APPENDICES

Informed consent materials

These materials have been designed in consultation with the Indigenous Reference Group of the Child Health Division at Menzies School of Health Research, and the Indigenous sub-committee to the Human Research Ethics Committee. Note that these forms were made site-specific by use of the community name and relevant contact details. An assent form was available for mothers who were younger than 16 years of age.

Biological specimens

Specimens include nasopharyngeal (NP) swabs, swabs of otorrhoea (discharge from the middle ear following spontaneous tympanic membrane perforation), and serum from whole blood. These specimens are stored at -80^{o}C. No human DNA is extracted for genetic analysis. Bacteria are cultured and stored at -80^{o}C. Bacterial and viral DNA are extracted for detection by pathogen-specific quantitative PCR. Serotype-specific pneumococcal IgG concentration and anti-protein D IgG concentration in serum are determined and pneumococcal serotype-specific opsonophagocytic activity determined. Residual serum is stored at -80^{o}C. Parents of participants are asked to consent to these specimens being used in future otitis media research. Consent may be withdrawn at any time if requested in writing.

PREVIX_BOOST study

Following the final assessments at infant age 7 months, parents are asked if we can contact them when their infant is approaching 12 months of age regarding a further study of the booster dose. Infants previously participating in the PREVIX_COMBO trial are eligible to be randomised to either Synflorix or PCV13 at 12 months of age. The primary outcome is immunogenicity at 18 months of age. Secondary outcomes are NP carriage and otitis media at 18 months and at 3 years of age.