Original Article



# Cross-sectional prevalence and risk factors for otitis media and hearing loss in Australian children aged 5 to 7 years: a prospective cohort study

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**Background:** This study aimed to provide estimates of the prevalence and associated risk factors for otitis media (OM) and hearing loss among urban Australian school-aged children.

**Methods:** This prospective cohort of participants were recruited from the Western Australian Pregnancy Cohort (Raine) Study, a pregnancy cohort established in Perth, Australia between 1989 and 1991. This study examines 1,344 2nd Generation Raine Study participants who completed tympanometry and audiometry assessment at 5 to 7 years of age. Primary outcomes included the presence of OM, diagnosed by tympanometry, and hearing sensitivity. The impact of thirteen other potential prenatal and environmental exposures were analyzed as secondary outcomes.

**Results:** The study found the cross-sectional prevalence of OM at 5 to 7 years of age was 22.5% (n=302). The prevalence of unilateral and bilateral OM was 11% (n=148) and 11.5% (n=155), respectively. The prevalence of bilateral hearing loss ≥26 dB four-frequency average was 2.1%.

**Conclusions:** The high prevalence of OM and its associated hearing loss persisting up to and beyond the age of school entry (5 to 7 years) is concerning as a significant hearing loss may interfere with their educational and social development. One in ten children with OM diagnosed by tympanometry had a significant, bilateral hearing loss.

**Keywords:** Otitis media; middle ear effusion; hearing loss; Raine study; prevalence

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## Introduction

Otitis media (OM), a broad term referring to a spectrum of inflammatory conditions involving the middle ear, affects an estimated 80% of children before the age of 4 years and thus continues to be a major cause of disease and morbidity in childhood (1). Although adults can be affected, children have a much higher prevalence of OM than adults, which is believed to be due to both immaturity of the immune system and Eustachian tube resulting in poor drainage of fluid in the middle ear (2). Although most children experience spontaneous resolution of symptoms with no lasting effects, some experience recurrent episodes and

clinical complications (3). OM may result in a temporary mild-to-moderate conductive hearing loss of between 15 to 40 dB (4,5). Extracranial complications such as mastoiditis and cholesteatoma are rare, with an overall incidence of mastoiditis ranging from 2 to 4.2 per 100,000 people in developed countries and an incidence of cholesteatoma between 5 to 6 per 100,000 people in Australia (6). Intracranial complications, such as meningitis, brain abscess, and sigmoid sinus thrombosis, are also rare with reported rates between 0.3% to 2% (7).

For those children who experience recurrent and more severe episodes of OM, extended periods of decreased hearing sensitivity may result. When this occurs around the age of school entry, there is significant concern it may lead to decreased performance in speech, language, behavioural and educational outcomes (8,9). Treatment of OM in childhood is responsible for significant health and economic burden in many developed countries and research is required to assess trends in OM prevalence and identify areas of focus to improve care. In Australia, the estimated annual cost of morbidity from OM is between AUD$1.05–2.6 billion (10). Figures from the United States show that diagnosis and treatment costs of acute OM in children accounts for approximately USD$2.88 billion annually (11).

Children of school-age are highly susceptible to adverse developmental sequelae from periods of decreased hearing sensitivity due to the normal education and socials interactions that children normally experience at this age. However, previous research has focused primarily on OM in early childhood (0–3 years) as this age group represents the peak prevalence of OM cases. The research following younger children with early OM and decreased hearing sensitivity demonstrate mixed findings of the impact of OM on developmental sequelae (11,12). There is far less evidence of the prevalence and potential developmental sequelae of OM in children 5 to 7 years of age. Previous research by Bennett & Haggard (12) found that children with middle ear effusion at 5 years of age had subsequent cognitive and behavioural deficits even at 10 years of age. Reports of the prevalence of OM in 5-year-old children typically range from 5–10% (13). However, higher rates have been reported in studies from the Middle East (14). The current study aims to provide estimates of disease prevalence and identifies associated risk factors for school-aged children based on an urban, predominantly Caucasian population in the setting of a developed nation. This information will inform primary prevention, clinical management, local policy, and future research.

Diagnosis of OM consists of two main types: acute OM (AOM) and OM with effusion (OME), each can present at different stages on a spectrum (15). AOM is characterized by a rapid onset of one or more signs or symptoms of inflammation in the middle ear, such as otalgia, fever, otorrhoea, or irritability; it typically results in a temporary middle ear effusion, often with decreased hearing sensitivity for up to 3 months. OME refers to the presence of middle ear effusion without signs or symptoms of an acute ear infection. Typically, a child is considered to have chronic OME if the middle ear effusion has been present for more than 3 months (16). Diagnosis of either AOM or OME can be confirmed by the detection of an effusion of the middle ear. Middle ear effusion (MEE) can be reliably identified by tympanometry and pneumatic otoscopy (17). Evidence suggests pneumatic otoscopy is more accurate than tympanometry, although great variability exists between studies in terms of the reported sensitivity and specificity values (17-19). However, pneumatic otoscopy takes longer to perform, is more difficult to interpret, and thus requires a greater level of clinician training than tympanometry, which was the diagnostic method used in many large-scale epidemiological studies (17,20).

The objectives of this study are to report the prevalence and risk factors for OM and hearing loss in school-aged children within a representative urban Australian cohort.

## Methods

### *Study design*

The study sample were part of the Western Australian Pregnancy Cohort (Raine) Study, a prospective pregnancy cohort study. Advantages of a prospective cohort study design include clarity of temporal sequence, the avoidance of selection bias at enrollment, and the ability to evaluate relationships between diseases and exposures.

### *Setting and participants*

This study examines 2$^{nd}$ generation (Gen2) Raine Study participants consisting of 2,868 live births recruited from King Edward Memorial Hospital in Perth, Australia between 1989 and 1991. Inclusion criteria for the Raine Study were women with a gestational age of 16–20 weeks, sufficient English proficiency to communicate with investigators, and an expectation to reside in Western Australia (21). The fifth year follow up of the Gen2 cohort

occurred between 1995-6. At the year 5–7 follow up visit, 2,280 participants in the Raine Study Gen2 cohort completed questionnaires and 1,344 attended the clinical examination involving tympanometry and audiometry. Children with missing tympanometry and audiometry data were excluded from this study.

### *Variables*

Primary outcomes of the study were the presence of OM and hearing sensitivity. Secondary outcomes involved risk factor identification of the following variables: sex, Aboriginal or Torres Strait Islander ancestry, maternal spoken language other than English, maternal ethnicity, poverty (annual family income below AUD$24,000 at birth), maternal education (completed high school), passive smoke exposure, allergies, day care attendance, alcohol consumption during pregnancy, asthma, multiparity, exclusive breastfeeding ceased within 6 months of birth, prematurity (<37 weeks), and low birth weight (<2,500 g).

### *Data measurement*

The presence of OM and hearing sensitivity were detected from a single clinical assessment. Clinically significant middle ear effusion indicative of OM was assessed using tympanometry and defined as a tympanic membrane compliance of <0.1 mL (22). Pure-tone audiometry was used to identify hearing loss defined as hearing levels of ≥26 dB four-frequency average (4FA) at 0.5, 1, 2 and 4 kHz. This dictated a broad classification of OM, which made the distinction between acute and chronic forms of OM undeterminable. Secondary outcomes data were obtained from a range of periodic parent-completed questionnaires completed from 16–20 weeks gestation up until the 5 to 7-year cohort follow-up.

### *Statistical methods*

The OM and hearing loss data were analyzed using frequency distributions and Pearson's X2 tests of demographic and potential risk factors based on the presence or absence of OM and/or hearing loss. Univariate and multivariable logistic regressions were undertaken to detect independent risk factors and assess the magnitude of relationships between potential risk factors and the presence of OM and/or hearing loss. In the multivariable regression, only exposures that were significant on the univariate regressions were included. Data were analyzed using Statistical Package for the Social Sciences (SPSS) v22.0. Interpretation of all analyses in this study considered a P value of less than 0.05 as statistically significant.

### *Ethical considerations*

The human ethics committee at King Edward Memorial Hospital approved participant recruitment and follow-up for the Raine Study. Initially, parents provided written informed consent for the use of stored data; at 17 years of age children were re-consented.

## Results

The average age of the cohort at the date of assessment was 5.96 years, SD 0.17 years. The prevalence of combined unilateral and bilateral OM at 5 to 7 years of age was 22.5% (n=302). Further classified, the prevalence of unilateral and bilateral OM was 11% (n=148) and 11.5% (n=155), respectively. Gender differences were found for both combined unilateral and bilateral OM (P=0.004) and unilateral OM (P=0.035) with females more likely to be affected than males (*Table 1*). Of note, the prevalence of bilateral hearing loss >25 dB four-frequency average (4FA) was 2.1% and the prevalence of bilateral OM combined with bilateral hearing loss was 1.2% (*Table 1*). Of the 155 participants with bilateral OM, 16 (10.3%) had a significant hearing loss ≥26 dB (*Table 1*). Frequency distributions of potential risk factors for OM and hearing loss (using combined unilateral and bilateral OM distributions) are summarized in *Table 2*.

Independent associations found for combined unilateral and bilateral OM included a protective effect for male gender (OR 0.69; CI: 0.53, 0.91; P<0.009) and increased risk for children whose mother spoke a language other than English (OR 1.86; CI 1.06, 3.25; P<0.030), and maternal non-Caucasian ethnicity (OR 1.57; CI: 1.02, 2.41; P<0.040). Similarly, for bilateral OM, independent associations included maternal spoken language other than English (OR 2.29; CI: 1.28, 4.09; P<0.005) and maternal non-Caucasian ethnicity (OR 1.73; CI: 1.05, 2.83; P<0.030). For bilateral hearing loss, combined unilateral and bilateral OM was the only identified independent association (OR 7.75; CI: 3.31, 18.15; P<0.001).

Subsequent multivariate regressions of significant associations revealed that male gender was the only factor to remain significantly associated (protective) with combined

**Table 1** Prevalence and characteristics of OM and hearing loss (HL) in the Raine study

| Characteristics at 5–7 years of age | Male, n (%) | Female, n (%) | P | Totals, n (%) |
|---|---|---|---|---|
| OM* | | | | |
| Combined unilateral and bilateral | | | 0.004 | |
| OM | 137 (19.4) | 165 (25.9) | | 302 (22.5) |
| No OM | 570 (80.6) | 472 (74.1) | | 1,042 (77.5) |
| Unilateral OM | | | 0.035 | |
| Yes | 66 (15.0) | 82 (20.6) | | 148 (11.0) |
| No | 374 (85.0) | 317 (79.4) | | 1196 (89.0) |
| Bilateral OM | | | 0.072 | |
| Yes | 71 (10.0) | 84 (13.2) | | 155 (11.5) |
| No | 636 (90.0) | 553 (86.8) | | 1189 (88.5) |
| HL** | | | | |
| Bilateral hearing loss 4FA ≥26 dB | | | 0.138 | |
| HL | 12 (1.5) | 19 (2.6) | | 31 (2.1) |
| No HL | 767 (98.5) | 703 (97.4) | | 1,470 (97.9) |
| Bilateral OM + bilateral HL 4FA ≥26 dB | | | 0.225 | |
| Yes | 6 (0.9) | 10 (1.6) | | 16 (1.2) |
| No | 696 (99.1) | 624 (98.4) | | 1,320 (98.8) |
| Missing | 77 | 88 | | |

*Male N=707, female N=637, total N=1344; **Male N=779, female N=722, total N=1501.

**Table 2** Frequency distributions of risk factors for combined unilateral and bilateral OM

| Combined unilateral and bilateral OM risk variables | No OM, n=649 (%) | OM, n=300 (%) | P value |
|---|---|---|---|
| Gender | | | 0.009 |
| Male | 356 (54.9) | 137 (53.5) | |
| Female | 293 (45.2) | 163 (46.5) | |
| Mother spoke language other than English | | | 0.030 |
| Yes | 29 (4.5) | 24 (8.0) | |
| No | 620 (95.5) | 276 (92.0) | |
| Maternal ethnicity | | | 0.040 |
| Other than Caucasian | 58 (8.9) | 260 (86.7) | |
| Caucasian | 591 (91.1) | 40 (13.3) | |
| Household income below poverty line at birth | | | 0.634 |
| Yes | 236 (38.1) | 113 (39.8) | |
| No | 383 (61.9) | 171 (60.2) | |

**Table 2** (*continued*)

**Table 2** (*continued*)

| Combined unilateral and bilateral OM risk variables | No OM, n=649 (%) | OM, n=300 (%) | P value |
|---|---|---|---|
| Maternal education (graduated high school?) | | | 0.595 |
| Yes | 276 (43.2) | 132 (45.1) | |
| No | 363 (56.8) | 161 (55.0) | |
| Passive smoke exposure | | | 0.081 |
| Yes | 190 (35.0) | 104 (41.4) | |
| No | 353 (65.0) | 147 (58.6) | |
| Day care attendance | | | 0.440 |
| Yes | 299 (67.3) | 135 (64.3) | |
| No | 145 (32.7) | 75 (35.7) | |
| Alcohol consumed during pregnancy | | | 0.923 |
| Yes | 230 (38.3) | 106 (38.0) | |
| No | 370 (61.7) | 173 (62.0) | |
| Parity | | | 0.899 |
| No older siblings | 301 (46.4) | 140 (46.8) | |
| 1 or more older sibling(s) | 348 (53.6) | 159 (53.2) | |
| Breastfeeding stopped ≤6 months | | | 0.537 |
| Yes | 256 (41.4) | 123 (43.6) | |
| No | 362 (58.6) | 159 (56.4) | |
| Other milk introduced <6 months | | | 0.620 |
| Yes | 426 (69.4) | 191 (67.7) | |
| No | 188 (30.6) | 91 (32.3) | |
| Premature (Gestation <37 weeks) | | | 0.802 |
| Yes | 44 (6.9) | 19 (6.5) | |
| No | 591 (93.1) | 274 (93.5) | |
| Low birth weight (<2,500 g) | | | 0.951 |
| Yes | 46 (7.1) | 21 (7.0) | |
| No | 601 (92.9) | 279 (93.0) | |

unilateral and bilateral OM and only maternal spoken language other than English to remain a significant risk factor for bilateral OM (*Table 3*). Univariate and multivariate regression models of combined unilateral and bilateral OM, bilateral OM, and bilateral HL are summarised in *Tables 3-5*, respectively.

## Discussion

This study focused on the identification of OM and hearing loss in children at 5 to 7 years of age. The prevalence rate of OM in the study population was 22.5% for unilateral and bilateral OM, and 11.5% for bilateral OM only. The cross-sectional prevalence of OM demonstrates significant variability among children of different ages and geographical regions. This prevalence estimate for combined unilateral and bilateral OM was higher than some other reports for the same age group. In a review by Zielhuis *et al.* (23) the average prevalence of OM was

**Table 3** Logistic regression of risk factors for combined unilateral and bilateral OM in the Raine study

| Risk factors unilateral and bilateral OM | Univariate models | | | Multivariable model | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | P | OR | 95% CI | P |
| Gender: male | 0.69 | 0.53, 0.91 | 0.009 | 0.65 | 0.47, 0.88 | 0.006 |
| One or both parents ATSI | 1.00 | 0.38, 2.65 | 0.997 | | | |
| Mother spoke language other than English | 1.86 | 1.06, 3.25 | 0.030 | 1.59 | 0.87, 2.89 | 0.132 |
| Maternal ethnicity: not Caucasian | 1.57 | 1.02, 2.41 | 0.040 | 1.38 | 0.87, 2.19 | 0.167 |
| Household income below poverty line at birth | 1.07 | 0.80, 1.43 | 0.634 | | | |
| Maternal education (graduated high school) | 0.93 | 0.70, 1.23 | 0.595 | | | |
| Smoking ever | 1.31 | 0.97, 1.79 | 0.081 | | | |
| Allergies | 1.29 | 0.93, 1.79 | 0.128 | | | |
| Day care attendance | 0.87 | 0.62, 1.23 | 0.440 | | | |
| Alcohol consumption during pregnancy | 0.99 | 0.74, 1.32 | 0.923 | | | |
| Asthma | 0.97 | 0.64, 1.47 | 0.896 | | | |
| Parity: 1 or more older sibling(s) | 0.98 | 0.75, 1.29 | 0.899 | | | |
| Exclusive breastfeeding stopped ≤6 months | 1.09 | 0.82, 1.45 | 0.537 | | | |
| Other milk introduced <6 months | 0.93 | 0.68, 1.25 | 0.620 | | | |
| Premature (Gestation <37 weeks) | 0.93 | 0.53, 1.63 | 0.802 | | | |
| Low Birth Weight (<2,500 g) | 0.98 | 0.58, 1.68 | 0.951 | | | |

**Table 4** Logistic regression of risk factors for bilateral OM in the Raine study

| Risk factors for bilateral OM | Univariate models | | | Multivariable model | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | P | OR | 95% CI | P |
| Gender: male | 0.74 | 0.53, 1.03 | 0.072 | | | |
| One or both parents ATSI descent | 1.29 | 0.44, 3.76 | 0.646 | | | |
| Mother spoke language other than English | 2.29 | 1.28, 4.09 | 0.005 | 1.97 | 1.05, 3.69 | 0.035 |
| Maternal ethnicity: not Caucasian | 1.73 | 1.05, 2.83 | 0.030 | 1.43 | 0.83, 2.44 | 0.195 |
| Household income below poverty line at birth | 1.14 | 0.80, 1.61 | 0.470 | | | |
| Maternal education (graduated high school) | 0.80 | 0.57, 1.13 | 0.208 | | | |
| Smoking ever | 1.18 | 0.81, 1.71 | 0.402 | | | |
| Allergies | 0.79 | 0.52, 1.19 | 0.259 | | | |
| Day care attendance | 0.68 | 0.45, 1.03 | 0.071 | | | |
| Alcohol consumption during pregnancy | 0.91 | 0.64, 1.31 | 0.616 | | | |
| Asthma | 0.99 | 0.60, 1.64 | 0.986 | | | |
| Parity: 1 or more older sibling(s) | 0.98 | 0.70, 1.38 | 0.925 | | | |
| Exclusive breastfeeding stopped ≤6 months | 0.85 | 0.60, 1.21 | 0.374 | | | |
| Other milk introduced <4 months: | 0.75 | 0.52, 1.08 | 0.116 | | | |
| Premature (Gestation <37 weeks) | 1.19 | 0.63, 2.23 | 0.596 | | | |
| Low birth weight (<2,500 g) | 1.22 | 0.66, 2.24 | 0.529 | | | |

**Table 5** Logistic regression of risk factors for bilateral HL in the Raine study

| Risk factors for bilateral HL | Univariate models | | | Multivariable model | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | P | OR | 95% CI | P |
| Gender: male | 0.58 | 0.28, 1.20 | 0.142 | | | |
| One or both parents ATSI (Aboriginal or Torres Strait Islander) | 0.00 | – | 0.998 | | | |
| Mother spoke language other than English | 1.77 | 0.53, 5.93 | 0.356 | | | |
| Maternal ethnicity: not Caucasian | 0.59 | 0.14, 2.49 | 0.473 | | | |
| Household income below poverty line | 1.75 | 0.86, 3.56 | 0.126 | | | |
| Maternal education (graduated high school) | 1.07 | 0.52, 2.19 | 0.863 | | | |
| Smoking ever | 0.62 | 0.26, 1.49 | 0.285 | | | |
| Allergies | 0.45 | 0.16, 1.29 | 0.137 | | | |
| Day care attendance | 0.48 | 0.20, 1.14 | 0.094 | | | |
| Alcohol consumption during pregnancy | 0.80 | 0.37, 1.74 | 0.582 | | | |
| Asthma | 1.27 | 0.48, 3.33 | 0.635 | | | |
| Parity: 1 or more older sibling(s) | 1.50 | 0.72, 3.16 | 0.282 | | | |
| Exclusive breastfeeding stopped ≤6 months | 1.08 | 0.51, 2.29 | 0.834 | | | |
| Other milk introduced <4 months | 0.72 | 0.33, 1.58 | 0.414 | | | |
| Premature (Gestation <37 weeks) | 1.38 | 0.41, 4.61 | 0.603 | | | |
| Low birth weight (<2,500 g) | 0.86 | 0.20, 3.65 | 0.837 | | | |
| Combined unilateral and bilateral OM | 7.75 | 3.31, 18.15 | <0.001 | 7.75 | 3.31, 18.15 | <0.001 |

15%. A number of studies have estimated prevalence of OM in a similar age group, including Humaid *et al.* (24) who reported an OM prevalence rate of 23.8% for children aged between 6 and 7 years, Okur *et al.* (25) who reported a prevalence rate of 10.4% for children aged between 6 and 8 years, and Apostolopoulos *et al.* (26) who reported a prevalence rate of 10.1% for children aged between 5 and 8 years. However, the definitions of OM in these studies all varied slightly based on what was considered an abnormal tympanogram and the duration of middle ear effusion. As a single assessment was used in this study, we could not indicate the chronicity of the OM or middle ear effusion and this has likely contributed to our estimates being among the higher estimates when compared with several previous studies. Our estimates for bilateral OM are more consistent with estimates from previous studies and likely reflect more significant ear disease for these children. The inclusion of hearing sensitivity is a strength of this study and demonstrates the impact of a single OM episode on hearing levels in children in the 5 to 7-year age group, with approximately 10% of OM cases having a significant bilateral hearing loss which may have implications for their schooling.

In studies to date, there is great variability in the prevalence and associated risk factors reported for OM. This study focused on early life predictors of later OM and hearing loss susceptibility. Overall, we found a lack of significant associations (or unexpected directions of effect) for OM compared to follow-ups at earlier time-points in childhood within the Raine Study and other cohorts. In the current study, univariate analysis revealed statistically significant associations between having OM and children whose mothers spoke a language other than English, maternal ethnicity other than Caucasian; male gender was protective against OM. On multivariate analysis, only male gender (protective) remained significant. Although this is supported by some other studies (26,27), it is inconsistent with a large proportion of international research, which finds an increased risk among males (28-32) or no association with gender (16,33-36). Considering our finding was not significant across all domains (e.g., for bilateral OM) this finding may be spurious and should be interpreted

with caution. It appears that the risk factors traditionally associated with OM during infancy and early childhood may not be responsible for an increased risk of OM in middle or later childhood, where other social and environmental factors may be stronger predictors of OM.

A limitation of the design of this study is the difficulties of following a large number of participants longitudinally and the potential for attrition or selection bias (37). Given 1,344 of 2,280 participants completed tympanometry and audiometry, the study renders the possibility of selection bias where some families may have been more motivated to participate in the ear and hearing screening assessment than others. However, we believe there is a low risk that a significant number families selected to attend this assessment specifically for hearing concerns, as the hearing assessment was just one of a suite of assessments conducted at the 5 to 7 year check, together with allergy testing, lung function test and other physical assessments. The potential for information bias was minimized by utilizing accurate instruments and systematic instruction for clinical examiners to reduce measurement error. Another limitation is the delay between data collection and analysis. The Senses Special Interest Group (SIG) for the Raine Study was only established in 2016, when study participants were already 27 years old, with ear and hearing variables previously unexamined. The availability of only a single time point for the detection of OM also meant we could not differentiate between AOM and OME in this study and all children with a low compliance tympanogram were considered to have OM; this could have also included children with ventilation tubes or dry tympanic membrane perforations. This broad definition of OM therefore means these prevalence results need to be interpreted with some caution. However, this still represents one of the few estimates of prevalence and risk factors for OM and hearing loss available in the region.

Passive smoke exposure was not found to be associated with OM in this study. Numerous studies, including two meta-analyses have demonstrated a relationship (38-40), while numerous others have not (24,26,40,41). Daycare attendance was also not found to be associated with OM at 5 to 7 years of age in this study. This is consistent with some previous studies (24), although a number of studies have identified daycare attendance to be a risk factor for OM (32,42). Previously, we showed an increased risk of daycare attendance on OM prevalence at 3 years of age (16). The lack of association at 5 to 7 years in this study may be due to development of stronger immune response in older children and exposure to pathogens through day care attendance, whilst increasing risk of OM at the time of exposure, may not lead to an increased susceptibility to OM later in childhood. The duration of breastfeeding was not associated with OM in the current study. Our previous analyses have shown a protective effect of breastfeeding at 3 years, but this effect does not appear to persist into later childhood (43). Our results showed no association between OM and a family income below the poverty line at birth. Low socioeconomic status has been variably linked to OM but income is just one of a number of potential variables indicative of socioeconomic status, with many studies showing a complex relationship involving multiple potential risk factors (29,30,31,43). Children with one or more older siblings were not at an increased risk of OM in this study at 5 to 7 years of age. However, some studies have reported a significant relationship between OM and the presence of one or more siblings, including in a previous analysis of this cohort at a at younger time point (3 years of age) (16). Low birth weight or prematurity were not found to be associated with OM in this study, which is consistent with several studies (16,36,40) with the exception of Engel *et al.* (32) who examined this outcome for OME at 0–2 years of age and hypothesized that this may be a time-dependent link, as the peak prevalence of OM is typically in the 6–24 month age range. Our previous analysis of risk factors in the Raine cohort for children at 3 years of age also did not find any association with prematurity or low birth weight (16).

In the Raine Study, the prevalence of bilateral hearing loss in 5 to 7-year-old children ≥26 dB was 2.1%. OM was identified as a strong risk factor for bilateral hearing loss (OR =7.75, CI: 3.31–18.15, P<0.001). In this study, the prevalence of bilateral OM with bilateral hearing loss was 1.2%; with 10.32% of participants with bilateral OM having a bilateral hearing loss. No other variable demonstrated a significant association with hearing loss. Reported prevalence rates from previous studies have varied considerably based on age and geographical region. For hearing loss of greater than 30 dB Streppel *et al.* (38) found a prevalence of 0.043% for children aged 2–19 years. For hearing loss greater than 27 dB in the better ear, Liu *et al.* (39) reported a prevalence of 0.66% in children under 15 years of age. For hearing loss greater than 25 dB, Apostolopoulos *et al.* (26) found a prevalence of 5.72% in children 6 to 12 years old; however, did not specify whether the included cases were unilateral or bilateral hearing loss. Of note, several studies have likely underestimated the prevalence of hearing loss by excluding children with mild hearing impairment or those not requiring a hearing device.

The prevalence of hearing loss depends greatly on the classification criteria used. This study used the WHO criteria which uses the best ear four-frequency average hearing level of ≥26 dB. Average hearing levels may not capture clinically significant hearing losses if they are variable or sloping across the frequency range (44). Therefore, this classification criteria may not have captured children who had predominately low-frequency hearing losses which is a common configuration in children with OM (10).

## Conclusions

In a community sample of Australian children, the cross-sectional prevalence of combined unilateral and bilateral OM of children with an average age of approximately 6 years was 22.5%. The prevalence of bilateral OM was 11.5%. The prevalence of bilateral hearing loss greater than ≥26 dB was 2.1%. The prevalence of bilateral OM with bilateral hearing loss was 1.2%. In this study, OM was the only significant risk factor for bilateral hearing loss at 5 to 7 years of age, despite the numerous pre-natal, peri-natal and environmental factors included in this study. This study highlights the high prevalence of OM during the early years of schooling in Australia. It is important that children, particularly those experiencing difficulties in the early years of schooling, are screened or assessed for OM and hearing loss.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The human ethics committee at King Edward Memorial Hospital approved participant recruitment and follow-up for the Raine Study. Initially, parents provided written informed consent for the use of stored data; at 17 years of age children were re-consented.

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