Combined (6)	599

Favors Controls   Favors Otitis Media

Fig 3. Meta-analysis of expressive language at age 2 to 5 years versus OME for group studies. Effect size is expressed as standard difference (*d*).

Fig 4. Meta-analysis of expressive language at age 1 to 2 years versus hearing for correlation studies. Effect size is expressed as Pearson correlation coefficient.

Citation	NTotal
Wallace 1988	25
Friel Patti 1990	151
Roberts 1998	85
Combined (3)	261

Favors Better Hearing   Favors Poorer Hearing

(95% CI: −0.30, −0.16). However, Casby's meta-analyses should be interpreted carefully, because he used multiple outcomes from a single cohort, combined results from group and correlation studies, combined studies for different age groups, and combined specific (eg, vocabulary) and overall measures of language.

Comparing the meta-analyses in this article that were significant versus nonsignificant is important. No differences were noted among studies in the

TABLE 5. Correlation Meta-Analysis of Receptive Vocabulary (PPVT) at Age 3 Years Versus OME

Author (Year)	N	Dir*	Test (Age, y)	R (95% CI)†
Teele et al[46] (1984)	200	E	PPVT (3)	−0.22 (−0.35, −0.08)
Paradise et al[7] (2000)	237	E	PPVT (3)	−0.13 (−0.25, 0)
Roberts et al[12] (2000)	79	E	PPVT (3)	−0.01 (−0.23, 0.21)‡
Shriberg et al[4] (2000)	67	R	PPVT (3)	0.23 (−0.01, 0.45)
Combined	583	E	PPVT (3)	−0.05 (−0.23, 0.13)§

* Direction of effect: expected (E) or reverse (R).
† Pearson correlation coefficient: $P < .05$ if 95% CI does not contain zero.
‡ Adjusted correlation coefficient.
§ Random effects combined $P = .564$; test of heterogeneity: $Q = 10.98$, degrees of freedom (df) = 3, $P = .012$.

TABLE 6. Group Data Meta-Analysis of Receptive Vocabulary (PPVT) at Age 3 Years Versus OME

Author (Year)	OM+ Group: N; Mean (SD)	OM− Group: N; Mean (SD)	P Value	Dir*	Test (Age, y)	d (95% CI)†
Teele et al[46] (1984)	80; 96.4 (15.3)	52; 101.4 (17.1)	.082	E	PPVT (3)	−0.31 (−0.67, 0.04)
Paradise et al[7] (2000)	64; 98.4 (14.8)	84; 104.0 (16.9)	.037	E	PPVT (3)	−0.35 (−0.68, −0.02)
Shriberg et al[4] (2000)	8; 113.0 (10.9)	51; 112.1 (10.8)	.809	R	PPVT (3)	0.09 (−0.67, 0.85)
Paradise et al[8] (2001)‡	203; 92.0 (13.0)	192; 92.0 (15.0)	1.00	R	PPVT (3)	0 (−0.20, 0.20)
Combined	355	379	.144	E	PPVT (3)	−0.16 (−0.37, 0.05)§

* Direction of effect: expected (E) or reverse (R).
† Standardized difference between groups: $P < .05$ if 95% CI does not contain zero.
‡ Groups differentiated by random assignment to tympanostomy tubes.
§ Test of heterogeneity: $Q = 4.71$, degrees of freedom (df) = 3, $P = .195$.

TABLE 7. Correlation Meta-Analysis of Expressive Vocabulary and Expressive Syntax at Age 3 to 5 Years Versus OME

Author (Year)	Expressive Vocabulary (NDW)				Expressive Syntax (MLU)			
	N	Test (Age, y)	Dir*	R (95% CI)†	N	Test (Age, y)	Dir*	R (95% CI)†
Roberts et al[44] (1991)	26	NDW (5)	E	0 (−0.39, 0.39)	26	MLU (5)	E	−0.22 (−0.56, 0.18)
Paradise et al[7] (2000)	237	NDW (3)	E	−0.04 (−0.17, 0.09)	237	MLU (3)	E	−0.07 (−0.20, 0.06)
Roberts et al[12] (2000)	79	NDW (3)	E	−0.11 (−0.32, 0.11)§	79	MLU (3)	E	−0.03 (−0.25, 0.19)‡
Combined	342	NDW (3–5)	E	−0.05 (−0.16, 0.05)§	342	MLU (3–5)	E	−0.07 (−0.18, 0.04)¶

* Direction of effect: expected (E) or reverse (R).
† Pearson correlation coefficient: $P < .05$ if 95% CI does not contain zero.
‡ Adjusted correlation coefficient.
§ Random effects combined $P = .192$; test of heterogeneity: $Q = .66$, df = 2, $P = .718$.
¶ Random effects combined $P = .330$; test of heterogeneity: $Q = .35$, degrees of freedom (df) = 2, $P = .837$.

TABLE 8. Group Data Meta-Analysis of Speech at Age 3 Years Versus OME

Author (Year)	OM+ Group: N; Mean (SD)	OM− Group: N; Mean (SD)	P Value	Dir*	Test (Age, y)	d (95% CI)†
Paradise et al[7] (2000)	64; 84.6 (7.8)	84; 86.5 (6.6)	.111	E	PCC (3)	−0.26 (−0.59, 0.07)
Shriberg et al[4] (2000)	8; 87.4 (3.6)	59; 86.3 (4.8)	.535	R	PCC (3)	.23 (−0.52, 0.99)
Paradise et al[8] (2001)‡	205; 85.0 (7.0)	193; 86.0 (7.0)	.155	E	PCC (3)	−0.14 (−0.34, 0.06)
Combined	277	336	.065	E	PCC (3)	−0.15 (−0.32, 0.01)§

§ Test of heterogeneity: $Q = 1.50$, degrees of freedom (df) = 2, $P = .472$.
* Direction of effect: expected (E) or reverse (R).
† Standardized difference between groups: $P < .05$ if 95% CI does not contain zero.
‡ Groups differentiated by random assignment to tympanostomy tubes.

significant versus nonsignificant analyses according to subject characteristics, OME documentation methods, or study designs. Two RCTs[6,9] contributed to the significant OME group analyses on receptive and expressive language, and 1 RCT[8] contributed to the nonsignificant analyses of vocabulary, syntax, and speech. However, none of the meta-analyses that were significant included data from the studies by Paradise et al[7,8,24] (only 1[8] of which was an RCT). Paradise et al[7,8,24] examined specific measures of language in vocabulary, syntax, and speech rather than

global measures of receptive and expressive language and did not examine hearing loss in relation to the language outcomes.

Hearing, but not OME, was a significant predictor of outcomes (Table 4), suggesting an association between hearing and language development. This linkage would conceptually make sense, because hearing loss, not OME, is hypothesized to affect children's language development. The hearing analyses, however, were done on infant language outcomes, whereas all other analyses were done on preschool

speech and language assessments. Thus, it is hard to compare the results and determine whether there would be similar findings for hearing in the preschool years.

The analyses of group data for OME (Table 3) but not the correlation studies (Table 2) suggested an association between OME and both receptive and expressive language. The most likely cause of this discrepancy is that the group analyses compared children with more-severe versus less-severe OME (because of randomization or comparison of the 2 most extreme cohorts), but the correlation analyses considered the distribution of OME for the whole cohort as a continuous variable. These data may possibly suggest a threshold amount for OME and/or associated hearing loss where having OME may place a child at greater risk for language differences and be more evident when analyses consider children with the least and most amounts of OME.

Several issues should also be considered when evaluating these meta-analyses of the studies examining the relationship of OME to speech and language development (see other reports on meta-analysis techniques[50, 54] for additional considerations). First, the methods to document OME differed among studies (Table 1); most studies used tympanometry, whereas some also used otoscopy. The age of OME documentation also differed and occurred during only the first year of life,[41,47] the first 2 years,[4,9,28,45] the first 3 years,[7,8,12,42,44,46] and after 2 years old.[6,43] Although there were variations in OME documentation, all documentation was prospective and done on multiple occasions. Second, few of the studies included repeated assessments of hearing status; therefore, it was not possible to relate hearing status during early childhood to outcomes. Third, children were recruited from many different sites including pediatric/primary care practices,[4,7,8,40,46] hospitals,[41,42,47] childcare centers,[12,44,45] community cohorts,[43] and otolaryngology clinics.[6,9] Some of the studies included a select group of children[12,45] rather than a random or broad sample. Last, some of the studies included children who had specific characteristics such as low birth weight,[41,42,47] had speech, language, behavior or learning problems,[6] or had failed hearing screenings.[9]

The diversity of the studies in this meta-analysis helps support the external validity of the findings. For example, we found similar results when we analyzed the data with or without the children in the RCT by Maw et al,[6] which included children with baseline speech, language, and learning problems. This trial also showed significant group differences in language at the 9-month follow-up that were no longer significant by 18 months. Despite the diversity of the samples included in the meta-analyses, the tests for heterogeneity were not significant (studies appeared homogeneous) for all the analyses with statistically significant results. Although the tests for heterogeneity were not significant in these analyses, there may be important differences between studies that were not detected. Yet, there was heterogeneity in 2 of the 7 analyses that included the studies of Shriberg et al,[4] who studied the same cohort from Dallas, Texas as Friel-Patti et al[40] There did not seem to be differences in the populations of children, OME documentation method, or study design of the Shriberg et al study,[4] as compared with the other studies.

These results raise the question of whether these meta-analyses were underpowered to detect significant associations between OME and speech and language. An additional question is: What is the number of participants required in a particular study to find a significant association between OME or hearing loss and later speech and language outcomes, given the extent of the relationship reported in the present meta-analyses? In the correlational studies, the median number of subjects per study was 82, with a mean correlation R of -0.10 for OME or hearing loss and the language outcomes. The median number of participants in the 8 correlational meta-analyses analyses was 342, with a mean R of -0.11. A sample size of 82 has 15% power to detect an R value of 0.10. An R value of 0.106 requires 696 participants for 80% power. In the group studies examined in the meta-analyses, the median number of participants was 100, with a standard difference mean of -0.20. For 100 subjects per group, there is 29% power to detect a SD of 0.20. A SD of 0.20 requires 394 subjects per group for 80% power, whereas a SD of 0.25 requires 253 subjects per OME group for 80% power. Thus, given the average sample size and degree of relationships reported, our analyses were somewhat underpowered to detect meaningful associations. Additionally, the random-effects model, as used in this study, assumes a population (distribution) of true effect size, with each source article representing 1 member of this population. As a consequence, the CIs are slightly broader and may reduce the power of the analysis.

Meta-analysis is a form of retrospective research and is prone to certain biases, especially when observational (not randomized) studies are combined.[54] Authors and editors may preferentially publish studies with positive results, causing the published literature to overestimate true effects. However, several studies reporting nonsignificant findings have been published and were included in the analyses. Although it is possible that we missed a significant study because of language bias (eg, including only English-language studies), we think that this is minimal and assume the linkages are similar in the United States and other countries. Last, all studies combined in the meta-analysis were weighted by sample size not by methodologic quality. For example, studies were included in which tympanometry was done at infrequent intervals,[42] analyses eliminated children with no OME between 6 and 18 months,[40] and at the time of developmental testing, bilateral OME[9] or hearing loss[42,43,47] was present. Although study quality has minimal impact on outcomes in meta-analyses of RCTs,[55] the impact on observational studies may be greater. In several analyses, however, we found no significant difference in effects sizes for the randomized versus observational (correlational) designs.

The meta-analyses presented in this article only assessed the association of OME to speech and lan-

guage during the preschool years and of OME-related hearing loss to language during infancy. To complete meta-analyses on each age grouping, data had to be available from ≥3 studies to justify statistical pooling. Other age groupings may be more sensitive to the effects of OME and associated hearing loss. Excluding some studies may have resulted in different conclusions.

The developmental outcomes examined were overall receptive and expressive language, vocabulary, syntax, and speech as measured by widely used standardized instruments with acceptable psychometric properties. Similarly, the nonstandardized measures (NDW to assess vocabulary, MLU to assess syntax, and percent consonants correct [PCC] to assess speech) are well-accepted measures of speech and language functioning. Other measures of language functioning such as phonological working memory or specific aspects of syntax such as word endings to mark plurals, which are not stressed and hard to hear, may be affected by OME-associated hearing loss.

Interestingly, the meta-analysis results were more significant for overall measures of expressive language than for the measures of individual domains of language: vocabulary (NDW) and syntax (MLU). We cannot tell whether this difference reflects a true difference in the impact of OME or a reflection of the studies included in the analyses. For example, the Paradise et al[7] study is included in the analyses of NDW and MLU (but not in the analyses of overall expressive language), because these are specific measures of language domains and not overall measures of expressive language. Additionally, because many of the studies within each group and correlation analysis did not include measures of factors such as dimensions of the home environment, which have been shown to be important predictor of children's language development,[56,57] we cannot rule out that factors that predispose children to experience more OME also may affect speech and language development. We used adjusted coefficients, when available, in the correlation analyses, but only 1 study provided this information.[12]

A final but important limitation of our study concerns the generalizability of the findings. The small effect sizes we found may be unimportant for most otherwise-healthy children with OME, but the impact may be different for children with developmental delays, from special populations (eg, Down syndrome), or with baseline hearing loss independent of OM. For these "at-risk" populations, even minor auditory degradation from OME could possibly impact developmental outcomes. Similar concerns exist for children with preexisting speech or language delays, who were excluded from all studies except 1,[6] and for low birth weight children who were included in only 1 small study.[41] Unfortunately, these same children are often systematically excluded from prospective studies and RCTs of the OME-development relationship.

Future research should measure hearing loss and other variables that may affect the OME developmental linkage. Most studies used OME, not hearing,

as the independent variable, although hearing loss rather than OME is hypothesized to affect language. Factors should also be studied that may mediate (ie, explanatory intervening variable such as hearing loss) or moderate (ie, interact with OME such as a highly responsive childcare environment) developmental outcomes. Although RCTs are optimal, well-planned prospective cohorts can suffice when randomization is impossible or unethical. Additionally, the impact of persistent OME and associated hearing loss should be studied in different populations including special populations of at-risk children with these study designs.

CONCLUSIONS

Meta-analysis provides a systematic review of the evidence but cannot substitute for assessing and treating each child individually. We found no to very small associations of OM to speech and language development in most children. However, the existing evidence was not always combinable or generalizable. Moreover, these results could leave many clinicians in a dilemma as to what to do when a child experiences persistent OME in early childhood. It may suggest that just ignoring the OME and associated hearing loss for a young child is a reasonable approach; however, this may not always be the case. The relative risk, for example, for a particular child of not screening hearing and missing a moderate degree of hearing loss caused by OME must be weighed against the advantages of giving the child the optimal language and learning environment. The data reviewed herein reflect outcomes for an "average," otherwise-healthy child; factors affecting the language development of each individual child must also be considered, including hearing status, language skills, development, and supportiveness of the child's environment.

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