

## Why let your baby be used as a guinea pig for the experimental meningococcal B (MeNZB) vaccine?

by Anitra Carr, PhD

I was disturbed to read a recent news release which stated that "Younger babies can now get MeNZB vaccine protection. The Independent Safety Monitoring Board (ISMB) has recommended that the vaccine designed to protect young New Zealanders from the epidemic strain of meningococcal B disease should be extended to all children aged six weeks and older". Approximately 4600 doses of the vaccine were administered to more than 4000 babies in the Auckland region and the ISMB reviewed the safety data for this age group and stated that "sufficient data on vaccinating these younger babies is now available for the decision to be made to extend the vaccine access to all babies aged from six weeks and up." The vaccine was originally licensed for a minimum age of six months. I wonder, however, if the parents of these infants were fully aware that their children were being used as guinea pigs for an untested and experimental vaccine that has been fast-tracked without the use of proper control groups and without proper phase three clinical trials being carried out? A vaccine that should only have been given provisional approval for use on a restricted basis for the treatment of a limited number of people, *ie*, not for vaccinating all New Zealand children under the age of 20.

Although the Ministry of Health (MoH) is urging parents to vaccinate their children, there are a number of important issues with respect to the efficacy and safety of the new MeNZB vaccine, especially in babies and younger children. For example, the vaccine produces antibodies in only 75% of the infants, toddlers and children who receive it, which means that 1/4 of children who receive the vaccine will have no protection at all against the disease. Since there is only a 1.5 fold increase in antibodies in six to ten week olds, it is unlikely that this would constitute enhanced protection against the meningococcal bacterium anyway and no efficacy trials have been performed in children. As a comparison, the vaccine against meningococcal A and C is not effective at all in children under the age of 18 months old. Furthermore, even with the recommended three doses, six weeks apart, the duration of protection is not yet established and may last only a matter of months with booster shots possibly required after as little as six months.

Another important issue with the MeNZB vaccine is that it is totally ineffective against other strains of meningococcal disease (including strains A, C, 29-E, H, J, K, L, W135, X, Y and Z, as well as sub-strains of group B meningococcal disease). Many of these strains are more virulent and have higher death rates than the NZB strain and account for more than half of the cases of meningococcal disease in New Zealand. Thus, vaccination of children against the NZB strain could result in their parents exhibiting a dangerous level of complacency and could result in early symptoms of the disease being ignored. Therefore, it is still important to be vigilant for the signs and symptoms of meningococcal disease (see Fact Box #1), even if your child is vaccinated, as in its early stages the disease may resemble a case of influenza but can progress very rapidly within a few hours.

### Fact Box #1

*Meningitis signs and symptoms in babies and toddlers:*

- High temperature, fever, possibly with cold hands and feet
- Vomiting or refusing feeds
- High pitched moaning, whimpering cry
- Blank, staring expression
- Pale, blotchy complexion
- Baby may be floppy, may dislike being handled, be fretful
- Difficult to wake or lethargic
- The fontanelle may be tense or bulging

However, what is of even greater concern is the possibility that the meningococcal vaccine may actually increase the susceptibility of infants and young children to the disease. A study carried out on the related meningococcal C vaccine in Canada found that it increased the risk of the disease in under two year olds by nearly 400% and in two to five year olds by 75%. Whether this is also true for the New Zealand meningococcal B vaccine is as yet unknown because, as stated above, long term trials have not yet been carried out. In other words, the babies being vaccinated now are the ones who will determine, in the long run, whether or not the vaccine is effective or possibly even detrimental. Animal studies have shown that immunised animals can lose, as a result of being immunised, their own natural defence. According to the Immunisation Awareness Society (IAS), immunity against specific meningococcal bacteria can weaken immunity against all other strains, thus it is possible that the present vaccination campaign by the MoH may be making New Zealand children more vulnerable to other meningococcal bacteria.

The MeNZB vaccine also results in a high level of adverse reactions with 80% of recipients exhibiting a wide range of side effects following vaccination (see Fact Box #2). The ISMB report indicates nearly 400 cases of petechial/purpuric rash (a symptom of meningococcal disease), nearly 50 new cases of thrombocytopenia (bleeding disorder) and over 400 cases of seizure (including febrile seizures). The ISMB is disregarding all cases of Sudden Infant Death Syndrome (SIDS) following administration of the vaccine as being "unrelated". The IAS reports that, so far, there have been 12 deaths in previously healthy babies and children following vaccination and at least 16 cases of serious adverse reactions requiring hospitalisation (such as anaphylactic reactions, seizures, and a child admitted soon after being vaccinated with all the symptoms of meningitis). According to the IAS there have also been over 9000 adverse reactions severe enough to warrant visits to the doctor, including many children off school following their vaccinations. However, since symptoms such as fever, vomiting and diarrhoea can have causes other than the vaccine, they are often dismissed by doctors and vaccinators as being unrelated to the vaccine, and as a result, many cases of adverse reactions are not being reported. Furthermore, although the MeNZB vaccine does not contain the mercury preservative Thiomersal, it does contain aluminium, at a dose that exceeds the allowable limit for babies in their first six months of life, following the recommended three vaccinations. Aluminium is a toxic element which itself can cause a number of vaccine-related side effects and has also been implicated in a number of serious diseases and, as such, should really not be injected into our children.

#### **Fact Box #2**

*Side effects of NZ meningococcal B vaccine in children:*

- redness, pain or swelling at the injection site
- drowsiness, irritability and crying in infants and toddlers
- change in eating habits, diarrhoea, vomiting, fever
- older children may feel tired and not want to play
- headache, nausea, feeling unwell, muscle and joint pain
- convulsion linked to high fever ("very rarely")

There are a number of contraindications for administration of the vaccine, including pregnant and lactating women as there is no clinical data for them (see Fact Box #3). The vaccine also should not be administered to individuals with a fever or other acute illness; a number of individuals with pre-existing respiratory or ear infections have exhibited fever-related seizures within days of vaccination. Although vaccinators are supposed to ask parents about their child's personal history, family history and recent health status (eg, immunisation history, current health status and adverse reactions to previous vaccinations) and check up on the child following their vaccination for any adverse reactions, these are often not done due to the workload. Since babies and young children often have respiratory and/or ear infections, I presume that many are being overlooked and are being vaccinated anyway, thus adding another burden to their already compromised and overworked immune systems. It is well known that individuals with immune deficiency are more susceptible to infections and less likely to respond to vaccination. Since babies have undeveloped immune systems, this strongly suggests that they would not respond

to being vaccinated, and vaccination may actually do them more harm than good, especially if they are already sick.

### **Fact Box #3**

*Individuals who should not receive the MeNZB vaccine:*

- pregnant and lactating women (as there is no clinical data)
- anyone with an acute illness or fever on the day of vaccination
- anyone with a previous allergic reaction to the vaccine or component of the vaccine

*Individuals needing extra precaution when receiving the vaccine:*

- anyone who has had a serious allergic reaction (anaphylaxis)
- anyone who has had a serious medical condition

The MoH states that the MeNZB vaccine can be given at the same time as other childhood immunisations, even though there is no data on concomitant use with other vaccines. However, I feel that this is yet another example of overtaxing an immature and already overwhelmed immune system. It should also be noted that the childhood vaccinations themselves have been implicated in an increased incidence of glue ear, asthma and eczema. This highlights the importance of breastfeeding babies and toddlers as breast milk imparts a degree of natural immunity to young children in the form of antibodies and white blood cells and reduces the incidence of diarrhoea, chest and ear infections, glue ear and bacterial meningitis. Research has shown that breastfeeding for less than three months is associated with an increased risk of meningococcal disease. The World Health Organisation recommends that babies be exclusively breastfed for the first six months and continue being breastfed for two years. Unfortunately, in New Zealand only 20% of babies aged four to six months are exclusively breastfed.

Although meningococcal meningitis is a serious disease, only a very small percentage (0.007%) of New Zealanders get the disease each year and of those, less than 4% will die. According to a recent study, up to 45% of us carry the meningococcal B bacterium in our noses and throats not only without it causing us any harm, but we also develop a natural immunity. It is not known what it is about the very small number of people mentioned above that makes them vulnerable to the disease. There are a number of risk factors associated with the disease apart from general ill health due to poverty, overcrowding and poor living conditions (see Fact Box #4). These include exposure to tobacco smoke, which enhances adhesion and invasiveness of the bacterium in the nasal mucosa; iron anaemia, which enhances virulence of the bacterium by more than 1000 fold; and the use of analgesics, such as acetaminophen and paracetamol (eg, Pamol). It is important to note that fever is the body's natural response to bacterial and viral infections, *ie*, it helps the body to fight off the infection. Not only does giving your child Pamol to decrease the fever mask the symptoms, but it also stops the body doing what it is supposed to do. Therefore, if your child is breastfed and/or has a healthy diet (especially one rich in vitamin C) and he or she is not exposed to tobacco smoke or unnecessary medication, then their chances of getting the disease are probably not high enough to warrant vaccination.

### **Fact Box #4**

*Major risk factors for meningococcal meningitis:*

- exposure to tobacco smoke (passive smoking)
- lack of iron in the diet (iron anaemia)
- use of Acetaminophen and Paracetamol (eg, Pamol)

*Other risk factors:*

- poverty, overcrowding, poor living conditions
- influenza or acute respiratory disease

It is unfortunate that "scare tactics" are being used by the MoH and media to promote the use of the vaccine, including graphic photos of the "meningococcal poster child". Schools are promoting the vaccine to school-aged children without their parents being present and the children and their parents are being actively pursued if consent to vaccinate is not provided. The MoH obviously wants to ensure a high uptake (>90% of all New Zealanders under the age of 20)

in order to justify their spending 200 million taxpayer dollars on the vaccine. However, it should be noted that the epidemic was declining naturally before the vaccine program was begun, and deaths are at their lowest since 1991, when the epidemic began, and have declined by 75% since their peak in 2001. Furthermore, the current rate of four cases of meningococcal B per 100,000 is well below the World Health Organisation (and MoH!) threshold of 10 cases per 100,000 used to justify the introduction of a new vaccine. If the vaccine works, and I believe that the evidence presented above lends a great deal of doubt to not only its efficacy but also its safety, then it would prevent at most one or two deaths out of a total of 700 deaths per year from all causes in under 20 year olds. Overall, it has been described by some as "a mass vaccination experiment of 1.15 million New Zealand children with an untested and experimental vaccine".

## References

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## Biography

Anitra has a PhD in Clinical Biochemistry, ten years biomedical research experience both in New Zealand and the United States, and has published in numerous international peer-reviewed scientific journals. She has also had a long term interest in complementary and alternative medicines and therapies. Anitra has two healthy daughters (a 4 year old and 10 month old), both of whom were born at home and neither of whom have been medicated or vaccinated.