

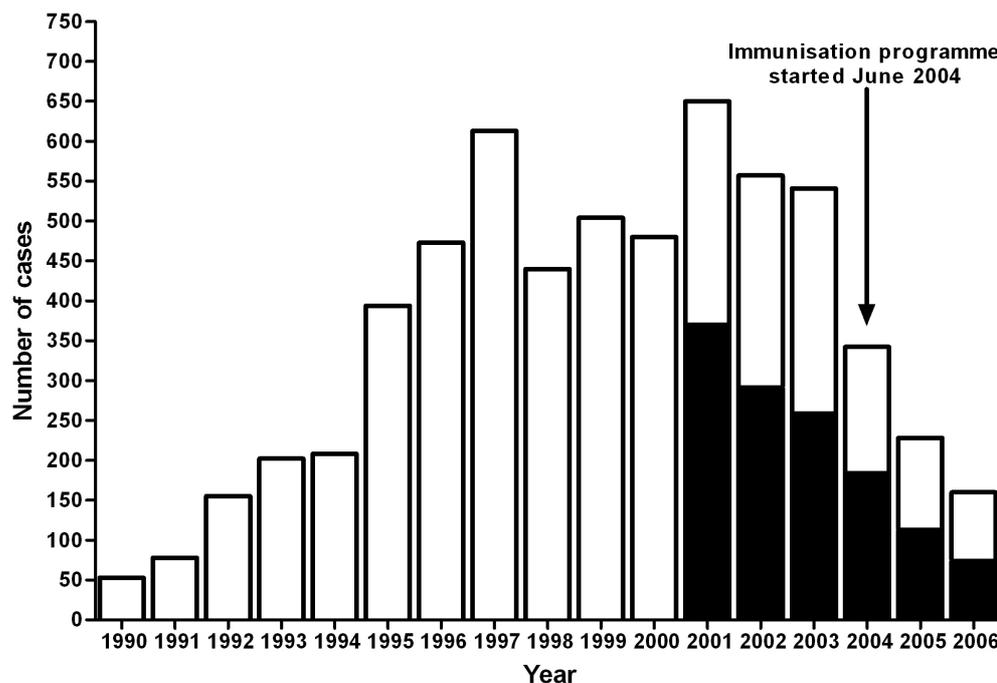


## Meningococcal B immunisation in New Zealand: why haven't we seen the data?

In mid-2004, the meningococcal B immunisation programme was introduced in Counties-Manukau followed by a progressive implementation throughout the country culminating in the nationwide programme by mid 2005. This roll-out had been preceded by several clinical trials. Achieving these impressive feats has required support, contributions and commitment toward the programme by many individuals, groups, and communities including governmental funding of approximately \$200 million. Despite the support of the medical community, there has been only one publication in the *New Zealand Medical Journal* describing any of the outcomes of the trials or of the programme itself.<sup>1</sup>

Recently, several reports have been published which provide some outcome data, but these reports are only likely to have been read by people with a special interest in the field. Martin et al. have published the comprehensive annual update of the epidemiology of meningococcal disease in New Zealand for 2006.<sup>2</sup> The incidence of meningococcal disease peaked in 2001 with 650 cases and has declined steadily since, as shown in Figure 1. 40-50% of cases occur in children under 5 years of age, and of those cases, 30% occur in children < 1 year and 20% in children aged 1-2 years.

**Figure 1. Incidence of meningococcal disease in New Zealand from 1991-2006. The black shading represents the proportion of cases due to the epidemic strain between 2001 and 2006. Data from Martin et al.<sup>2</sup>**



A seroresponder following immunisation is defined as a four-fold or greater rise in the titre of serum bactericidal antibody which is accepted as a surrogate marker of an effective immune response to immunisation.<sup>3</sup> Oster et al reported data on the immunogenicity of the vaccine.<sup>4</sup> These data are shown in Table 1 and suggest that, with the current administration schedule (6 weeks/3 months/5 months/10 months), 45% of infants are not seroresponders after 3 doses, increasing to 87% at the time of the fourth dose. It is not clear from these data how quickly immunogenicity wanes following the fourth dose.

**Table 1. Proportion of seroresponders following 3 doses of meningococcal B vaccine given every 6 weeks, and following a 4<sup>th</sup> dose. Data from Oster et al.<sup>4</sup>**

Age at initial immunisation	% seroresponders 6 weeks after 3 <sup>rd</sup> dose (age of child)	% seroresponders 4–5 months after 3 <sup>rd</sup> dose (age of child)	% seroresponders 6 weeks after 4 <sup>th</sup> dose (age of child)
6–10 weeks	53% (6 months)	13% (8.5–9 months)	69% (10–11.5 months)
6–8 months	74% (10–12 months)	Not reported	Not reported
16–24 months	75% (20–28 months)	Not reported	100% (31.5–46.5 months)

Finally, Kelly et al reported that rates of meningococcal disease were 3.7 times higher in unvaccinated cases compared with vaccinated cases over the first 2 years of the immunisation programme.<sup>5</sup> Models of disease incidence estimated that immunisation prevented 54 cases of meningococcal disease and 1.7 fatalities over this 2-year period.

Taken together, these data, along with other data presumably gathered but not yet published, should allow important questions about the vaccine to be answered. These questions include:

- How does the observed efficacy of the vaccine compare with predictions of its efficacy?
- Is the current timing of immunisations appropriate and is/are subsequent dose(s) required?
- Given the decline in incidence of meningococcal disease, is nationwide administration appropriate or should immunisation be targeted at high-risk groups?
- How does the cost-effectiveness of the meningococcal B programme compare with other vaccines of proven efficacy that are currently not funded such as pneumococcal, varicella, and HPV vaccines?

Hopefully, the New Zealand medical community will be given the opportunity to see the results of the clinical trials and immunisation programme soon.

Mark Bolland  
 Research Fellow  
 The University of Auckland  
 Auckland

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