



MeNZB™ vaccine: considerations for stopping vaccination of infants

Background

A “tailor-made” vaccine was developed in response to New Zealand’s epidemic of group B meningococcal disease that had been occurring since 1991, resulting in over 6023 cases and 245 deaths. The vaccine (MeNZB™) was offered to all New Zealanders under 20 years of age during a national campaign from 2004 to 2006. From 2006, the vaccine continued to be publicly funded for infants from 6 weeks of age to 5 years of age. The epidemic is waning. It is timely, therefore, to evaluate the advantages and disadvantages of ceasing the MeNZB™ vaccination programme.

Immunogenicity

A four-fold rise in serum bactericidal assay (SBA) levels has been set as the criteria to define a successful immune response to the vaccine. The clinical trials showed that around 75% of young children develop a successful immune response after a course of 3 doses. Responses are lower, however, for infants starting the programme at 6 weeks of age with around 53% developing the four-fold rise after a course of three.

Hence, the recommendation for a 4th dose at 10 months in this age group to stimulate higher SBA levels, matching the older infants and toddlers.

Duration of Protection

MeNZB™ is a vaccine designed for epidemic control. It is known internationally that these vaccines do not have long lasting duration of action. Data from the MeNZB™ trials have shown that the detectable duration of immunity post-vaccination is measured in months rather than years, with the majority of young children having measurable antibody levels below the protective levels (less than four-fold SBA levels) 7 months after the third dose. Immunity does decline less rapidly in the older children.

Disease Reduction

The effectiveness of this programme has been evaluated via its effect on disease incidence. A regression model based on conservative estimates has estimated that the programme produced a 73% (95% CI = 52% - 85%) reduction in the incidence of meningococcal disease in vaccinated people. Overall, the programme has been calculated to have prevented 54 meningococcal cases and 1.7 deaths over the roll-out period (2004-2006).

Effectiveness of continuing with the current infant programme for MeNZB

Taking into consideration both short duration of protection and current MeNZB™ vaccination coverage rates, it can be predicted that only approximately 40% of children between 6-17 months of age are currently protected against the epidemic strain of meningococcal disease.

Introduction of the conjugate pneumococcal vaccine, Prevenar®.

Consideration of the timing for the cessation of MeNZB™ is also influenced by the upcoming change to the immunisation schedule with the planned introduction of Prevenar®, offered as 4 doses to children aged 6 weeks, 3 months, 5 months and 15 months of age. The Medsafe license for MeNZB™ states that concomitant use with vaccines other than the routine Hib, DTaP-IPV, and Hepatitis B vaccines, should “be considered only if medically important and not on a routine basis”. The NZ MeNZB™ trials were undertaken with the childhood vaccines current at that time and did not include Prevenar® so there is no data to support the concurrent administration of MeNZB™ with Prevenar®. However, international experience indicates no problems are anticipated, either from the point of view of the immune response or safety of either vaccine.

Conclusions

The MeNZB™ vaccine programme was designed for short-term mass administration during an epidemic situation. The vaccine confers short term protection and relies on a high level of vaccination coverage to reduce disease incidence. The mass vaccination campaign has been effective at reducing disease. The epidemic is now clearly waning and disease rates are much lower than when the mass vaccination campaign was undertaken. Recognising that disease rates are currently low and duration of immune protection is short, continuing with the infant schedule programme is unlikely to offer much further benefit.

The introduction of the pneumococcal vaccine Prevenar® on 1 June 2008 is a timely point to review the use of the MeNZB™ vaccine alongside the infant schedule.