

Anti-immunisation scare: the inconvenient facts

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Introduction

Over the last few years immunisation rates in Australia have fallen. As a result there have been outbreaks of the infectious diseases immunisation is designed to combat. Earlier this year there was a significant outbreak of pertussis (whooping cough) with at least three children dying from this preventable disease.

There has been a lot of media attention focused on the immunisation issue, and in an attempt at 'balanced' reporting the views of individuals and groups who oppose immunisation have been given plenty of coverage. The most well known example of this was the ABC TV *Quantum* two part series aired on September 26 and October 3, 1996.

The Australian Skeptics have been critical of the media in the past when they have unquestioningly given coverage to issues such as alien abductions or astrology. Can we now have our cake and eat it too? Is it reasonable to expect the media to only present the 'immunisation is good' message? Are there really two sides to the immunisation 'debate'? This is the question the sceptical scientist should be asking.

Perhaps the answer lies in the distinction between scientific evidence and individual opinion. There will be a number of different opinions, or beliefs, about immunisation but, as the Australian Skeptics have so often observed, believing something to be so does not necessarily make it so.

There is no scientific doubt about the efficacy of immunisation, and my concern about some of the media coverage is that this has not always been made clear.

This has not entirely been the fault of the media, though. Part of the responsibility must lie with so-called mainstream scientists, who have at times been unwilling to appear alongside immunisation opponents. The latter are often more media savvy, and are always willing to accept airtime or print space to state their views. Whilst I can well understand the reticence felt when faced with an invitation to respond to an anti-immunisation spokesperson armed mostly with anecdotes, I believe more attention should be paid to combating their misinformation.

Initially it was my intention to write an article that reviewed the scientific evidence for and against immunisation, but I have decided, instead, to review the quality of the science of one particular, very public, opponent of immunisation - Dr Viera Scheibner.

Dr Viera Scheibner describes herself as a retired principal research scientist. She has a PhD in micropaleontology and in 1993 published a book - *Vaccination 100 Years of Orthodox Research shows that Vaccines Represent a Medical Assault on the Immune System*.

I decided to review Dr Scheibner's work because she is highly regarded within anti-immunisation circles. She has given lectures both here and overseas, and more importantly she was the sole expert witness called to oppose immunisation in the Human Rights and Equal Opportunities Commission hearing regarding the right of Maroochy Shire Council to exclude unvaccinated children from their child care centre.¹

Dr Scheibner is staunchly anti-immunisation and she claims that she has come to this view as a result of collecting "just about every publication written on the subject of the effectiveness and dangers of vaccines".²(pxv) Lest there be any confusion I will allow Dr Scheibner to make her own position quite clear:

...there is no evidence *whatsoever* that vaccines of any kind - but especially those against childhood diseases - are effective in preventing the infectious diseases they are supposed to prevent. 2 (pxv)
[emphasis added]

Before I go on to examine Dr Scheibner's claims, and the objectivity of her research, in more detail it is important to make the following points unambiguously clear:

1. Vaccines are not 100% safe.³⁻¹¹
2. Vaccines are not 100% effective.¹²⁻¹⁸
3. Parents have a right to objective information prior to deciding whether to immunise their children.

It is not my intention to argue the first two points, and I am prepared to agree that, like any medical procedure, there

are occasional individuals who suffer a seriously adverse reaction to immunisation. This reality, though, is not an argument for cessation of all immunisation, just as the occasional tragic outcome from coronary bypass graft surgery is not a valid argument for stopping all such surgery.

My primary concern is as follows: Are parents who base their decision not to immunise their child on reading Dr Scheibner's book making a truly informed choice? Has Dr Scheibner presented her material in a scientifically balanced way? Is she telling the whole story?

Immunology 101

Immunisation is the process of artificially inducing immunity or protection from disease.¹⁹ This may be done either by stimulating the body's immune system with a vaccine or toxoid to produce antibodies, or through the use of an externally produced antibody.

A vaccine is a suspension of live or killed organisms (bacteria or virus), or parts of organisms. A toxoid is a modified bacterial toxin that has been rendered non-toxic but is still able to stimulate anti-toxin production.¹⁹ Immunising agents usually also contain a suspending fluid, preservatives, stabilizers and adjuvants. The most commonly used adjuvants are aluminium salts, and are used to enhance the immune response.¹⁹ The aim of an immunisation program is to reduce the incidence of, or to eliminate a particular disease. Immunisation has both a direct and an indirect effect.²⁰ The direct effect is the protection induced in the individual receiving the immunising agent. The indirect effect is the reduction of the incidence of the disease in others - so called 'herd immunity'.²¹

Deciding whether a particular immunisation program is successful depends upon a comparison of the number of cases of disease prevented with the range, severity, and incidence of adverse effects. That is, a comparison of the risks and the benefits.

The paradox of a successful immunisation program is that the more widespread immunisation becomes the more attention will be given to vaccine related illness. When immunisation rates are low, and the incidence of infectious diseases such as whooping cough are high, the risk from the disease is clearly far greater than the risk of harm from the vaccine.²⁰

As immunisation rates increase, though, the disease becomes scarcer and eventually a point will be reached at which the risk from the vaccine approximates the risk of contracting the disease.²⁰ It is important, if high immunisation rates are to be obtained, for this 'conflict' between the individual (risk of immunisation) and society (benefit of herd immunity) to be acknowledged.

This imperfect match between the individual and society is one important reason why, when one reviews the history of immunisation research, so much effort has gone (and is continuing to go) into the development of safer and more efficacious vaccines.

Pertussis

Pertussis (also known as whooping cough) is a highly contagious respiratory infection caused by the organism *Bordatella pertussis*.²² Pertussis causes violent episodic coughing which can make it hard for a child to eat, drink, and in some cases, breathe. Children under six months of age and children born prematurely, or with congenital abnormalities are particularly susceptible to complications, and suffer higher fatality rates.

Because of the decrease in the incidence of this disease over the course of the twentieth century it is difficult to fully appreciate how serious a condition it can be. At the end of the nineteenth century in the UK one child in every thousand under the age of fifteen died from the disease.⁴ In the US in the early 1940s it caused more deaths in children under two years-of-age than any other acute infection besides pneumonia and diarrhoeas.²⁴

The pertussis vaccine is usually given in combination with those for tetanus and diphtheria. This immunising agent is commonly referred to as DTP, or Triple Antigen. In Australia it is routinely given at two, four, six, and 18 months of age. A booster may also be given at age four to five years, prior to school entry.

Dr Scheibner asserts that DTP immunisation is ineffective and unsafe. More than this, though, she specifically claims that DTP immunisation is an important cause of Sudden Infant Death Syndrome (SIDS).

The battle lines are drawn

In reviewing the development of the pertussis vaccine earlier this century Dr Scheibner mentions two studies reporting on epidemics that affected the Faeroe Islands, and reports that:

In both epidemics six patients of the 3.926 vaccinated died and 26 among the 1.073 unvaccinated

cases died.2(p15)

This result appears to support a contention that is anathema to Dr Scheibner - namely that immunisation is effective - but she is not about to be discouraged, going on to say:

So the vaccine seemed to provide some degree of protection; however, *the numbers of vaccinated and unvaccinated are so different that any comparison is scientifically invalid.*2(p15) [emphasis added]

Any first year statistics student will be able to tell Dr Scheibner that this is incorrect. In performing a statistical analysis between two populations such as this (vaccinated vs unvaccinated) the samples do not have to be the same size, or even similar, as long as each separate sample is large enough.²⁴

In this case the sample sizes are more than adequate and when the analysis is done on the figures provided by Dr Scheibner the difference between the populations is highly significant, with a p value of <0.0001.

It is difficult to understand how a "principal research scientist" could make such a fundamental error, and does not instill great confidence in Dr Scheibner's ability to critically and objectively analyse the literature.

Dr Scheibner goes on to discuss the trials conducted in the UK in the 1940s under the auspices of the Whooping-cough Immunisation Committee of the Medical Research Council. She particularly refers to the trials conducted between 1946 and 1950, reported in the *BMJ* in 1951.²⁵

There were approximately equal numbers of children (3,358 vs 3,352) in two study groups. The 'vaccinated' group were immunised with pertussis vaccine, whilst the 'unvaccinated' group were given a vaccine containing no pertussis organisms. This 'anticatarrhal' vaccine contained killed suspensions of *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Corynebacterium hofmannii*, and *Neisseria catarrhalis*.

For all the trials there were 149 cases of pertussis diagnosed in the vaccinated group, and 687 in the unvaccinated. The average attack rate in the 'home exposures' group (children exposed in their own homes to infection in one or more siblings) was 18.2% for the vaccinated and 87.3% for the unvaccinated.²⁵

This time Dr Scheibner cannot attempt to dismiss the result based on sample size difference, so she tries a different approach:

This difference in attack rates cannot be attributed solely to a protective effect of the pertussis vaccines because the so-called unvaccinated group who served as a 'control' were in fact given the anti-catarrhal vaccine like the pertussis vaccine, this anti-catarrhal vaccine contained a number of foreign proteins (antigens) and had the ability to lower the resistance of the recipients. For this reason alone, the above trial cannot be considered valid. 2(p16)

Because a truly inert placebo, such as water or normal saline, was not used in these trials it is theoretically possible that the control vaccine had an effect such as Dr Scheibner proposes. Unfortunately for Dr Scheibner the attack rate in the 'unvaccinated' group was compared to the rate in the general population, and over the whole period of the trials there was no difference noted.

If, as Dr Scheibner suggests, the anti-catarrhal vaccine was making children more susceptible to pertussis, why was the disease incidence in this group no different to the general population that did not receive the vaccine?

Once again one can only speculate as to why Dr Scheibner would choose to exclude this important information.

One can also ask why Dr Scheibner chose to exclude the final report of this Committee, published in 1959.²⁶ Perhaps the answer lies in the report's general conclusion:

The results of the trials clearly showed that it was possible by vaccination to produce a high degree of protection against the disease. 26(p1000)

Dr Scheibner proceeds to discuss a number of reports from the 1940s and 50s that comment on adverse effects from the pertussis vaccine. As noted earlier it is not my intention to try and prove that vaccines are 100% safe. There is no doubt that these early versions of the pertussis vaccine were associated with a number of adverse effects, and it is not unreasonable to comment on this in a historical review of the development of the vaccine.

What is unreasonable is to imply, as Dr Scheibner does, that the safety profile of the pertussis vaccine in the 1930s and 1940s should be a determining factor in deciding whether to use it today.

Dr Scheibner's apparent lack of objectivity is again on display when she mentions a 1976 paper by Noah²⁷:

Although there was a lower incidence of whooping cough in fully immunised children compared with those partly immunised, the fact remains that the incidence in both groups was quite high. If the pertussis vaccine were effective, no immunised child should have contracted the disease. 2(p20)

[emphasis added]

This assertion by Dr Scheibner is, not surprisingly, unreferenced, and she would be hard pressed to find any immunologist, or immunology text, who would support it. Such a statement appears to demonstrate a poor understanding of the basis of immunisation, and the epidemiology of disease.

Effect of reducing immunisation

One important demonstration of the efficacy of immunisation, including pertussis immunisation, is the observed increase in incidence of diseases that occurs when there is a decline in immunisation rates in a previously well-immunised population. Dr Scheibner discusses two of these 'natural experiments' that took place in the UK and Japan respectively. There is, once again, no confusion regarding her opinion:

Reports of increased epidemics shortly after a fall in vaccination are quite untrue and, at best, exaggerated. 2(p29)

In the UK during the 1970s concern about the efficacy of the pertussis vaccine led to a decline in immunisation rates. There followed two epidemics in 1977-79 and 1981-82.²⁸ Dr Scheibner is keen to find a reason other than reduced immunisation for these epidemics, and so she concentrates on a letter written by Professor Gordon Stewart²⁹ that offers her some support.

Professor Stewart enumerates a number of criticisms of the conclusions that had been reached in an article by Miller *et al* reviewing the risks and benefits of pertussis immunisation Dr Scheibner carefully documents Professor Stewart's criticisms, but chooses to ignore the reply to Stewart that immediately follows his letter, and addresses these criticisms.³⁰

If Dr Scheibner is attempting to provide balanced information to allow parents to make up their own mind then this would not seem to be the way to achieve this.

In Japan in 1974-5 two children died following DTP immunisation.³¹ The Ministry of Health and Welfare temporarily halted the DTP immunisation program, and though this only lasted a couple of months public confidence had been eroded. The DTP immunisation rate, which had reached 85% by 1972 fell to 13.6% in 1976.³¹

Before looking at what happened to the incidence of pertussis during this period it might be useful to remember that Dr Scheibner states there is no evidence "*whatsoever*" that vaccines are effective.

Dr Scheibner discusses an article on the history of pertussis immunisation in Japan by Kanai³¹, but once again she appears to have kept from her readers information that fails to accord with her views.

The following are the figures for the cases of pertussis, and deaths from the disease, for the years just prior to the decline in DTP immunisation (1974-5) and for the years following.

Year	Cases	Deaths
1970	655	5
1971	206	4
1972	269	2
1973	364	4
1974	393	0
1975	1,084	5
1976	2,508	20
1977	5,450	20
1978	9,626	32
1979	13,092	41

Table 1.
Pertussis cases and deaths in Japan 1970-79.
Immunisation suspended in early 1975.
Data taken from Kanai³¹

In addition, it was reported that 90% of the 1975+ cases were in unvaccinated children.³¹ These figures were thought to clearly demonstrate "the importance and effectiveness of pertussis vaccine"³²(p123), and also served to provide

"convincing evidence that pertussis is still a fatal disease of babies..."³¹(p114)

On the basis of these figures no other conclusion is scientifically valid, and this is probably the reason why Dr Scheibner ignored the results.

Dr Scheibner's review of the Japanese situation provides further support for the contention that her research methods are somewhat sloppy. For example, she mentions the two Japanese deaths and claims that following these "doctors in the Okayama Prefecture boycotted the vaccine."²(p46)

The two deaths in Japan occurred in December 1974 and January 1975. In the Okayama Prefecture doctors had not been using DPT vaccine since April 1973, because of concerns over adverse effects. This Prefecture experienced an epidemic in 1974 and in 1977 was considered a pertussis prevalent area.³¹ One can only wonder at the irony of Dr Scheibner's comments later in her book:

Proponents of vaccination are so enmeshed in their belief in the efficacy of vaccines that they appear totally oblivious to evidence to the contrary."²(p53)

It would not be stretching things too far to suggest that this is the proverbial pot calling the kettle black!

Sweden, Sweden, Sweden

Another of Dr Scheibner's key points is the situation in Sweden, where immunisation against pertussis was suspended in 1979 in response to concerns about the efficacy of the vaccine then in use.³³ It seems that we are supposed to conclude that because a country like Sweden stopped immunising their children all other countries should follow suit.

What Dr Scheibner may not want her readers to know, though, is that following suspension of immunisation there was an increase in reported cases of pertussis in Sweden.²⁸ She also omits to explain why Sweden, if it is a country opposed to immunisation, has been so involved in research into newer pertussis vaccines?³³ Why waste the time and money if they believe immunisation is ineffective?

Dr Scheibner apparently repeated her claims about Sweden when she appeared before the Human Rights and Equal Opportunities Commission in July 1996.¹ It is difficult to understand how Dr Scheibner could appear as an expert witness on immunisation, and not be aware that in many areas of Sweden general immunisation against whooping cough was recommenced in 1995. This decision was based upon the results of trials of newer acellular vaccines, such as the one reported by Gustafsson et al.³³

It is also difficult to understand how such an expert witness, who has "collected just about every publication written on the subject", could not be aware of Sweden's experience with other immunisation programs.

For example, combined measles, mumps, rubella (MMR) immunisation was commenced in Sweden in 1982.³⁴ Table 2 shows the resulting change in the number of hospitalized cases of measles and the number of cases of measles encephalitis.

If immunisation was not responsible for the post 1982 decline then what was?

Year	Cases	Encephalitis
1981	372	15
1982	388	15
1983	248	8
1984	81	1
1985	9	0
1986	11	0
1987	10	0

Table 2.
Hospitalised measles cases, and encephalitis cases in Sweden.
MMR immunisation commenced in 1982.
>From Christenson.³⁴

Another example is Hib vaccine, which was introduced in Sweden in 1992, and was accompanied by a rapid decline in the incidence of *H. influenzae meningitis* and *bacteraemia*.³⁵ In the pre-vaccination period of 1987-91 the average annual incidence of these conditions was 34.4 per 100,000 children aged 0-4. By 1994 the incidence in this age group had fallen to 3.5 per 100, 000.³⁵

Did Dr Scheibner mention these results when she appeared before the Human Rights and Equal Opportunities

DTP and SIDS

One of the more important concerns regarding immunisation, particularly with the DTP, is a possible link with Sudden Infant Death Syndrome (SIDS).³⁶ This is a matter of great concern to parents and health care workers alike, and it is important to carefully examine the available evidence?

The peak time for SIDS is between two and four months of age, which is also the recommended time for the first two doses of DTP. We would therefore expect many cases of SIDS to occur in close time proximity to immunisation merely by chance.

Particularly in those cases where autopsy is unable to identify a cause of death such a close temporal relationship, and the understandable need by grieving parents to understand why this happened to their child, are easily exploited by anti-immunisation advocates.

I will let readers of *the Skeptic* decide for themselves whether Dr Scheibner's research in this area qualifies her for the title 'expert witness'.

Dr Scheibner notes a 1982 report of four unexplained deaths that occurred in Tennessee in the late 1970s.³⁷ She first attempts to draw a link between these deaths and immunisation:

All four deaths were classified as sudden infant death syndrome (SIDS), and all had received their first vaccination of diphtheria-tetanus toxoids-pertussis (DTP) vaccine and oral polio vaccine²(p59)

She is forced, however, to concede that the author of the paper found "no evidence to support a causal relationship."³⁷(p421) In her discussion of this study she fails to mention that the author of the paper concluded:

The findings of our study combined with the NIH results provide no support for reducing efforts to immunise infants with DTP.³⁷(p421)

Dr Scheibner then mentions the preliminary results of a study demonstrating a possible association between DTP and SIDS presented at a meeting in 1982.³⁸ Though the final results of this study had not been published at the time of the publication of Dr Scheibner's book (nor published since) she seems to be prepared to accept these preliminary results as sound science because they support her beliefs.

Dr Scheibner devotes nearly a whole page to this 'study' and only one sentence to formally published studies that found no link between SIDS and DPT.^{39,40} She also manages, in her discussion of SIDS, to ignore completely the Institute of Medicine Report discussing the DPT vaccine.³⁶ This found no link between SIDS and DTP immunisation.

The Japanese experience

One of Dr Scheibner's trump cards is her claim that in Japan, following the shift in age of immunisation to two years, the SIDS rate declined. She makes much of this in her book:

In 1975 Japan raised the minimum vaccination age to two years; this was followed by the virtual disappearance of cot death and infantile convulsions.²(p19)

When Japan moved the vaccination age to two years, the entity of cot death in that country disappeared ²(p43)

The most important lesson from the Japanese experience is that when the vaccination age was moved to two years, the entity of cot death disappeared. ²(p49)

The seeming and widely perpetuated dilemma: '*is there or is there not a causal relationship between DPT injections and cot death*' has, quite adequately and indeed without a shadow of a doubt, been resolved by the Japanese experience with cot death. ²(p62-3)

This claim of Dr Scheibner's has been unquestioningly repeated in other anti-immunisation material.⁴¹⁻⁴³

Dr Scheibner's claim rests upon her analysis of two papers, one by Noble *et al*⁴⁴ and the other by Cherry *et al*.²⁸ After reviewing both these papers it is clear that Dr Scheibner's analysis of them is at best sloppy, and at worst blatantly dishonest.

In Japan during the period concerned there was in place a Vaccine Compensation System, and the data presented by Noble and Cherry relate to claims made through this system.^{28,44} Compensation was commonly awarded for events

considered possibly due to immunisation, unless there was clear evidence that this was not the case. Approximately two thirds of claims submitted were accepted.

Noble and Cherry both report that when the minimum immunisation age was moved from three months to two years there were no claims made through the compensation system for vaccine related sudden death.^{28,44} They do not claim, as Dr Scheibner suggests, that there were no deaths from SIDS in Japan following the change in immunisation age.

Claims for vaccine related sudden death stopped, not because children were no longer dying, but because their deaths no longer occurred during a period when they were also receiving immunisation. How can you claim for a vaccine-related death if no vaccine was given?

If Dr Scheibner is really claiming that no children in Japan died from SIDS once the DTP immunisation age was changed she provides no evidence to support this claim, and I do not believe she can.

The drop in compensation claims suggests that the purported reactions in i