Concomitant vaccination of Meningococcal B with infant immunisation schedules

Analysis of Medically Attended events

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1 Outline

This document details the analysis of medically attended events for the work investigating the reactogenicity of the Meningococcal B (MenB) vaccine given either concomitantly or separately to infant immunisation schedules on the National Immunisation Program (NIP). The following sections detail the notation and modelling approaches. To simplify the examples we assume there are no covariate effects on the outcome and that there is only one scheduled timepoint.

2 Notation

Suppose that there are N (eligible) responders to the AusVaxSafety survey soliciting reactogenicity information within three days of vaccination for infants who received a MenB vaccine and their NIP scheduled vaccines either concomitantly or separately. We denote these individual responders with $i \in \{1, 2, \dots, N\}$.

We denote the vaccination *strategy* for responder i with $s_i \in \{\text{Concomitant} = 1, \text{Separate} = 2\}$ representing whether the vaccinations were delivered concomitantly or separately. Responder i has one survey response if $s_i = \text{Concomitant}$ and two survey responses if $s_i = \text{Separate}$. The scheduled NIP timepoints for responder i are denoted $t_i \in \{2 \text{ months} = 1, 4 \text{ months} = 2, 6 \text{ months} = 3, 12 \text{ months} = 4\}$. Covariates sex, Indigenous status and comorbidity for responder i are denoted $w_i \in \{\text{Male} = 0, \text{Female} = 1\}$, $x_i \in \{\text{Non-Indigenous} = 0, \text{Indigenous} = 1\}$ and $z_i \in \{\text{No} = 0, \text{Yes} = 1\}$, respectively.

The event of interest (medically attended adverse events) is defined in the following section.

3 Modelling

3.1 Scenario A

In Scenario A, the objective of the model is to estimate the probability of **at least one** medically attended event reported by responders receiving each strategy. As an event may only occur once per responder, i.e., either no events or at least one event, we denote MA for responder i with $y_i \in \{\text{Zero MA} = 0, \text{At least one MA} = 1\}$. The model is:

$$
\begin{aligned}
y_i &\sim \text{Bernoulli}(p_i) \\
\text{logit}(p_i) &= \mu_{s_i,t_i} + w_i \times \beta + x_i \times \gamma + z_i \times \delta \\
\mu_{s_i,t_i} &\sim \text{N}(a, b) \\
\beta, \gamma, \delta &\sim \text{N}(0, 1)
\end{aligned}
$$

Here, p_i is the probability of responder i reporting at least one MA and μ_{s_i,t_i} is the log odds of a responder receiving strategy s_i at scheduled timepoint t_i reporting at least one event. The log odds ratios for sex, Indigenous status and comorbidity are represented by β, γ and δ, respectively. The hyperparameters a and b would be chosen so that the prior distributions are weakly informative and will depend on the specific outcome. For each scheduled timepoint t_i, the difference in event probabilities can be calculated with $\text{logit}^{-1}(\mu_{\text{Concomitant},t_i}) - \text{logit}^{-1}(\mu_{\text{Separate},t_i})$.

Fit the model, extract the posterior distributions and visualise:

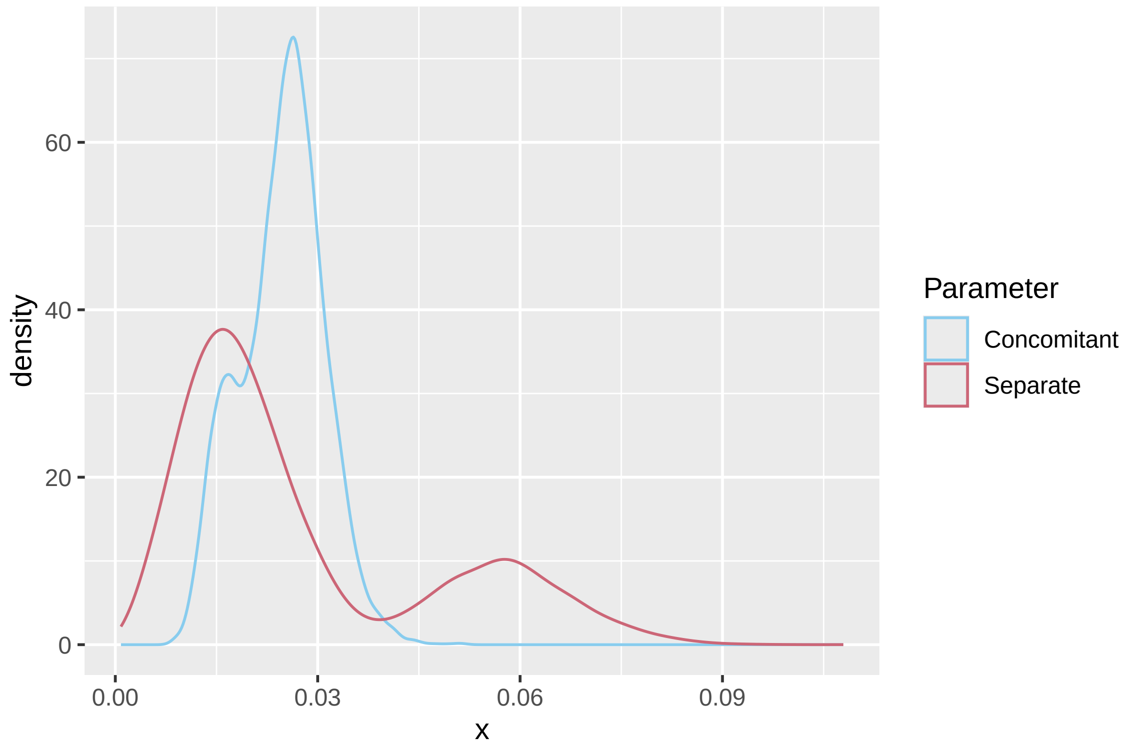

Figure 1: Posterior distributions for Scenario A parameters.

The means and 95% credible intervals for the event probabilities for each strategy are:

```
## [1] "Concomitant strategy: 0.02 (0.01, 0.04)"
```

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## [1] "Separate strategy: 0.03 (0.01, 0.07)"
```