

An IMAC response to “*Investigate before you Vaccinate* by Sue Claridge”

Summary

This book is a collation of articles from the Immunisation Awareness Society, NZ newsletters compiled by Sue Claridge, a spokesperson for this organisation. The author claims to present the “other side” of immunisation to assist in the informed consent process. The author raises concerns about vaccine safety, government cover-up, conspiracy for profit, alleged silencing of vaccine critics within the medical profession and presents a variety of arguments to suggest vaccines are ineffective.

The Immunisation Advisory Centre (IMAC) seeks to provide a brief critique for readers of the book. IMAC agrees with the following points raised by the book:

- Breastfeeding, good nutrition, sanitation and hygiene have played and will continue to play an important role in preventing the spread of infectious diseases and in reducing mortality from them.
- Individuals and/or their caregivers have a right to accurate information to make an informed decision about whether or not to vaccinate. (However, IMAC believes this work actually hinders the process by espousing incorrect interpretations of the current evidence from orthodox medical literature).

False Claims

IMAC finds the following claims put forward in the book to be contrary to the overall conclusions of current evidence from orthodox medical literature (these are detailed briefly in later sections):

- Doctors who condemn vaccination are silenced.
- Smallpox vaccination didn't work.
- Vaccines overload the immune system.
- Vaccinations bypass parts of the immune system.
- Mass vaccination has played no role in the decline of morbidity and mortality from infectious diseases.
- Vaccines are contaminated with toxic chemicals and viruses.
- Vaccinations don't work and herd immunity is a myth.
- Vaccinations are unsafe.
- Pharmaceutical companies, the government and the medical profession conspire together for profit.
- Unvaccinated children are healthier.
- Homeopathic immunisation prevents illnesses.

Claridge recommends reading materials and websites from a number of Complementary and Alternative practitioners, as well as professionals trained in orthodox medicine who choose not to practice some aspects of conventional medicine, including vaccination. There are a number of common concerns raised by these groups which are concisely and thoroughly addressed in the New Zealand Immunisation Handbook 2006, ch20 “Vaccination questions and concerns”.

[http://www.moh.govt.nz/moh.nsf/pagesmh/4617/\\$File/2006-20questions.pdf](http://www.moh.govt.nz/moh.nsf/pagesmh/4617/$File/2006-20questions.pdf)

In summary, while the author presents some valid points in this book, IMAC is concerned about the misleading nature of many of the claims that, in our opinion, are not supported by the overall conclusions from the evidence presented by orthodox medical literature.

Throughout this article, links to personal accounts of vaccine-preventable diseases are also provided.

Breastfeeding

Breastfeeding is a well-established preventative intervention for providing infants with protection against a variety of infectious diseases including diarrhoeal illnesses, respiratory tract infections, otitis media, urinary tract infection, neonatal septicaemia and necrotizing enterocolitis (1). Breastfeeding may also provide passive immunity to vaccine preventable diseases such as *Haemophilus influenzae* type B(2) and measles(3). Factors in breast milk may enhance the immune response to both vaccination and natural infection. However, the immunity acquired by breastfeeding is a passive transfer of antibody (provided the mother has developed antibodies and they are secreted in the breast milk) that demonstrates a tendency to decay more rapidly relative to the active immune response created by natural infection or a primary course of infant immunisation(4).

Informed consent

IMAC agrees with Claridge that the decision to vaccinate should be a decision based on informed consent as consistent with the Health and Disability Commissioner's Code of Rights(5). Informed choice, however, can only be made on the basis of accurate information. For the reasons outlined below and in subsequent sections, "Investigate before you Vaccinate" does not provide a consumer with accurate information and therefore hinders the informed consent process.

It is important to note that one study or observation does not prove anything in itself, but adds to the overall body of evidence, much as one tree adds to a forest. An examination of the overall body of evidence is required to ascertain an accurate view of current medical understandings. For example, a few studies suggested vaccination might be associated with asthma. However, a number of other large studies, including a review and a large cohort study found no evidence of a link. Chance and methodological problems with these few studies may allow for a link that was not there. When one looks at the evidence as a whole it doesn't support a link between asthma and vaccination(4). If we then say that vaccination causes asthma, this is not a true representation of the overall conclusions of the evidence available from the medical literature, and therefore does not help a patient or caregivers make an informed decision.

Vaccination critics

Claridge complains that "the standard response to any criticism of vaccination is to silence the dissenters."

Many scientists are employed in academic positions, and an important part of their responsibilities is to examine and critique the validity and accuracy of research findings. A recent example of appropriate scientific research leading to action is that of the withdrawal of a rotavirus vaccine. When the flag was raised by doctors and researchers showing a potential problem with the vaccine it was promptly withdrawn from the market (6). There are many examples of funded studies questioning the safety of vaccines being published and also a significant amount of active research in the area.

Smallpox vaccination

Claridge argues that “Jenner was faced with clear evidence that vaccinated people still contracted smallpox despite having been vaccinated” to imply that efforts to eradicate smallpox by vaccination did not work.

The actual facts are not as simplistic. The vaccine did induce immunity in most subjects, although this persisted for only 5-10 years. A number of countries were therefore required to use a ring re-vaccination strategy to contain smallpox and prevent its re-establishment in the community. Notably, however, ring vaccination only was used in parts of Africa and yet the disease was still eliminated. It is also widely accepted that there were a number of severe adverse reactions related to smallpox vaccination, but in the context of the time, the risks of smallpox outweighed the risks of vaccination(7).

Contrary to the author’s claims, historical and medical data attest to the effectiveness of vaccination in the elimination of smallpox.

Vaccines and the Immune System

According to Claridge, “there has been concern that vaccines overload the immune system.” There is no evidence to support this claim. Vaccines do not “overload” the immune system, which is very capable of responding to a great many foreign organisms all at once, many times more than are found in vaccines(8,9). From the moment you are born you are exposed to thousands of organisms, and continue to be exposed on a daily basis. Vaccines are used for only a few potentially severe organisms.

Conventional vaccines are not responsible for “skewing” the immune system by “suppressing” the cellular arm of the immune system. It is important to remember that a specific immune response (its qualitative and quantitative profile) is generated against a particular challenge (hence specific). Conventional viral vaccines do not suppress the cellular arm of the immune system(10). This is further supported by a study using MMR vaccine which found Interferon-gamma was the principal cytokine produced after primary measles immunisation, suggesting primary measles immunisation induces predominantly a TH1 (cellular) type response(11).

It is interesting to note also, that although more vaccines have been added to the NZ immunisation schedule, technological changes have actually reduced the total number of antigens an individual is exposed to by vaccination(12).

Vaccinations bypass the immune system.

The author believes that “vaccination ignores thousands of years of evolutionary wisdom and does what nature would never allow - provides viruses and bacteria...with direct access to the bloodstream.” Firstly, the content of the vaccine is delivered to the skin (intra-dermal or subcutaneous), muscle (intramuscular) or gut(oral). Secondly, the immune system is quite capable of dealing with intruders wherever they occur(12). For example, an attenuated measles vaccine is injected into the skin, yet produces a response that protects an individual from natural infection via the airways(4). Vaccines produce an immune response using the same chemical pathways as natural infection, even if the response is not as broad as natural infection(13).

Vaccination and its role in preventing infectious disease.

IMAC agrees with Claridge that environmental and host factors (nutrition, hygiene, sanitation, socioeconomic disparities), etc., will affect the individual's response to infection.

Evidence from orthodox medical literature would agree that there are a number of host and environmental factors that influence infectious disease mortality and morbidity. For example, changes in standard of living, including provision of sewerage, limits the spread of infections via the faecal-oral route, for example, rates of childhood exposure to hepatitis A virus are lower in countries with developed economies than in countries with developing economies, as can be demonstrated by the epidemiologic changes in parts of Brazil as hygiene improved(14). (Ironically, vaccination against hepatitis A may now be more "necessary" since a greater proportion of the adult population will not have been infected with hepatitis A during childhood and are therefore at increased risk of fulminant liver disease if they contract hepatitis A as an adult..)

Adequate nutrition is important in the reduction of morbidity and mortality due to infection, for example vitamin A deficiency and measles. The Australian College of Paediatrics also supports the use of vitamin A supplementation in New Zealand and Australian infants hospitalized with measles when there is pre-existing marginal nutrition or vitamin A deficiency in the patient or their community, as well as for older patients with certain medical conditions(15). Deficiencies of micronutrients, including selenium and vitamin C, may predispose to infection. What the authors neglect to mention is that the current evidence demonstrates alteration of immune system parameters due to micronutrient deficiency for the most part *in the context of protein-energy malnutrition* (16,17). It would be difficult from current evidence to generalise this to individuals within countries with developed economies such as New Zealand, where protein-energy malnutrition is rare.

Changes in the standard of living have undoubtedly reduced the incidence of, and complications from, infectious diseases, but it would be difficult to conclude from current evidence that these improvements alone are responsible for the dramatic reduction in infectious disease rates. Despite the relatively well-developed infrastructure in New Zealand (housing, sewerage, etc.) measles has not been eliminated and epidemics still regularly occur(4). Mathematical modeling from a mass immunisation campaign in New Zealand suggests that mass vaccination prevented 90-95% of cases during the last measles epidemic(4).

It is clear, therefore, that a number of factors affect immune response to infectious organisms and can have marked effects on infectious disease morbidity and mortality. Therefore orthodox medical opinion would support the use of socio-environmental and lifestyle modification for the prevention and control of infectious diseases. It must be noted, however, that the above phenomena are risk rather than causative factors for infectious disease, and that strategies to address the above factors are highly unlikely in themselves to provide individuals with specific immunity to certain infectious agents or prevent the circulation of an organism within a community. Vaccination has the potential, and in some cases has demonstrated the ability, to offer both.

Vaccinations, contamination and vaccine components.

Claridge argues that components in vaccines include compounds that cause vCJD, SV40 virus, and an avian retrovirus. She also argues for the toxicity of vaccine components such as thiomersal, aluminium, formaldehyde and 2-phenoxyethanol.

According to the author, foetal calf serum used in cell cultures to develop vaccines predisposes to the development of vCJD (mad cow disease). For vaccines that use material from cows as part of the production process, the manufacturer must satisfy licensing authorities that it is using material from a BSE(Bovine Spongiform Encephalopathy)-free area(4). Also, if vaccines caused vCJD, we would expect cases to be distributed worldwide, reflecting vaccination distribution. Instead, vCJD cases are almost entirely restricted to the UK(18).

The author also suggests that vaccines are contaminated with harmful viruses, including SV40 virus. Some polio vaccine batches in the 1950's and 1960's may have been contaminated by SV40 virus. Since 1963, manufacturing processes have eliminated this virus as a contaminant(4). Long-term follow-up of a vaccinated cohort exposed to SV40 virus has not demonstrated an increased rate of cancer(19). The reverse transcriptase enzyme that allegedly came from an avian virus was subsequently found to be from the chick cells the vaccine virus was grown on(20).

The safety of both thiomersal and aluminium has been examined and established:

- Aluminium levels in vaccination do not exceed currently accepted safe levels in humans. Humans absorb more aluminium from the food chain than vaccination. The aluminium from vaccines appears to be excreted soon after vaccination(21).
- Thiomersal - a previous IMAC publication thoroughly addresses the safety of thiomersal (no longer used in childhood vaccinations in New Zealand). This document can be downloaded at <http://www.immune.org.nz/?t=721> .

Claridge also raises concerns about vaccine residues and preservatives. 2-phenoxyethanol is used to preserve some vaccines. There is no evidence to suggest that it poses a risk to children. It is also commonly used in cosmetics, baby care products, eye and eardrops and aromatherapy products to protect against contamination. Formaldehyde is used in the manufacturing process of some vaccines. It is not part of vaccine contents, however there may be traces remaining in the final product at a level of 27 parts per million(13).

Vaccine effectiveness and herd immunity

According to Claridge, "there are numerous studies which have established that outbreaks of disease have occurred in highly vaccinated populations worldwide." She then chooses pertussis as an example.

Using the example of the acellular pertussis vaccine some simple arithmetic will demonstrate the presence of a relationship between vaccine effectiveness, immunisation coverage and infection. Taking the pertussis vaccination as an example and using an effectiveness figure of 85% for convenience (the actual figure for the vaccine used in New Zealand is 84% after completion of the 3-dose primary series(22)), imagine a group of 100 children. If 60% of children are given a pertussis vaccine that is 85% effective, then:

- 51 of the 100 children will be immune (60 x 85%)

- 49 will be non-immune
 - 40 who are not vaccinated
 - 9 because of vaccine failure

Therefore 18% (9 out of 49) cases of pertussis could conceivably occur in fully vaccinated children. If the proportion of vaccinated children is changed to 90%, then:

- 76 of the 100 children will be immune (90 x 85%)
- 24 will be non-immune
 - 10 who are not vaccinated
 - 14 because of vaccine failure

Now, 58% (14/24) cases of pertussis could conceivably occur in fully vaccinated children. More of the population as a whole is immune to pertussis in the scenario with higher vaccination coverage, even though most cases occur in the vaccinated group. The logical conclusion that can be drawn from this analysis is not that pertussis vaccination does not work, but that as vaccination rates increase a greater proportion of cases are seen in those fully vaccinated.

Again, Claridge uses similar arguments concerning measles vaccination. It is interesting to note that in New Zealand, mass vaccination against measles has:

- increased the time interval between epidemics(23) and, if immunisation coverage is high enough, mathematical modeling suggests epidemics would not be triggered in the first place(24)
- been shown to reduce the last epidemic that occurred in New Zealand in 1997(25)

It must also be noted that US data finds that secondary vaccine failure for the MMR vaccine used in New Zealand (correctly administered) is rare, if it exists at all(26).

The concept of herd immunity is also unfairly attacked as a “medical unicorn”. It can be demonstrated, however, that the herd immunity phenomenon existed and was responsible for the eradication of smallpox, and is theoretically possible for measles if sufficient vaccination rates can be maintained(26).

On the basis of current evidence, however, the author is correct in stating that mass BCG vaccination is not tenable in New Zealand. This is no longer practiced in New Zealand. A case can be made for selective BCG immunisation under some circumstances(27,28).

Concerning Hepatitis B vaccination, the author claims “the rationale for vaccinating babies against hepatitis B is their accessibility” and implies that most New Zealand children are not at risk of hepatitis B – it is only the lifestyle practices of some adults and adolescents that puts them at risk. A quick overview of the characteristics of hepatitis B and the vaccine demonstrates a quite different rationale for the current practices of hepatitis B vaccination in New Zealand.

Hepatitis B virus can be transmitted vertically (mother to neonate), or horizontally (person-to-person) through contact with infected body fluids (blood, semen, vaginal fluid, etc.). Three major patterns of infection are seen in Asia and the Western Pacific: vertical transmission at birth, infection acquired in childhood, or adolescent and adult transmission due to lifestyle practices(27). In the pre-vaccination era, transmission occurred commonly among school-aged children in New Zealand, although the exact mechanisms are unclear(4). It has been demonstrated that

desiccated hepatitis B-infected blood can remain infectious for a week(28). Hepatitis B infections acquired in infancy and childhood have an increased risk of developing a chronic carrier state that is a major risk factor for cirrhosis and hepatocellular carcinoma(29). Hepatitis B is an independent risk factor for cirrhosis and hepatocellular carcinoma. The effects of alcohol are additive, but not necessary, for the development of hepatocellular carcinoma(30).

The rationale for the practice of hepatitis B vaccination in New Zealand, therefore, is to reduce the risk of:

- Vertical transmission of the virus at birth from carrier mothers
- Horizontal transmission among children (particularly those of school age)
- Horizontal transmission among adolescents and adults due to lifestyle and occupational practices
- Prevention of spread from carriers to their household and sexual contacts

The Hepatitis B screening programme, aimed to find cases of carriers (to whom the vaccination is of no use and in whom vaccinating creates a false sense of security), treat those infected and reduce the risk of their close contacts acquiring hepatitis B infection(31).

Examination of efficacy data on hepatitis B vaccination demonstrates that a primary course of vaccination when administered with hepatitis B immunoglobulin in neonates provides 80-97% protection against infection(32), and protective antibody levels are reached in 95% in New Zealand children, although vaccine response is lower in adulthood (approximately 70% in adults over 40 years). There is also some evidence for achieving a response in persistent non-responders through booster vaccinations, repeat primary courses or different methods of vaccine administration(33-35).

From this brief survey of the epidemiology of hepatitis B and the efficacy of the hepatitis B vaccine, the rationale behind the current strategy of universal infant immunisation and birth doses for infants of carrier mothers as well as selective immunisation of at risk groups, becomes evident as the optimal strategy in achieving control of hepatitis B in New Zealand.

Vaccine Safety

A number of claims are advanced by the authors including a presentation of VAERS (the American Vaccine Adverse Event Reporting System) data that is interpreted to mean that there have been 1936 deaths from vaccines, claims that vaccine reactions are under-reported and then specific concerns about DTP, MMR, hepatitis B, polio and Hib vaccines. These are addressed below.

VAERS and other passive surveillance data.

As well as taking into consideration trial data both during vaccine development and after licensure and use, there are processes in New Zealand (and many countries overseas) for the reporting and investigation of adverse events following immunisation(4). An adverse event following an immunisation may be related to the vaccine or co-incidental. For example, a fever that develops after immunisation may be a reaction to the vaccine or a consequence of a viral illness acquired around the

time of vaccination. For an event to be associated with vaccination, there must be a statistically significant increase in rates of the event in a vaccinated population compared to a comparable unvaccinated population.

The VAERS data presents a record of adverse EVENTS that occur after a vaccination (as discussed above, these may or may not be related to the vaccine). This data can then be assessed against the background rates of events in the population to see if the events are occurring at an increased rate due to vaccination. In addition, New Zealand has also used active surveillance systems when introducing new vaccinations. In this situation, all hospitalizations in the relevant age group are assessed for vaccination status and then cases are investigated to determine if there is any evidence for a link between the person's condition and the vaccination. This method of active surveillance was used as a further confirmation of MeNZB™ vaccination safety in New Zealand(36).

“Only a fraction of adverse events are reported to passive surveillance systems”

Usual, expected mild reactions are generally not reported, and yes, it is possible that a few adverse events that may be related to immunisation are not reported, perhaps because of a failure to link the event to vaccination. It is important to note, however, that vaccine risks are estimated by a variety of sources, including controlled trials prior to licensure, and post-marketing surveillance both in New Zealand and overseas.

All vaccines used in New Zealand are considered medicines and must satisfy Medsafe, the regulatory authority in the following areas to obtain and maintain a license(37):

- assessing the safety, quality and efficacy of medicines before they are marketed
- auditing manufacturers, packers and wholesalers of medicines to ensure their premises and practices meet an acceptable standard
- monitoring the safety of medicines on the market

Any person who is concerned that an adverse event may be related to a vaccination is welcome to file a notification with CARM (Centre for Adverse Reactions Monitoring).

It is important to note that the ACC is a no-fault compensation programme. A successful claim does not necessarily attribute cause of the problem to the vaccine. Similar programmes exist overseas. The USA has introduced a no fault compensation because of the litigious risk to vaccination manufacturers in the US (October 1st 1988), many of whom were going out of business, leading to a potential crisis in vaccine supply(38). Many pharmaceutical companies are choosing not to continue making vaccines due to the financial risks involved and potential for considerable loss(39). The increasing cost of vaccine development and production, mergers of manufacturers and relatively low revenues from vaccine sales compared with other pharmaceutical products such as lipid lowering drugs, may have contributed to the reduction in vaccine manufacturers in the past 25 years(39).

Pertussis Vaccination

In this section, according to Claridge, “Sudden Infant Death Syndrome (SIDS) is one of the most common, but unfortunately little recognized, outcomes of vaccination.” Evidence from orthodox medical literature continues to exonerate pertussis vaccination(40). A New Zealand study even suggests that immunisation may protect against SIDS(41).

The relationship of pertussis vaccination to brain damage is somewhat more controversial. An independent review of a large British study found that the evidence suggests an association between whole cell pertussis vaccination and acute encephalopathy. The reviewers noted that there was evidence showing that some children in the original British study who had suffered acute encephalopathy were found to have long-term neurological consequences whether they were from the vaccinated or unvaccinated group. The reviewers therefore concluded that the evidence may be consistent with a link between whole cell pertussis vaccination and chronic nervous system dysfunction “described by the [British study] in those children who experience a serious acute neurological illness within 7 days of DPT vaccination”(42). The NZ immunisation handbook(4), summarises the arguments against a link as understood by the current medical evidence, namely:

- Brain damage and forms of developmental delay become apparent in the first 1-2 years of life – the same time immunizations are scheduled
- No specific type of brain damage has been linked to whole cell pertussis vaccination
- Studies are cited which find no association with neurological illness
- Studies on acellular pertussis vaccination (now the only forms licensed in New Zealand) show no association with neurological illness

New Zealand data for infants under 1 year of age during the last epidemic suggests a disease rate of 327.5 per 100,000(4). Approximately 5% or 5000 per 100,000 of infants develop encephalopathy from the disease(43). Therefore, leaving it to chance alone, there is a 16 in 100,000 chance (5% x 327.5 per 100,000) of acquiring encephalopathy due to pertussis infection. The rate of acute encephalopathy from whole cell pertussis vaccination is at most 0.9 per 100,000 and for permanent brain damage 0.32 per 100,000(4). Acellular pertussis vaccination is not associated with permanent brain damage. Even when the data for whole cell pertussis vaccination is used, careful examination shows it is much “safer” (in terms of statistical probability) to vaccinate infants against pertussis rather than leave things to chance.

Hypotonic Hyporesponsive Episodes are quite rare and follow-up studies do not indicate an increased rate of long-term consequences(44), even in patients who receive further pertussis-containing vaccinations(45).

Pertussis – Anna’s story: <http://www.immune.org.nz/?t=696>

MMR

Claridge cites a US study that she says “showed a causal relationship between measles vaccination and encephalopathy. This study indicates a statistically significant association between encephalopathy and MMR vaccination at 8-9 days. There were 48 cases out of an estimated 75 million MMR doses, giving a rate of <1 per million doses(46). However, a recent US study failed to find a relationship between MMR and encephalopathy(47). If such a relationship exists, this compares quite favourably to a rate of encephalopathy of 1 per 1000 or (1000 per million) in natural measles infection(48). The link between MMR and autistic spectrum

disorders has been widely disproved(49,50), and there is no link between MMR and Guillain-Barre Syndrome (GBS)(51). Contrary to the author's claims, the balance of evidence does not support an association between rubella vaccination and chronic arthritis(52), although arthralgia (joint pain) is a recognized, uncommon side effect of vaccination. The rate of aseptic meningitis from the mumps component of the MMR vaccine currently licensed in New Zealand is much lower than that of natural mumps infection(4). Claridge rightly points out that MMR vaccination can cause thrombocytopaenia. This, however, can be treated(4).

Measles – Fofou Susana's Story: <http://www.immune.org.nz/?t=699>

Mumps – John's Story: <http://www.immune.org.nz/?t=700>

Rubella – Beth's Story: <http://www.immune.org.nz/?t=701>

Polio vaccination

The paper used by Claridge to provide support for her argument that the change from oral polio vaccine (OPV) to inactivated polio vaccination (IPV) increased fatality rates merely suggested a possible association. As the study authors rightly point out "One of the major difficulties in interpreting VAERS data are that when vaccines are co-administered, as is common with pediatric vaccines, it is often impossible to disentangle their separate and joint effects". A common phenomenon is a higher rate of reports after a change in immunisation policy, which perhaps is reflected in the increased reporting rate of serious and fatal IPV reports in 1998. To encourage reporting of any possibly vaccine-induced adverse event, VAERS solicits reports from health professionals, vaccine manufacturers, patients, and parents. VAERS includes any report submitted, no matter how tenuous the connection with vaccination might seem. Many adverse events reported are only coincidentally associated with vaccination because childhood vaccines are administered to nearly all infants(53). Current evidence does not indicate safety concerns with combination vaccines including IPV as a component(54).

Polio: Sheryl's Story: <http://www.immune.org.nz/?t=705>

Hepatitis B vaccination

Claridge alleges that hepatitis B vaccination has left a "trail of destruction", in spite of evidence from orthodox medicine. Hepatitis B vaccination has not been linked to MS(55), chronic fatigue syndrome(56), diabetes(57), and suicide, AIDS, RSV or GBS (58). Rarely, hepatitis B vaccination may cause thrombocytopaenia which can be treated with corticosteroids and does not pre-dispose to thrombocytopaenia from other vaccinations(59). There are some case reports of a temporal relationship between hepatitis B vaccination and arthralgia, but a causal relationship between the two is not proven(60). Current evidence therefore supports the safety of hepatitis B vaccination.

Hepatitis B – Jennifer's Story: <http://www.immune.org.nz/?t=697>

Hib Vaccination

The study put forward by Claridge to claim that Hib vaccination is related to GBS(61) actually reports on one case where the vaccinee developed GBS after Hib

vaccination. The authors are merely putting forward an hypothesis. A large observational study failed to find any safety concerns with the Hib vaccine currently licensed in New Zealand(62).

Haemophilus influenzae type b – Mark’s story: <http://www.immune.org.nz/?t=698>

Vaccination, the vaccine industry and the medical profession

“The vaccine industry earns billions of dollars annually. In New Zealand alone, millions of dollars are spent each year on purchasing early childhood vaccinations and administering them,” states Claridge. Pharmac has been successful in minimizing the costs of drugs, including vaccines and in reducing the rate of increase of expenditure to sustainable levels. Of an annual budget of \$500 million, the annual figure of \$6.3 million is a very small proportion(63). There is also some need for GPs and nurses to cover the costs of administering vaccinations, hence the use of government subsidies. The Ministry of Health rightly points out that there is “a shared interest between commerce (selling vaccines) and public health (preventing illness)”(4).

The Health of Vaccinated vs. Unvaccinated Children.

This is already thoroughly covered in an IMAC critique of an IAS pamphlet (the organization that the author is a spokeswoman for). Relevant excerpts are given below (the full document is available at:
http://www.immune.org.nz/site_resources/Professionals/IAS_critique_2003.pdf)

“The evidence supplied suggesting that unvaccinated children have fewer health problems than vaccinated children is just plain silly. A survey conducted in the manner described has so much potential for bias that the results can only be described as nonsense. The survey by Mike Godfrey invited readers of Healthy Options magazine (unlikely to be a representative sample of the New Zealand population) to send in a completed survey asking parents if their children had been vaccinated and whether they suffered from a number of health problems. This is used as a teaching example to undergraduate medical students of how not to conduct meaningful research. Mike Godfrey has never published any research on vaccination in a peer-reviewed forum. A survey such as this would not meet the strict criterion for proper unbiased research.

“There have been a number of properly designed, more rigorous studies carried out to investigate whether vaccination predisposes to more health problems. These studies use validated research methods and have been published in respected peer reviewed medical journals.”

Neurological disorders: Vaccination has been repeatedly exonerated as a risk factor for neurological disorders such as epilepsy, autism and developmental delay(64-66). One of the most serious sequelae from vaccine preventable diseases is brain damage, therefore the prevention of the diseases obviously results in fewer intellectually disabled people. For example, following a comprehensive vaccination campaign in Finland against Measles Mumps and Rubella, the most common form of encephalitis (caused by mumps virus) disappeared from the country(67). There is a rare association between the MMR vaccine and encephalitis at around 1/1,000,000.

Asthma: There is no association between vaccination and allergy including asthma(68-71). Some studies have demonstrated a slight protective effect(68).

Ear infections: Ear infections (otitis media) are caused by bacterial and viral organisms. These include streptococcal, pneumococcal and Haemophilus influenzae

b, viruses such as the respiratory syncytial virus and influenza. Vaccines against these agents can reduce the incidence of ear infections. Immunisation against influenza protects against some ear infections. New vaccines are under development which will act against more of the organisms that contribute to ear infections and have the potential to further reduce the problem(73-79).

Tonsillitis: While there is no present anti-tonsillitis vaccine, vaccines have the potential to be developed that could protect against this problem(80).

Apnoea: Vaccination decreases the incidence of apnoea (stopping breathing) in infants. As this condition is often caused by pertussis (whooping cough) this finding is not surprising. Monitoring babies following immunisation shows no increase in apnoea(81, 82). However very preterm babies may be at risk of increased apnoea following vaccination.

Diabetes: Reviews of the evidence have concluded that vaccination is not a risk factor for diabetes(83,84).

Homeopathic immunisation

Claridge's recommendation of homeopathic immunisation is in direct contradiction to the recommendations of the UK Faculty of Homeopathy(85), and the dearth of evidence from orthodox medical literature(86). Homeopathic immunisation or homeoprophylaxis therefore cannot be recommended as a viable alternative to conventional immunisation on the basis of current medical evidence.

Conclusion

This work by Sue Claridge raises some valid points about breast-feeding. However, it contains a number of misleading interpretations of the evidence as it currently stands in orthodox medical literature. Sadly, this work falls short of the author's aim to assist in the informed consent process. IMAC is therefore concerned about the misconceptions that could be propagated by the opinions presented in this book.

References

- Claridge S. 2003 Investigate before you vaccinate. *The Immunisation Awareness Society*, Auckland, New Zealand
1. Hanson, L., Breastfeeding provides passive and likely long-lasting active immunity. *Ann Allergy Asthma Immunol.* 1998; 81:523-537.
 2. Silfverdal, S., Bodin, L., Ulanova, M., Hahn-Zoric, M., Hanson, L., Olcen, P., Expression of idiotypic antibodies -1 and -2 and breastfeeding in relation to antibodies against *Haemophilus influenzae* type b in children. *Scandinavian Journal of Immunology.* 2006; 63:371-375.
 3. Oyedele, O., Odemuyiwa, S., Ammerlaan., W, Muller, C., Adu., F., Passive immunity to measles in the breastmilk and cord blood of some Nigerian subjects. *Journal of Tropical Pediatrics.* 2005; 51(1): 45-48.
 4. Ministry of Health, 2006. NZ Immunisation handbook 2006. *Ministry of Health*, Wellington, New Zealand.
 5. Health And Disability Commissioner, The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996, Rights of Consumer and Duties of Provider
<http://www.hdc.org.nz/theact/theact-the-codeclause2> Retrieved 21 December, 2006.
 6. Anonymous. Intussusception among recipients of rotavirus vaccine--United States, 1998-1999. *MMWR - Morbidity & Mortality Weekly Report* 1999;48(27):577-81
 7. Belongia, E., Naleway, A., Smallpox vaccination: the good the bad and the ugly. *Clinical Medicine and Research.* 2003; 1(2):87-92,
 8. Institute of Medicine. Immunization Safety Review: Multiple Immunizations and Immune Dysfunction. Washington: National Academy Press, 2002.
 9. Martinez X, Brandt C, Saddallah F, Tougne C, Barrios C, Wild F, et al. DNA immunization circumvents deficient induction of T helper type 1 and cytotoxic T lymphocyte responses in neonates and during early life. *Proceedings of the National Academy of Sciences of the United States of America.* 1997; 94(16):8726-31.
 10. Henderson DA. The eradication of smallpox. *Sci Am*1976;235:25-33.
 11. Pabst HF, Spady DW, Carson MM, Stelfox HT, Beeler JA, Krezolek MP. Kinetics of immunologic responses after primary MMR vaccination. *Vaccine.* 1997;15(1):10- 14.
 12. Roitt, I., Brostoff, J., Male, D., 2001., *Immunology.* 6th Ed. Mosby. Edinburgh.
 13. Plotkin, S., Orenstein, W., 2004. *Vaccines.* 4th Ed. Saunders. Pennsylvania.
 14. Vitral, L., Gaspar, A., Souto, F., Epidemiological pattern and mortality rates for hepatitis A in Brazil, 1980-2002 – A review. *Mem Inst Oswaldo Cruz, Rio De Janeiro.* 2006;101(2): 119-127.
 15. Australian College of Paediatrics. Policy statement: vitamin A supplementation in measles. *Journal of Paediatrics and Child Health.* 1996; 32:209-210. cited in *NZ Immunisation Handbook, 2006; Ministry of Health, Wellington, NZ p221.*
 16. Bhaskaram, P., Micronutrient malnutrition, infection and immunity: an overview. *Nutrition Reviews.* 2002; 60(5):S40-S45.
 17. Cunningham-Rundles, S., McNeely, D., Moon, A., Mechanisms of nutrient modulation of the immune response. *J Allergy Clin Immunol.* 2005; 115:1119-1128.
 18. Minor, P., Will, R., Sailsbury, D., Vaccines and variant CJD. *Vaccine.* 2001; 19:409-410.
 19. Strickler, H., Rosenberg, P., Devesa, S., Hertel, J., Fraumeni, J., Goedert, J., Contamination of poliovirus vaccines with simian virus 40 (1955-1963) and subsequent cancer rates. *JAMA.* 1998; 297(4):292-295.
 20. WHO, Reverse transcriptase activity in chicken-cell derived vaccine. *Weekly Epidemiological Record.* 1998; 73(28):209-212.
 21. Lindblad, E., Aluminium adjuvants – in retrospect and prospect. *Vaccine.* 2004; 22:3658-3668.
 22. Salmaso, S., Mastrantonio, P., Tozzi, A., Stefanelli, P., Anemona, A., degli Atti, M., Giammanco, A., Sustained efficacy during the first 6 years of life of 3-component acellular pertussis vaccines administered in infancy: the Italian experience. *Pediatrics.* 108(5):e81.
 23. Tobias, M., Christie, S., Mansoor, O., Predicting the next measles epidemic. *NZ Public Health Report.* 1997; 4(1):1-3.
 24. Roberts, M., 2004. A mathematical model for measles vaccination. Internal report to the Ministry of Health. cited in *NZ Immunisation Handbook, 2006; Ministry of Health, Wellington, NZ p210.*
 25. Mansoor, O., Blakely, T., Baker, M., Tobias, M., Bloomfield A., A measles epidemic controlled by immunisation. *NZ Public Health Report.* 1997. Ministry of Health, Wellington, New Zealand.
 26. Fine, P., Herd immunity: history, theory, practice. *Epidemiologic Reviews.* 1993; 15(2): 265-302.
 27. Colditz, G., Berkey, C., Mosteller, F., Brewer, T., Wilson, M., Burdick, E., Fineberg, H., The efficacy of Bacillus Calmette-Guerin vaccination of newborns and infants in the prevention of tuberculosis: a meta-analysis of the published literature. *Pediatrics.* 1995; 96(1):29-35.

28. Fine, P., Primary prevention of leprosy. *International Journal of Leprosy and Other Mycobacterial Illnesses*. 1996; 64(4):S44-S49.
29. Gust, I., Epidemiology of hepatitis B infection in the Western Pacific and South East Asia. *Gut*. 1996; 38(Suppl2):S18-S23.
30. Bond, W., Favero, M., Petersen, N., Gravelle, C., Ebert, J., Maynard, J., Survival of hepatitis B virus after drying and storage for one week. *Lancet*. 1981:550-551.
31. Tovo, P.-A., Lazier, L., Versace, A., Hepatitis B virus and hepatitis C virus infections in children. *Curr Opin Infect Dis*. 2005; 18:261-266.
32. Kremsdorf, D., Sussan, P., Patalini-Brechot, P., Brechot, C., Hepatitis B virus-related hepatocellular carcinoma: paradigms for viral-related human carcinogenesis. *Oncogene*. 2006; 25:3823-3833.
33. Ministry of Health, Report 5.4 The surveillance phase of the national hepatitis B carrier screening and surveillance programme. Ministerial Review of Targeted Policies and Programmes, 2005., Ministry of Health, Wellington, New Zealand.
34. Wong, V., Ip, H., Reesink, H., Lelie, P., Reerink-Brongers, E., Yeung, C., Ma, H., Prevention of the HBsAg carrier state in newborn infants of mothers who are carriers of HBsAg or HBeAg by administration of hepatitis-B vaccine and hepatitis-B immunoglobulin. *Lancet*. 1984; 8383:921-926.
35. European Consensus Group on Hepatitis B Immunity. Are booster immunizations needed for lifelong hepatitis B immunity? *Lancet*. 2000; 355:561-565.
36. Health Research Council, 2004. Safety following MeNZB™ immunisation. Health Research Council Report., Wellington, NZ, 20 Dec 2004.
37. New Zealand Medicines and Medical Devices Safety Authority - Medsafe, Information for Consumers – How medicines are regulated <http://www.medsafe.govt.nz/Consumers/Regulate.asp#Pre> . Retrieved 21/12/06.
38. National Vaccine Advisory Committee. A report of the National Vaccine Advisory Committee strengthening the supply of routinely recommended vaccines in the United States: Centre for Diseases Control (CDC), 2003.
39. Anonymous. Intussusception among recipients of rotavirus vaccine--United States, 1998-1999. *MMWR - Morbidity & Mortality Weekly Report* 1999;48(27):577-81.
40. Jonville-Bera, A-P., Autret-Leca, E., Barbeillon, F., Paris-Llaldo, J., Sudden unexpected death in infants under 3 months of age and vaccination – a case-control study. *Br J Clin Pharmacol*. 2001;51:271-276.
41. Mitchell, E., Stewart, A., Clements, M., Ford, R., Immunisation and the sudden infant death syndrome. *Archives of Disease in Childhood*. 1995;73(6):498-501.
42. Stratton, K., Howe, C., Johnson, R., DPT and chronic nervous system dysfunction: a new analysis. Washington, DC, Institute of Medicine, National Academy Press *quoted in NZ Immunisation Handbook, 2006; Ministry of Health, Wellington, NZ p378*.
43. Greenberg, D., von Konig, C.-H., Heininger, U., Health burden of pertussis in infants and children. *Pediatr Infect Dis J*. 2005; 24:539-543.
44. Gold, M., Hypotonic hyporesponsive episodes following pertussis vaccination. A cause for concern? *Drug Safety*. 2002; 25(2):85-90.
45. Goodwin, H., Nash, M., Gold, M., Heath, T., Burgess, M., Vaccination of children following a previous hypotonic-hyporesponsive episode. *J Pediatr Child Health*. 1999; 35:539-542.
46. Weibel, R., Caserta, V., Benor, D., Evans, G., Acute encephalopathy followed by permanent brain injury or death associated with further attenuated measles vaccines: a review of claims submitted to the National Vaccine Injury Compensation Program. *Pediatrics*. 1998; 101(3):383-387.
47. Ray, P., Hayward, J., Michelson, D., Lewis, E., Schwalbe, J., Balck, S., Shinefield, H., Marcy, M., Huff, K., Ward, J., Mullooly, J., Chen, R., Davis, R., Encephalopathy after whole-cell pertussis or measles vaccination. Lack of evidence for a causal association in a retrospective case-control study. *Pediatr Infect Dis J*. 2006; 25:768-773.
48. Horwitz, O., Grunfeld, K., Lysgaard-Hansen, B., Kjeldsen, K., Epidemiology and natural history of measles in Denmark. *American Journal of Epidemiology*. 1974; 100(2):136-149.
49. Madsen, K., Vestergaard, M., MMR vaccination and autism. What is the evidence for a causal association? *Drug Safety*. 2004; 27(12):831-840.
50. Immunisation Advisory Centre, MMR and Autism <http://www.immune.org.nz/?t=719> retrieved December 2006
51. Patja, A., Paunio, M., Kinnunen, E., Juntilla, O., Hovi, T., Peltola, H., Risk of Guillain-Barre syndrome after mumps-measles-rubella vaccination. *J Pediatr*. 2001; 138:250-254.
52. Slater, P., Ben-Zvi, T., Fogel, A., Ehrenfeld, M., Ever-Hadani, S., Absence of an association between rubella vaccination and arthritis in underimmune postpartum women. *Vaccine* 1995; 13: 1529-1532

53. Wattigney, W., Mootrey, G., Braun, M., Chen, Surveillance for poliovirus vaccine adverse events, 1991 to 1998: Impact of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine *J Pediatr.* 2001; 107:e83
54. Halperin SA, Davies HD, Barreto L, Guasparini R, Meekison W, Humphreys G, Eastwood BJ. Safety and immunogenicity of two inactivated poliovirus vaccines in combination with an acellular pertussis vaccine and diphtheria and tetanus toxoids in seventeen- to nineteen-month-old infants. *J Pediatr.* 1997; 130(4):525-31
55. Sadovnick, A., Schelfele, D., School-based hepatitis B vaccination programme and adolescent multiple sclerosis. *Lancet.* 2000; 355:549-550.
56. Zuckerman, J., Protective efficacy, immunotherapeutic potential and safety of hepatitis B vaccines. *Journal of Medical Virology.* 2006; 78:169-177.
57. DeStefano, F., Mullooly, J., Okoro, C., Chen, R., Marcy, S., Ward, J., Vadheim, C., Black, S., Shinefield, H., Davis, R., Bohlke, K., Childhood vaccinations, vaccination timing and risk of type 1 diabetes mellitus *J Pediatr.* 2001;108(6):E112.
58. McMahon, B., Helminiak, C., Wainwright, R., Bulkow, L., Trimble, B., Wainwright, K., Frequency of adverse reactions to hepatitis B vaccine in 43,618 persons *Am J Med.* 1992;92(3):254-6.
59. Ronchi, F., Cecchi, P., Falcioni, F., Marsciani, A., Minak, J., Muratori, G., Tazzari, P., Beverini, S., Thrombocytopenic purpura as adverse reaction to recombinant hepatitis B vaccination. *Arch. Dis. Child.* 1998;78:273-274.
60. Mailliefert, J., Sibilia, J., Toussiro, E., Vignon, E., Eschard, J., Lorcerie, B., Juvin, R., Parchin-Geneste, N., Piroth, C., Wendling, D., Kuntz, J., Tavernier, C., Gaudin, P., Rheumatic disorders developed after hepatitis B vaccination. *Rheumatology.* 1999; 38:978-983.
61. Gervais, A., Caftisch, M., Suter, S., Haenggell, C.-A., Guillain-Barre syndrome following immunization with *Haemophilus influenzae* type b conjugate vaccine. *Eur J Pediatr.* 1993;152:613-614.
62. Davis, R., Balck, S., Shinefield, H., Mahoney, L., Zavitkovskya, A, Lewis, E., Nikasc, A., Guessc, A., Coplanc, P., Post-marketing evaluation of the short term safety of COMVAX®. *Vaccine.* 2004;22(3-4):536-543.
63. Annual Review, 2002, PHARMAC, Wellington, NZ.
64. Makela A, Nuorti JP, Peltola H. Neurologic disorders after measles-mumps-rubella vaccination. *Pediatrics.* 2002;110(5):957-63.
65. Stoto MA, Cleary SD, Foster VB. Immunization Safety Review: Epidemiological studies of MMR vaccine and autism. Washington: *Institute of Medicine*, 2001.
66. Stratton K, Almario D, McCormick MC. Immunization Safety Review: Hepatitis B vaccine and Demyelinating Neurological Disorders. Washington: Institute of Medicine, 2002.
67. Koskiniemi M, Vaheri A. Effect of measles, mumps, rubella vaccination on pattern of encephalitis in children. *Lancet.* 1989;1(8628):31-4.
68. Anderson HR, Poloniecki JD, Strachan DP, Beasley R, Bjorksten B, Asher MI, et al. Immunization and symptoms of atopic disease in children: results from the International Study of Asthma and Allergies in Childhood. *American Journal of Public Health* 2001;91(7):1126-9. Institute of Medicine.
69. Immunization Safety Review: Multiple Immunizations and Immune Dysfunction. Washington: *National Academy Press*, 2002.
70. Henderson J, North K, Griffiths M, Harvey I, Golding J. Pertussis vaccination and wheezing illnesses in young children: prospective cohort study. The Longitudinal Study of Pregnancy and Childhood Team. *BMJ* 1999;318(7192):1173-6.
71. Nilsson L, Kjellman NI, Storsaeter J, Gustafsson L, Olin P. Lack of association between pertussis vaccination and symptoms of asthma and allergy [letter]. *Jama* 1996;275(10):760.
72. Offit PA, Hackett CJ. Addressing Parents' Concerns: Do Vaccines Cause Allergic or Autoimmune Diseases? *Pediatrics.* 2003;Vol. 111(No. 3):653 - 659.
73. Heikkinen T, Chonmaitree T. Importance of respiratory viruses in acute otitis media. *Clinical Microbiology Reviews.* 2003;16(2):230-41. 57.
74. Russell F, Mulholland K., Prevention of otitis media by vaccination. *Drugs.* 2002;62(10):1441-5.
75. Spare ref?///////? Marchisio P, Cavagna R, Maspes B, Gironi S, Esposito S, Lambertini L, et al. Efficacy of intranasal virosomal influenza vaccine in the prevention of recurrent acute otitis media in children. *Clinical Infectious Diseases.* 2002;35(2):168-74.
76. Snow JB, Jr. Progress in the prevention of otitis media through immunization. *Otology & Neurotology.* 2002;23(1):1-2.
76. Briles DE, Hollingshead SK, Nabors GS, Paton JC, Brooks-Walter A. The potential for using protein vaccines to protect against otitis media caused by *Streptococcus pneumoniae*. *Vaccine.* 2000;19(Suppl 1):S87-95. 61.

77. Anderson LJ. Respiratory syncytial virus vaccines for otitis media. *Vaccine*. 2000;19(Suppl 1):S59-65.
78. Glezen WP. Prevention of acute otitis media by prophylaxis and treatment of influenza virus infections. *Vaccine*. 2000;19(Suppl 1):S56-8.
79. Rosen C, Christensen P, Hovelius B, Prellner K. Effect of pneumococcal vaccination on upper respiratory tract infections in children. Design of a follow-up study. *Scandinavian Journal of Infectious Diseases - Supplementum*. 1983;39:39-44.
80. Herzig P, Hartmann C, Fischer D, Weil J, von Kries R, Giani G, et al. Pertussis complications in Germany--3 years of hospital-based surveillance during the introduction of acellular vaccines. *Infection*. 1998;26(4):227-31.
81. Tappin DM, Ford RP, Nelson KP, Price B, Macey PM, Dove R. The febrile stress of routine vaccination does not increase central apnoea in normal infants. *Acta Paediatrica*. 1997;86(8):873-80.
82. Institute of Medicine. Immunization Safety Review: Multiple Immunizations and Immune Dysfunction. Washington: National Academy Press, 2002.
83. Welcker M, Neumann DA. Reference Guide on Vaccines and Vaccine Safety: National Partnership for Immunisation, 2003.
84. Immunisation Advisory Centre. A critique by the Immunisation Advisory Centre (IMAC) of the Immunisation Awareness Society pamphlet "What's all the fuss about?" 2003
http://www.immune.org.nz/site_resources/Professionals/IAS_critique_2003.pdf retrieved December 2006
85. English J. 1992. The issue of immunisation. *British Homeopathic Journal* 81: 161–3. cited in *NZ Immunisation Handbook, 2006; Ministry of Health, Wellington, NZ p368*.
86. Kleijnen J, Knipschild P, ter Riet G. 1991. Clinical trials of homoeopathy. *BMJ* 302: 316–23. cited in *NZ Immunisation Handbook, 2006; Ministry of Health, Wellington, NZ p368*.