Author's response to reviews

Title: Otitis media in children vaccinated with either 7-valent or 10-valent pneumococcal conjugate vaccines: a cross sectional comparison

Authors:

Amanda J Leach (Amanda.Leach@menzies.edu.au)
Christine Wigger (Christine.Wigger@menzies.edu.au)
Ross Andrews (Ross.Andrews@menzies.edu.au)
Mark Chatfield (mark.chattfield@menzies.edu.au)
Heidi Smith-Vaughan (heidi.smith-vaughan@menzies.edu.au)
Peter S Morris (peter.morris@menzies.edu.au)

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Author's response to reviews: see over
REVIEWER ONE
We are again very grateful for your detailed scrutiny of our article. We have responded to your queries below and made changes to the article as indicated in bold.

MAJOR COMPULSORY REVISIONS

1. Selection process for enrolment

METHODS

Participant recruitment and consent.
Lines 128 to 132 now read “In these remote communities where the birth cohort is between 5 and 45 infants per year, we aimed primarily to see all children under 36 months of age as well as older children (up to 6 years of age) if available. No random selection methods were used. Individual families were approached with information about the study. Consent was sought from parents for their child (regardless ear health status or history) to have an ear examination, ….”

RESULTS.

Region and communities.
We have added the following explanation of the context in which this research is occurring.
Lines 228 to 236 now read “Mobility is high amongst these families. We have previously found that around 84% of young children (< 30 months of age) may be present in a community at any one visit. Many additional factors influenced coverage during the course of this surveillance including Traditional Owner approvals to access the community, unscheduled cultural ceremonies such as funerals, parental consents, weather events, availability of accommodation for research staff, and the cost of travel. The sampling strategy thus resulted in differing proportions of children from 25 communities and 7 regions being seen over time (up to 44% age-eligible children were seen each year in the largest communities).”

We are very mindful of the potential bias this process may have in determining OM prevalence (Line 372), however the findings are robust when the analysis is conducted for subgroups such as for the larger communities, across age groups, or adjusting for inconsistent community representation (Line 369).

2. Clinical relevance of change in prevalence of purulent (suppurative) OM and non-purulent OM.

The apparent shift in clinical severity has implications for management of OM in these high risk children. The recommended management for suppurative OM is for antibiotic treatment and regular clinical review. Tympanoplasty may be required. Management of non-suppurative OM is watchful waiting with audiological assessment if OME persists, or if language or communication delays are suspected. Tympanostomy tubes and/or adenoidectomy may be considered for persistent hearing loss.
Lines 356 to 358 now read “Implications of this shift from suppurative to non-suppurative disease could result in reduced rates of antibiotic prescribing and a change in demand for surgical procedures such as tympanoplasty and tympanostomy tubes.”

3. Hypothesis generating

We agree that these types of studies are inferior to randomised controlled trials, and causality cannot be assigned. Our primary hypothesis was that there would be a shift in severity of ear disease in association with the change from PCV7 to PHiiD-CV10 (Line 107).

Lines 104 to 107 now read: “Through ongoing surveillance of otitis media over this period, we were able to compare the community level impact of PCV schedule on OM and explore potential associations between OM severity and risk factors.”

We believe the information to be of value and that the findings should be further investigated in RCTs, which we are currently undertaking. Our discussion provides consideration of the limitations inherent in this type of data.

MINOR ESSENTIAL REVISIONS:

1. Gender: Yes, contrary to most risk factor studies which find males to be at greater risk of OM, we found female gender to be associated with suppurative OM. We do not have an explanation for this finding.

2. OR has been deleted from the abstract.

3. Line 223. “less” has been changed to “not more”

4. Line 296: “Comparisons of OM prevalence between recipients of non-mixed PCV schedules (353 PCV7- and 319 PHiiD-CV10-recipients) showed almost ….”

5. Line 350: we have added absolute to the 12% reduction, now “12% absolute reduction”.

6. Line 385: The discussion now reads “We have not presented a comprehensive separate analysis of the impact of a booster PPV23 dose.” Whilst we have observed a potential difference in TMP between 23PPV- vaccinated and non-vaccinated children, this was not an a priori analysis. Line 304 now reads “In a post-hoc analysis, we found that compared to 39 age-eligible children in the PCV7 group who did not receive PPV23, …”