# Prevalence and risk factors for parent-reported recurrent otitis media during early childhood in the Western Australian Pregnancy Cohort (Raine) Study

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**KEYWORDS**

Otitis media; glue ear; epidemiology; Raine Study; prevalence; risk factors

**LIST OF ABBREVIATIONS**

AOM: Acute otitis media

dB HL: Decibel (hearing level)

OM: Otitis media

OME: Otitis media with effusion

OR: Odds ratio

CI: 95% confidence interval

rOM: Recurrent otitis media

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**ABSTRACT**

**Objective:** To describe the prevalence and risk factors of recurrent otitis media (rOM) in an urban Australian population at 3 years of age.

**Methods:** Cross-sectional examination of prevalence and risk factors of rOM in 2280 participants from the Raine Study enrolled from public and private hospitals in Perth, Western Australia, between 1989 and 1991. Parental report questionnaires at 3 years of

age were used for rOM identification, with secondary confirmation by otoscopic examination at 1, 2 or 3 years of age.

**Results:** The prevalence of parent-reported rOM was 26.8% (611/2280) and 5.5% (125/2280) for severe rOM in the Study. Independent associations were found between rOM and the presence of older siblings, attendance at day care, and the introduction of other milk products at ≤4 months of age. Independent associations for severe rOM were the presence of allergies and attendance at day care.

**Conclusions:** Prevalence rates of rOM within the Raine Study children are similar to a number of other known cohorts. Parity, presence of allergies, attendance at day care and introduction of other milk products at ≤4 months are highlighted as specific risk factors for rOM in this population and presence of allergies and attendance at day care being risk factors for severe rOM. Diagnosis of rOM by parent report and the delay between data collection and reporting are limitations of this study. However, as there is very limited published information on OM in urban, non-Indigenous Australian children, this study improves our understanding of OM for this group.

## INTRODUCTION

Otitis media (OM) is a common disease in childhood that is estimated to affect over 90% of children before their second birthday[1] with an estimated cost of treatment in Australia between AUD$100-400 million per annum[2]. It is, therefore, essential to have accurate estimates of disease prevalence as well as knowledge of associated risk factors in order to guide local policy, future research and clinical management. The clinical course of recurrent OM and its sequelae are varied; some children will experience a spontaneous resolution of symptoms with no lasting effects, whilst others will receive

medication, with or without surgical intervention (myringotomy and tympanostomy tubes), which is often effective in resolving or stopping the progression of the disease[3]. Unfortunately many children will experience recurrent and more severe episodes of the disease that can lead to extended periods of decreased hearing sensitivity.

It has been proposed that reduced hearing sensitivity due to chronic or recurrent OM may result in various short and long term developmental sequelae[4]. However, whilst some short-term effects associated with recurrent OM have previously been demonstrated[5-7], a number of longitudinal studies have also shown these deficits resolve in the longer term[9].

Previous OM research within Australia has focussed primarily on Indigenous Australian children[10]. Whilst non-Indigenous Australian children do not share the same risks of developing some of the more serious complications of OM, they may be at risk of adverse developmental and educational outcomes due to the temporary conductive hearing loss associated with the disease. Currently, there is a dearth of evidence which addresses the prevalence and associated risk factors of recurrent otitis media in typical urban non-Indigenous Australian populations[11, 12], with current OM estimates based on international prevalence data applied to Australian population statistics[12].

OM is a broad term referring to inflammation of the middle ear cleft, with or without effusion. Acute otitis media (AOM) is characterised by rapid onset of signs and symptoms, such as otalgia and fever, or acute infection within the middle ear. Otitis media with effusion (OME) refers to a non-purulent fluid in the middle ear space, often

occurring as a result of previous infection but where the signs and symptoms of acute infection are absent and there is no perforation of the tympanic membrane[1]. A major obstacle to consistent research regarding OM prevalence and risk factors is the lack of universally accepted diagnostic criteria. In a survey of 165 clinicians, 147 different clinical definitions of AOM were provided, with no definition used by more than six clinicians[8]. Diagnosis of either AOM or OME requires the presence of an effusion, which can be reliably detected only by tympanometry and pneumatic otoscopy[2]. Recurrent OM (rOM), whether AOM or OME, may result in a temporary mild-moderate conductive hearing loss, usually between 15-40 dB HL and there are therefore significant concerns that both short-term and long-term development may be adversely affected when recurrent or prolonged episodes of AOM or OME occur in early childhood (0-3 years); this is a time period which is considered to form a significant part of the sensitive period for language development[13, 14].

The objectives of this study were to report the prevalence and associated risk factors for recurrent OM during early childhood in a representative urban Australian cohort, to fill a gap in our knowledge of rOM within an Australian context.

## METHODS

### *Participants*

Participants were from the Western Australian Pregnancy Cohort (Raine) Study, which enrolled approximately 2868 pregnant women from public and private hospitals in Perth, Western Australia between May 1989 and November 1991. Of these, 2280 participants had completed data pertaining to the presence of OM in their child or

children (in the case of twins or triplets) at three years of age. Inclusion criteria for mothers in the Raine Study were gestational age between 16-20 weeks, sufficient English to understand study assessments and an expectation to deliver and stay resident in Western Australia[15]. Exclusion criteria for this study were children with missing rOM data. Participant recruitment and follow-up for the Raine Study was approved by human ethics committees at the main maternity unit, King Edward Memorial Hospital and the paediatric unit, Princess Margaret Hospital, in Perth, Western Australia. Parents provided written informed consent and children were re-consented at age seventeen for the use of stored data. Data from the Raine Study, using the current rOM variable, has previously been utilised as part of a recent Genome Wide Association Study[18] of OM.

*rOM Identification*

OM in the Raine Study was assessed by parental report measures, with secondary confirmation using otoscopy. Parents were asked at the three-year cohort follow-up the yes/no question "Has your child ever in his/her life [had] otitis media (middle ear infection)? If so, how many?" (Appendix I). Parents were also asked if their child had ever had glue ear (Appendix I). Clinical examinations were performed by a specialist nurse at the same time as the parental questionnaire (approximately three years of age). Secondary confirmation of OM was obtained if, at either of the first-year, second-year or third-year follow-ups, clinical examination with otoscopy revealed any of the following: presence of scarred, retracted, inflamed or perforated tympanic membranes, the presence of middle ear effusion or ventilation-tubes (i.e. grommets) *in situ*. Due to the broad nature of the classification of OM in the cohort, we were unable to determine the specific clinical features for individual participants. The parental report of three or

more episodes of OM in the first three years of life constituted a diagnosis of rOM in the cohort, and children with >7 episodes of OM were considered to have severe rOM.

*Data Analysis*

The data analysis was conducted in three phases. Firstly, exploratory analyses examined categorical data based on parental report of OM, glue ear and the number of OM episodes were summarised and compared by gender using frequency distributions and Pearson's chi-squared tests (Table 1). Secondly, distributions of demographic and clinical risk factors between groups, based on the presence or absence of rOM, were compared using Pearson's chi-squared tests (Table 2). Thirdly, univariate and multivariable logistic regression was performed to identify independent risk factors and evaluate the effect of risk factors on the presence of rOM and severe rOM. Univariately significant factors were adjusted for in the multivariable regression (Table 3 & Table 4). For all analyses, $p<0.05$ was considered statistically significant. Data was analysed using SPSS v19.0 (Chicago, Illinois).

**RESULTS**

Overall prevalence of rOM in the study population at three years of age was 26.8% (611/2280), with a prevalence of 5.5% (125/2280) for severe rOM (Table 1). There was no significant gender difference for rOM or severe rOM. However, glue ear affected significantly more males than females (Table 1). Frequency distributions of OM episodes and glue ear according to parental report were not significantly different between males and females (Table 1).

**Table 1: Prevalence and characteristics of recurrent OM in the Raine Study**

| OM characteristics at 3 years of age | Male n=1154 (%) | Female n=1123 (%) | $p^{\#}$ | Totals n=2277 (%) |
|---|---|---|---|---|
| **rOM Prevalence** | | | 0.056 | |
| rOM+ | 327 (28.3) | 284 (25.3) | | 611 (26.8) |
| rOM- | 827 (71.7) | 839 (74.7) | | 1666 (73.2) |
| | | | | |
| **OM episode ever** | | | 0.207 | |
| Yes | 436 (37.7) | 402 (35.8) | | 838 (36.8) |
| No | 690 (59.7) | 686 (61.0) | | 1376 (60.4) |
| Missing | 30 (2.6) | 36 (3.2) | | 66 (2.8) |
| | | | | |
| **Glue ear ever** | | | 0.030* | |
| Yes | 100 (8.6) | 65 (5.7) | | 165 (7.2) |
| No | 1002 (86.8) | 1007 (89.7) | | 2009 (88.2) |
| Missing | 54 (4.7) | 52 (4.6) | | 106 (4.6) |
| | | | | |
| **Number of OM episodes per child** | **n=436 (%)** | **n=402 (%)** | | **n=838 (%)** |
| ≤2 | 205 (17.6) | 174 (15.4) | 0.301 | 379 (45.2) |
| 3 to 6 | 116 (10.0) | 125 (11.1) | 0.086 | 241 (28.7) |
| ≥7 | 74 (6.4) | 51 (4.5) | 0.078 | 125 (14.9) |
| Missing | 41 (9.4) | 52 (12.9) | | 93 (4.1) |

*# p values relate to gender comparisons*
**indicates a significant value*

Frequency distributions of putative rOM risk factors in the cohort are shown in Table 2 and odds ratios for these risk factors in Table 3. Independent associations were found for a number of risk factors in the univariate analysis that remained significant in the multivariable model, after adjusting for the univariately significant risk factors. Significant independent associations for rOM included the presence of older siblings (OR 1.64 [CI 1.27, 2.12]; $p$<0.001), allergies (OR 1.66 [CI 1.26, 2.19]; $p$ <0.001), attendance at day care (OR 1.87 [CI 1.41, 2.48]; $p$< 0.001), and introduction of other milk products at ≤4 months of age (OR 1.49 [CI 1.06, 2.09]; $p$=0.022). For severe rOM, only the presence of allergies (OR 1.1.69 [CI 1.04, 2.75]; $p$ <0.034) and attendance at day care (OR 2.47 [CI 1.27, 4.76]; $p$< 0.007) remained as significant independent associations (Table 4).

**Table 2: Frequency distributions of risk factors between recurrent OM groups (+ve and –ve) in the Raine Study**

| OM Risk Factors | rOM- n=1666(%) | rOM+ n=611(%) | *p* |
|---|---|---|---|
| **Gender** | | | |
| Male | 827 (49.6) | 327(53.5) | 0.056 |
| Female | 839 (50.4) | 284(46.5) | |
| | | | |
| **Aboriginal or Torres Strait Islander status** | | | |
| One or both parents ATSI | 37 (2.2) | 11 (1.8) | 0.546 |
| No parents ATSI | 1629 (97.8) | 600 (98.2) | |
| | | | |
| **Mother spoke language other than English** | | | |
| Yes | 100 (6.0) | 23 (3.8) | 0.042* |
| No | 1566 (94.0) | 588 (96.2) | |
| | | | |
| **Maternal ethnicity** | | | |
| Caucasian | 1462 (87.7) | 585 (95.7) | <0.001* |
| Other | 204 (12.2) | 26 (4.2) | |
| | | | |
| **Household income below poverty line at birth** | | | |
| Yes | 636 (38.2) | 225 (36.8) | 0.484 |
| No | 955 (57.3) | 361 (59.1) | |
| | | | |
| **Maternal education (graduated high school?)** | | | |
| Yes | 686 (41.2) | 254 (41.6) | 0.847 |
| No | 945 (56.7) | 343 (56.1) | |
| | | | |
| **Mother smoked during pregnancy** | | | |
| Yes | 434 (26.0) | 137 (22.4) | 0.202 |
| No | 1194 (71.7) | 340 (55.6) | |
| | | | |
| **Passive smoke exposure (years 1-3)** | | | |
| Yes | 562 (33.7) | 215 (35.2) | 0.461 |
| No | 839 (50.3) | 316 (41.8) | |
| | | | |
| **Allergies (years 1-3)** | | | |
| Yes | 348 (20.9) | 188 (30.8) | <0.001* |
| No | 948 (56.9) | 322 (52.7) | |
| | | | |
| **Day care attendance (years 1-3)** | | | |
| Yes | 739 (44.3) | 346 (56.6) | <0.001* |

| | | | |
|---|---|---|---|
| No | 375 (22.5) | 99 (16.2) | |
| | | | |
| **Alcohol consumed during pregnancy** | | | |
| Yes | 574 (34.5) | 252 (41.2) | 0.005* |
| No | 960 (57.6) | 319 (52.2) | |
| | | | |
| **Asthma (diagnosed in years 1-3)** | | | |
| Yes | 195 (11.7) | 95 (15.5) | 0.015* |
| No | 1471 (88.3) | 516 (84.4) | |
| | | | |
| **Parity** | | | |
| No older siblings | 836 (50.1) | 256 (41.9) | <0.001* |
| 1 or more older sibling(s) | 829 (49.7) | 355 (48.1) | |
| | | | |
| **Breastfeeding stopped ≤6 months** | | | |
| Yes | 702 (42.1) | 285 (46.6) | 0.137 |
| No | 837 (50.2) | 294 (48.1) | |
| | | | |
| **Other milk introduced** | | | |
| **<4 months** | | | |
| Yes | 816 (49.0) | 343 (56.1) | 0.015* |
| No | 712 (42.7) | 234 (38.3) | |
| **<6 months** | | | |
| Yes | 1087 (65.2) | 435 (71.2) | 0.051 |
| No | 441 (26.5) | 142 (23.2) | |
| | | | |
| **Premature** | | | |
| **(Gestation <37 weeks)** | | | |
| Yes | 143 (8.6) | 47 (7.6) | 0.478 |
| No | 1483 (89.0) | 552 (90.3) | |
| | | | |
| **Low Birth Weight (<2500g)** | | | |
| Yes | 144 (8.7) | 48 (7.8) | 0.550 |
| No | 1517 (91.0) | 561 (91.8) | |

## Table 3: Logistic regression of risk factors for recurrent OM in the Raine Study

| Risk Factors for rOM | *Univariate models* | | | *Multivariable model*[#] | | |
|---|---|---|---|---|---|---|
| | **OR** | **95% CI** | ***p*** | **OR** | **95% CI** | ***p*** |
| Gender: Male | 1.17 | 0.97, 1.14 | 0.061 | | | |
| One or both parents ATSI (Aboriginal or Torres Strait Islander) | 0.81 | 0.41, 1.59 | 0.546 | | | |
| Mother spoke language other than English | 0.68 | 0.47, 1.00 | **0.042*** | 0.89 | 0.45, 1.78 | 0.751 |
| Maternal ethnicity: not Caucasian | 0.32 | 0.21, 0.48 | **<0.001*** | 0.34 | 0.18, 0.66 | **0.001*** |
| Household income below poverty line at birth | 1.05 | 0.91, 1.21 | 0.484 | | | |
| Maternal education (graduated high school) | 0.97 | 0.86, 1.13 | 0.847 | | | |
| Passive smoke exposure (years 1-3) | 1.02 | 0.83, 1.25 | 0.461 | | | |
| Allergies (years 1-3) | 1.58 | 1.28, 1.97 | **<0.001*** | 1.66 | 1.26, 2.19 | **<0.001*** |
| Day care attendance (years 1-3) | 1.77 | 1.37, 2.29 | **<0.001*** | 1.87 | 1.41, 2.48 | **<0.001*** |
| Alcohol consumption during pregnancy | 1.32 | 1.09, 1.61 | **0.005*** | 0.99 | 0.77, 1.29 | 0.983 |
| Asthma (diagnosed in years 1-3) | 1.39 | 1.07, 1.81 | **0.015*** | 1.15 | 0.80, 1.64 | 0.459 |
| Parity: 1 or more older sibling(s) | 1.40 | 1.16, 1.69 | **<0.001*** | 1.64 | 1.27, 2.12 | **<0.001*** |
| Exclusive breastfeeding stopped ≤6 months | 1.16 | 0.96, 1.40 | 0.137 | | | |
| Other milk introduced: | | | | | | |
| <4 months | 1.28 | 1.05, 1.55 | **0.015*** | 1.49 | 1.06, 2.09 | **0.022*** |
| <6 months | 1.24 | 0.99, 1.55 | 0.051 | 1.01 | 0.68, 1.50 | 0.945 |
| Premature (Gestation <37 weeks) | 1.10 | 0.85, 1.42 | 0.478 | | | |
| Low Birth Weight (<2500g) | 1.08 | 0.84, 1.39 | 0.550 | | | |

[#] *adjusted for Mother spoke language other than English; Maternal ethnicity; Allergies (years 1-3); Day care attendance (years 1-3); Alcohol consumption during pregnancy; Asthma (diagnosed in years 1-3); Parity; Other milk introduced <4m*

**Table 4: Multivariate logistic regression of risk factors for severe OM (>7 episodes) in the Raine Study**

| | *Univariate models* | | | *Multivariable model*[#] | | |
|---|---|---|---|---|---|---|
| **Risk factors for severe rOM** | **OR** | **95% CI** | ***p*** | **OR** | **95% CI** | ***p*** |
| | | | | | | |
| Gender: Male | 1.35 | 0.91, 1.99 | 0.130 | | | |
| | | | | | | |
| One or both parents ATSI (Aboriginal or Torres Strait Islander) | 0.35 | 0.04, 2.68 | 0.311 | | | |
| | | | | | | |
| Mother spoke language other than English | 3.71 | 0.49, 28.03 | 0.204 | | | |
| | | | | | | |
| Maternal ethnicity: not Caucasian | 2.36 | 0.71, 7.81 | 0.160 | | | |
| | | | | | | |
| Household income below poverty line at birth | 1.26 | 0.84, 1.88 | 0.268 | | | |
| | | | | | | |
| Maternal education (graduated high school) | 0.91 | 0.62, 1.36 | 0.655 | | | |
| | | | | | | |
| Passive smoke exposure (years 1-3) | 1.04 | 0.68, 1.57 | 0.869 | | | |
| | | | | | | |
| Allergies (years 1-3) | 1.91 | 1.24, 2.93 | **0.003*** | 1.69 | 1.04, 2.75 | **0.034*** |
| | | | | | | |
| Day care attendance (years 1-3) | 2.58 | 1.36, 4.89 | **0.004*** | 2.47 | 1.27, 4.76 | **0.007*** |
| | | | | | | |
| Alcohol consumption during pregnancy | 0.92 | 0.62, 1.39 | 0.712 | | | |
| | | | | | | |
| Asthma (diagnosed in years 1-3) | 1.50 | 0.91, 2.47 | 0.115 | | | |
| | | | | | | |
| Parity: 1 or more older sibling(s) | 1.17 | 0.80, 1.73 | 0.417 | | | |
| | | | | | | |
| Exclusive breastfeeding stopped ≤6 months | 1.17 | 0.79, 1.75 | 0.429 | | | |
| | | | | | | |
| Other milk introduced: | | | | | | |
| <4 months | 1.32 | 0.82, 2.14 | 0.253 | | | |
| <6 months | 1.44 | 0.95, 2.185 | 0.082 | | | |
| | | | | | | |
| Premature (Gestation <37 weeks) | 0.95 | 0.43, 2.07 | 0.889 | | | |
| | | | | | | |
| Low Birth Weight (<2500g) | 1.19 | 0.58, 2.44 | 0.634 | | | |

[#] *adjusted for Allergies (years 1-3); Day care attendance (years 1-3)*

## DISCUSSION

This is the first published study known to the authors that reports the prevalence and adjusted risk factor findings of rOM during early childhood in an urban Australian environment using a representative cohort of children. Considerable national and regional variability in prevalence rates for rOM have previously been reported. The prevalence rate of rOM in the Raine Study was higher than the British Columbia[16] cohort at 3 years of age (7.8%) which had stricter classification criteria for rOM (rOM classified as 3 episodes within 6 months or 4 episodes within 12 months) and lower than the Boston[17] cohort at 3 years of age (46%) which used similar rOM classification criteria (rOM classified as 3 episodes of OM at any time in the first 3 years of life).

We are not aware of any other empirical studies examining the possible association of maternal alcohol consumption during pregnancy and rOM. However, the World Health Organisation[30] have listed maternal alcohol consumption as a possible risk factor for OM. Previous studies of children with Fetal Alcohol Syndrome (FAS) have proposed immune deficiencies and Eustachian tube dysfunction (secondary to embryonic malformations of the first and second branchial arches) to account for the very high prevalence of rOM (77-93%) in this population[31-34].Whilst maternal alcohol consumption during pregnancy was identified as a significant risk factor for rOM using univariate analysis in this study, no independent association was shown on multivariate analyses. The level of alcohol consumption by mothers in the Raine Study was wide-ranging (from “less than once a week” to “several times a week”), and the current results do not suggest an independent association between alcohol consumption and an increased incidence of OM.

Independent associations were found for the presence of allergies in the first three years of life and this is supported by previous studies as well as clinical guidance[41-43]. The presence of older siblings and day care attendance were both also shown to be independent risk factors for rOM in this population. These variables have previously been reported as predisposing to OM[35, 39, 40, 44] and are typically attributed to the increased chance of acquiring the pathogens involved in OM or upper respiratory tract infections from contact with siblings or other children[35, 39, 40]. Maternal ethnicity (non-Caucasian) was independently associated as a protective factor for rOM, indicating no significantly increased risk of rOM to children born to mothers from other ethnic groups in the Raine Study. This is in keeping with other studies that have also shown a lower risk of OM in African American and Asian infants[47].

Whilst duration of breastfeeding was not a significant risk factor for rOM in the cohort, consistent with recent studies[23, 39], the introduction of other milk products before four months of age was associated with a greater risk of rOM. Breastfeeding exclusively for at least four months has previously been associated with a reduced number of OM episodes [45]. The many health benefits of breast-feeding are universally accepted, but there is still equivocal evidence regarding its effect on the incidence of OM with some studies showing clear support for the positive benefits of breastfeeding[1, 17, 27, 46] whilst others indicate no association[22, 40, 41]. The current findings from the Raine Study suggest a protective effect of exclusive breast feeding for at least 4 months; however, the mechanism for a protective effect is still unclear[45].

Socio-economic status indicators such as household income and maternal education showed no significant association in the Raine Study. Once again, results from previous studies are varied, with some studies demonstrating no significant association between OM and socio-economic status[17, 35] whilst others show a reduced risk of developing OM if mothers were classified in the highest socio-economic group[36].

Childhood exposure to passive smoking was not significantly associated with increased risk for rOM in the cohort. Exposure to passive smoking is thought to increase the risk of OM through an effect on mucociliary clearance[19], decreased ciliary beat frequency[20] or mucus hypersecretion[21], and is one of the most studied risk factors of rOM. There are a number of studies that do not show an association[22-24], whilst others appear to show a clear association[25-28]. It has, however, been argued that socio-economic factors, such as quality of housing and housing tenure (owned or rented), may artificially exaggerate this association[29]. It is also possible that measurement of passive smoking exposure via direct measurement of serum cotinine levels, rather than via parent-report, is a more accurate and reliable measure of passive smoking exposure[19].

Gestational age <37 weeks was also shown to not be a significant risk factor for rOM in the Raine Study and this supports the findings of previous studies that show no, or a very weak, association between rOM and prematurity[37, 38].

There were a number of commonly associated risk factors for rOM that were not available in the Raine Study cohort. Family history of rOM, pacifier use, upper-respiratory tract infection and snoring are all risk factors that a number of previous

studies[1, 16, 17, 35], systematic reviews[48] and meta-analyses[49] have previously shown to have independent associations with rOM.

A limitation of this study is the classification of rOM. Others[16, 17] have used a similar classification system to this study in utilising a parent-report measure, which we have been able to supplement with examination by otoscopy. Ideally, continuous monitoring of children including confirmation of middle ear disease by tympanometry or pneumatic otoscopy is required. However, the skills, equipment and expertise for this are often not available when aiming to examine OM as part of a large-scale, longitudinal, multidisciplinary population cohort, such as the present study. In such cases, parental-report measures are often recommended[50] and continue to be used[51] to identify a broad presentation of OM that may include children with a wide range in severity of symptoms. The sensitivity of parental-report OM has been estimated to be between 75-95%, with a specificity of 65-100%[52], with parents more likely to underestimate the number of episodes if the child had <6 episodes and overestimate episodes if the child had >6 episodes.

The definition of rOM used for this study can therefore be seen as a broad phenotype for OM, based on parent-report and clinical observation, rather than a robust clinical diagnosis with tympanometry. Although this study presents key findings for a range of risk factors in the prenatal, perinatal and postnatal period in an urban Australian population, the use of parent-report measures is a limitation and results should be interpreted with caution.

## CONCLUSION

The prevalence of rOM in early childhood was 26.8% for Western Australian children in the Raine Study. Significant risk factors associated with rOM included presence of older siblings, day care attendance, allergies and the introduction of other milk products at ≤4 months of age. For severe rOM, the presence of allergies and attendance at day care were the only significant risk factors. Maternal education, passive smoking exposure, sex, household income, exposure to passive smoking, maternal alcohol consumption, Indigenous ethnicity, breastfeeding duration <6 months, gestational age and birth weight were not significant risk factors in this cohort. This study contributes to current multinational paediatric prevalence estimates of rOM and associated risk factors. It also presents the first specific values for urban Australian populations alongside the identification of predisposing risk factors. Given the wide variation in reported prevalence figures and risk factors for rOM across populations, local findings are particularly important for regional and national treatment and prevention programmes.

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**Appendix I: Parental report questionnaire at the 3 year follow-up:**

Q79. Has your child ever had (in his/her life)

- otitis media (middle ear infection)? ☐ 70

  N No
  Y Yes How many times? ___

- glue ear? ☐ 71

  N No
  Y Yes