MeNZB™ Quick Guide

A quick guide to the MeNZB™ report
The Meningococcal Gold Rush

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http://www.scoop.co.nz/stories/HL0502/S00064.htm

The three questions all parents, health professionals and the media should be asking:

- **Is it necessary?**
- **Does it work?**
- **Is it safe?**

1. The general public and the New Zealand government have been told that New Zealand is caught in the grip of a unique meningococcal B epidemic, caused by a single strain of bacteria [MenBe].
2. This strain of meningococcal B is found in a number of countries and has been confirmed in only 48 percent of meningococcal cases in New Zealand.
3. Only 43 percent of meningococcal deaths in 2003 and 2004 were caused by the strain of bacteria targeted by the MeNZB™ vaccine. This is a 76% decline from peak levels in 2001.
4. The general public and the New Zealand government have been told that a one-off vaccine for our 'unique' or 'orphan' strain of meningococcal B bacteria was developed by Chiron Corp. Yet Chiron bought the rights to a vaccine developed in Norway by the Norwegian Institute of Public Health in 1999.
5. While Cabinet papers are partially censored, available data suggests that Chiron will receive about 140 million dollars.

6. The Norwegian Government did not use their meningococcal B vaccine nationally. Annette King said in parliament in Oct. 2004 that this was because the cost-benefit ratio did not stack up.
7. The Norwegians said the vaccine lacked efficacy. To date, the Norwegian vaccine has never been licensed.
8. Cabinet, the public and some health officials involved in the roll-out have been told that the MeNZB™ vaccine confers herd immunity. The MenBe researchers acknowledge that it does not.
9. The "independent" cost-benefit analysis presented to cabinet was conducted by senior meningococcal vaccine researchers and their colleagues at Auckland University.
10. These same researchers would be receiving several millions of dollars for conducting the NZ trials. The authors declared in the report to cabinet there were no conflicts of interest.
11. A more objective cost-benefit analysis by Treasury in 2001 noted that the cost to benefit ratio was seven times that normally used by Pharmac to approve funding of prescription drugs. This figure was before the natural decline in case-load [50 percent] and mortality [75 percent] had begun.
12. Cabinet approved this vaccine after being told by the MOH that without intervention there would be 20 deaths a year for the next 10 years, and this vaccine would avert 13.6 of those.
13. The figure of 20 deaths includes deaths from seven strains of meningococcus bacteria.
14. Less than half of meningococcal deaths can be attributed to the epidemic MenBe strain. The average death rate in the last three years has declined naturally by about 70 to 80 percent.
15. Based on 2003 and 2004 figures, if the vaccine proves effective then it could avert one or two deaths per year out of a total of 700 deaths for the 0 to 20 age group per annum.
16. Based on that cost-benefit, the government would be spending 100 billion in preventing the rest of the 700 from dying.
17. Deaths from MenBe are at their lowest levels since 1991 when the epidemic began.
18. Chiron would only sign the contract with the New Zealand government if it were able to manage the trials as well as supply the vaccine for the roll out and trials, a large conflict of interest.
19. An unlicensed meningococcal C vaccine produced by Chiron called "Menjugate" was used as the control or "placebo" during some of the trials. Chiron recently withdrew its US license application, despite completing expensive phase 3 clinical trials.
20. Phase 3 trials are the most definitive of all trials. They look at effectiveness and safety.
21. The Minister says that phase 3 trials are unnecessary as data from Norway can be used. Approval of MeNZB™ based on the Norwegian phase 3 trials is like approving Vioxx because it is similar to Celebrex. The danger of Vioxx was

revealed only after extensive phase 3 trials. Following completion of extensive phase 3 trials the Norwegian vaccine was not approved for mass use as the results didn't stack up.

22. The Minister's expert advisory committee expressed concern that there was no scientific evidence that the MeNZB™ vaccine would work.
23. The MeNZB™ adverse event monitoring system is conflicted. It is made up of handpicked pro-vaccine specialists. Two are colleagues of MenBe researchers.
24. The adverse event monitoring system used for the MeNZB™ vaccine collects data only on a pre-determined range of side-effects. This is not good pharmaco-vigilance and is not normal medical practice.
25. The MOH has been downloading school rolls in their entirety into their National Immunisation Register with all the children's ID information. Given that informed consent has not been sought or given this appears to constitute a form of unauthorized surveillance.
26. The Minister's expert advisory committee expressed written concern that the vaccine used in the trials was not the vaccine manufactured by Chiron, and now being injected into 1.15 million New Zealand children.
27. The Chiron manufactured MeNZB™ vaccine, made in their Italian plant, had only a handful of children involved in its trial, and the expert committee cited how the trial was incomplete and the evidence on efficacy was "far from compelling."
28. Is the MeNZB™ rollout in New Zealand a large uncontrolled experimental trial?
29. Medicines Assessment Advisory Committee (MAAC) the minister's statutory advisory experts were concerned at the fact that there was no evidence of efficacy for the vaccine.
30. Trials for 6-10 week babies revealed a 55percent antibody response. This has been communicated to GPs, but not to the public. The result has been described by the MenBe researchers privately as "disappointing" but to the public as exciting.
31. Annette King, the Minister of Health has not denied that 2 deaths of children occurred during the trials.
32. Since the Meningococcal Gold Rush report was written MOH documents reveal at least 10 previously healthy children have died following vaccination. (Read the Independent Safety Monitoring Board (ISMB) report below)
33. None of these deaths have been assessed using published MedSafe guidelines for pharmaco-vigilance classification. (1. see below)
34. Given that each of these deaths falls outside of the pre-determined range of side-effects, each has been assessed as having died from non-vaccine related matters.
35. In New Zealand only healthy children are eligible for vaccination. Therefore, using proper classification, 12 deaths (including the two during the trials) have occurred in previously healthy children. (read notes to reading the ISMB report, below)

36. There have been documented cases of anaphylaxis and Guillain-Barré syndrome that should have been classified as "certain". (Read: Notes to reading the ISMB report below)
37. There have been at least 16 serious adverse reactions requiring hospitalization.
38. There have been an estimated 9,706 adverse reactions severe enough to warrant going to a GP. This means that 1 in 16 children will have an adverse reaction severe enough to warrant being taken to a GP for medical assessment.
39. Despite the above, the MOH has stated that no safety issues have emerged during the MeNZB™ campaign.
40. In January five year old Kaytlen Marie Destiny Nisbett, who had been fully vaccinated with MeNZB™ died from meningococcal C. Her mother Donna Hutton was told there was no vaccine for meningococcal C. Meningococcal B immunisation programme director Jane O'Hallahan said in response to Kaytlen's death that scientists are years away from developing a vaccine against all strains of the disease.
41. There are two fully licensed meningococcal vaccines against meningococcal A, C, Y, and W-135 in New Zealand. (2. see below)
42. These strains cause about 50 percent of all meningococcal deaths in NZ. Whilst there are fewer cases percentage wise, these strains have much higher death rates than the MenBe strain.
43. Assuming the vaccines work - the Ministry of Health would appear to have deliberately prevented the public from choosing additional protection by not promoting the vaccines. Oddly it would appear that drug companies have not taken advantage of this opportunity to promote their products. Why?

(1) http://www.medsafe.govt.nz/Profs/adverse/causalitymarc.htm

(2) The vaccines are:
MENOMUNE™ ACWY
http://www.medsafe.govt.nz/Profs/Datasheet/m/MenomuneACYW135inj.htm
MENCEVAX ACWY
http://www.medsafe.govt.nz/Profs/Datasheet/m/Mencevaxacwyinj.htm
MENINGITEC® (Men C vaccine)
http://www.medsafe.govt.nz/Profs/Datasheet/m/Meningitecinj.htm

The Independent Safety Monitoring Board (ISMB) report:
http://www.immunise.moh.govt.nz/documents/surveillanceofadverseevents.pdf

Official adverse reaction classifications:
http://www.medsafe.govt.nz/Profs/adverse/causalitymarc.htm

Notes to reading the ISMB report:

- One anaphylaxis was attributed to MeNZB™:

Using Ministry of Health guidelines for classifying adverse reactions, should have been classified as certain

- One case of mild Guillain-Barré Syndrome, and was discharged within three days of admission. The ISMB said, "The temporal relationship between vaccination and symptoms onset does not mean the case was due to the vaccine:"

Using Ministry of Health guidelines for classifying adverse reactions, should have been classified as probable

- 373 petechial/purpuric rash cases were detected, but only five occurred within seven days following receipt of MeNZB™ and had no other cause attributed, e.g., a viral infection. The ISMB said, "This temporal relationship does not mean the cases were due to the vaccine:"

Using Ministry of Health guidelines for classifying adverse reactions, these five cases should have been classified as possible.

Note: the response has been limited to seven days. Why? How many other had petechial/purpuric rashes after seven days? Petechial/purpuric rash is a symptom of meningococcal disease. In the past, many of these would have been classified as meningococcal disease... now, anyone who has received the vaccine won't have that diagnosis... unless it becomes serious or tests as a men C or other type.

- 46 new cases of thrombocytopenia were detected, but only three occurred within 8 weeks following receipt of MeNZB and had no other cause attributed, e.g., a viral infection. The ISMB said, "This temporal relationship does not mean the cases were due to the vaccine*:"*

Using Ministry of Health guidelines for classifying adverse reactions, these 3 cases should have been classified as possible.

Note the extension of the delay to eight weeks. Why was this not done for other symptoms such as petechial/purpuric rashes?

- 428 cases of seizure detected, but only six were febrile seizures occurring within fours days following receipt of MeNZB™. However, five of these febrile cases clearly had concurrent infections, e.g., otitis media, and the sixth had a possible respiratory viral infection:

Using Ministry of Health guidelines for classifying adverse reactions, all six should have been classified as probable or at least possible.

Why has the delay been trimmed to four days? Would there have been too many at seven days? Otitis media is not necessarily an infection... more often than not it isn't. Regardless, these kids were supposed to have been screened as being healthy.

Note Regarding SIDS and ISMB:

The ISMB apparently discards all cases of SIDS following administration of the *MeNZB*™ vaccine because 'SIDS is unrelated to vaccine use.'

What if, for instance, MeNZB™ increases the risk of SIDS by 50 percent. If all cases of SIDS are discounted because SIDS is 'unrelated to vaccine use' how will we ever know?

Note regarding GP visits:

CARM reviewed 5,427 MeNZB™ vaccinations administered between 19 July and 12 September and found that 150 people returned to their general practitioner during a six-week period following vaccination with reactions that were judged to be possibly or probably related to vaccination.

Extrapolated to 351,177 doses of MeNZB™ administered to 155,612 children and young people in the Auckland region that equates to 9,706 possible or probable adverse events requiring a visit to the GP.

That is 1 in 36 vaccinations resulting in a GP visit. That means that 95,000 children can expect adverse reactions severe enough to warrant going to a GP at a cost of as much as $4.5 million to the government in subsidized medical costs.

To summarise:

1. **Is the MeNZB™ vaccine necessary?**
   - Cases of meningococcal disease caused by the strain of bacteria targeted by the MeNZB™ vaccine have declined by nearly 50 percent since peak levels in 2001.
   - Deaths due to meningococcal disease caused by the strain of bacteria targeted by the MeNZB™ vaccine have declined by nearly 75 percent since peak levels in 2001.
   - If it works, the MeNZB™ vaccine will prevent at most 1-2 deaths per year out of 700 deaths in under 20 year olds.
   - Most deaths are now caused by other strains of meningococcal bacteria for which licensed vaccines have been available for some time.
2. **Does the MeNZB™ vaccine work?**
   - "The Committee is concerned at the lack of efficacy data…" Minister's Expert advisory committee.
   - "The MeNZB™ vaccine will be rolled out without the efficacy data" Dr Jane O'Hallahan, MOH.
3. **Is the MeNZB™ vaccine safe?**

Actual: Following 351,177 doses of MeNZB™	**Expected: Following 3,450,000 doses of MeNZB™**
• 12 possible deaths	• 118 possible deaths
• 16 serious adverse reactions requiring hospitalisation	• 157 serious adverse reactions requiring hospitalisation
• 9,706 adverse reactions severe enough to warrant going to a GP.	• 95,000 adverse reactions severe enough to warrant going to a GP.

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- **Does it work?**
- **Is it safe?**

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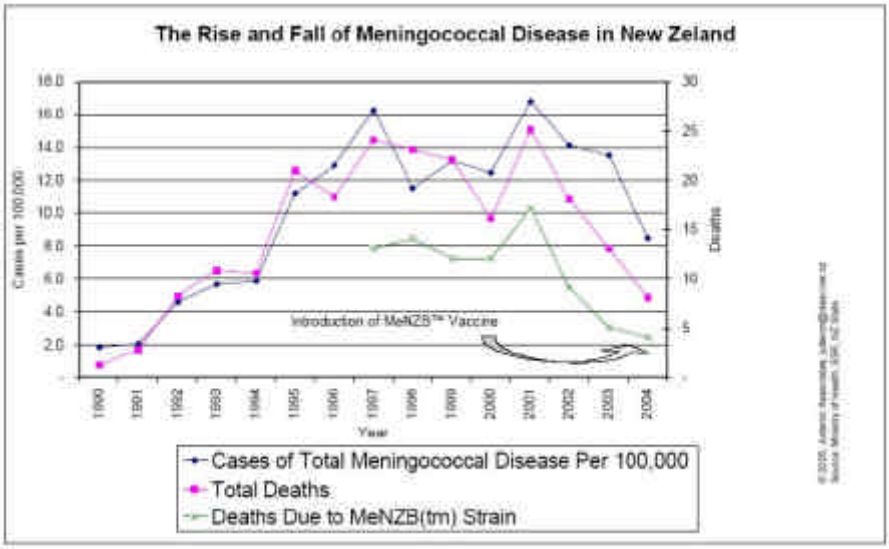

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Ron Law's career spans twenty years as a medical laboratory scientist,(including 10 years as a clinical biochemistry lecturer,) 5 years as a university business management lecturer, including research methodology, 4 years as executive director of a trade association, and more recently as an independent risk & policy analyst. Ron has a masters degree in international business studies. He was appointed by the Ministry of Health as a member of the expert group that advised the Director General of Health on the reporting and management of medical injury in New Zealand's healthcare system.