

**PneuMum**  
is a randomised controlled vaccine trial that aims to find out if pneumococcal immunisation of mothers in the last few months of pregnancy or at delivery can prevent ear disease in Aboriginal and Torres Strait Islander infants  
Mothers will receive Pneumovax, a 23 valent pneumococcal polysaccharide vaccine recommended for all Indigenous people in the Northern Territory from 15 years of age but not routinely given in pregnancy.

*This is a brief technical summary of the PneuMum study. Talking to us does not mean that you have to be involved. For more information, please call the PneuMum mob at Menzies on 08 8922 8773.*

**Background and rationale**

Aboriginal and Torres Strait Islander children experience the highest rates of acute and chronic ear infections in the world, resulting in permanent ear damage, hearing loss and educational disadvantage. These infections are mainly bacterial. *Streptococcus pneumoniae* (pneumococcus) is the predominant pathogen. Pneumococcal colonisation and infection begins within days of birth, months before any potential immunological protection from infant pneumococcal conjugate vaccine may be expected. New strategies are needed to eliminate, or at least delay, this early-onset pneumococcal colonisation.

Maternal immunisation with polysaccharide pneumococcal vaccine is one additional strategy that may protect newborn infants through transplacental antibody transfer, increased secretory antibody in breast milk, and/or by reducing carriage (and transmission to the infant) of maternal pneumococci. Previous small studies using this strategy have been encouraging, but there have been no studies properly evaluating carriage or disease endpoints in infants.

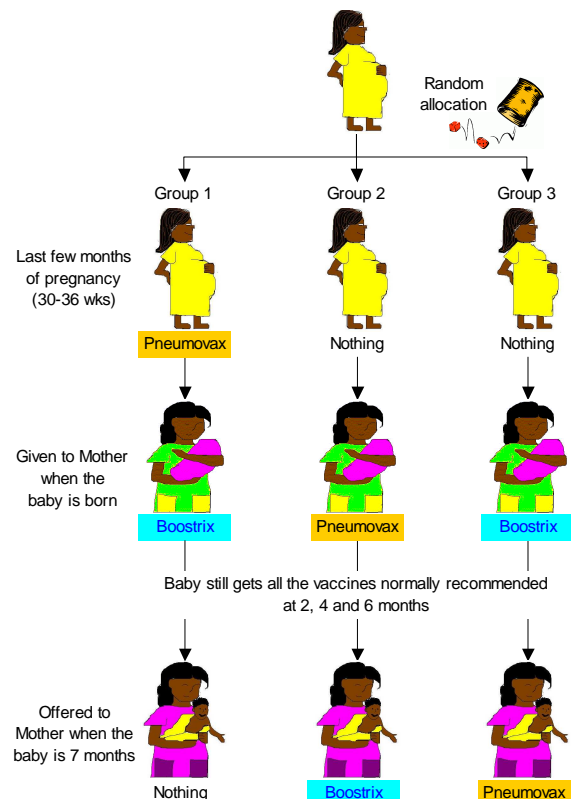
**Methodology**

The study, which has been funded by National Health and Medical Research Council, will not go ahead without the consent of communities and individual women within each community. We hope to recruit 210 Indigenous women aged 18-39 years who have an uncomplicated pregnancy. We only expect to recruit a small number of women from each community at any one time, up to four women from the Darwin urban area each month and four from the participating remote communities (about 8 per month).

We will contact potential subjects to seek informed consent to participate. We will provide participants with information that explains the disease, reasons for the study, and potential harms/benefits of involvement. All participants will have documentation of appropriate antenatal investigations to ensure pregnancy is proceeding normally, as far as can be determined.

Following recruitment, mothers will be randomly assigned to one of three groups (see Figure), receiving Pneumovax in the last few months of pregnancy, immediately postpartum, or seven months after childbirth (the control group). Boostrix, recommended for new parents to prevent pertussis (whooping cough), will also be given at delivery to conceal the intervention groups.

Although currently recommended for all Indigenous persons in the Territory from 15 years of age and for others in high-risk groups, uptake of Pneumovax among women of child-bearing age has been low. Boostrix is recommended but not currently funded for parents, so would normally need to be purchased on prescription through a pharmacist.



### Outcomes

The primary outcome will be prevalence of ear infection at seven months of age, defined as middle ear effusion or tympanic membrane perforation or acute otitis media. Pneumatic otoscopy, video-otoscopy and tympanometry will be used in the ear examinations. The primary analyses will be a direct comparison of the proportion of infants in the control group (Group 3) who have carriage of vaccine type pneumococci at seven months of age compared to infants in each of the other two groups and a similar comparison of the proportion with middle ear disease at that age.

There is a clear link between carriage of pneumococci in the first few months of life and the extraordinarily high rates of acute and chronic ear infections among Indigenous children, leading to hearing loss and educational disadvantage. Our study has the potential to demonstrate clinically significant benefits for infants in the first few months of life, the critical period before they have the opportunity to get protection from the scheduled pneumococcal conjugate vaccine (Prevenar).

- If maternal immunisation can eliminate, or at least delay, early-onset pneumococcal colonisation in infants it could have a substantial impact on ear disease.
- If the results of our study suggest antenatal vaccination reduces pneumococcal carriage or ear disease it would support moves to establish a much larger safety and efficacy studies of pneumococcal vaccination during pregnancy.
- If similar results are achieved from postnatal vaccination, it would provide evidence that such studies are not warranted and that the policy emphasis should be to ensure unvaccinated mothers are offered pneumococcal vaccination prior to discharge from hospital.

In addition to funding support from the National Health and Medical Research Council, the PneuMum study has been endorsed as an in-kind project by the Cooperative Research Centre for Aboriginal Health and has received in-principle support from the World Health Organization and the Centre for Disease Control of the Northern Territory Department of Health and Community Services.

### The PneuMum Team

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If you have any complaints or concerns regarding the study, you can also contact:  
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