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Further to my letter to the MJA, and your response, I am submitting the following for inclusion as an extended editorial or opinion piece in the MJA.

I was not willing to comply with your request for a letter restricted to the specific issue of reporting rates for immunisation adverse reactions. The issue is complex, and I believe that it is the author's prerogative as to the content of a submission, just as it is the Journal's prerogative to accept or reject such submissions.

I believe these are important issues, and are not helpful or useful if dealt with superficially, as would be required for such a letter. Honesty in reporting of statistics, accuracy in data collection, real versus perceived immunisation rates, and a means of bringing the community together on this issue are major issues, brought sharply into focus in this current debate. As doctors, we must face our profession's shortcomings if we are to develop better systems and learn from past errors.

If you are unwilling to use the article, I would appreciate your earliest possible notice. I have another publication outlet available, and would use this article as it stands while the issue remains relevant and important to doctors.

*Length of contribution - 3,200 words*

Signed,

Dr Mark Donohoe MB BS

# Immunisation - Lessons from the current debate

Dr Mark Donohoe MB BS

## **I. Introduction**

The immunisation debate is a necessary and important factor in Australia reaching an appropriate level of vaccination. It has, however, become an emotional issue in recent months, leading some authors to go so far as to promote tactics to enforce immunisation on those who have made an informed choice not to vaccinate<sup>1</sup>.

This debate, therefore, is important for reasons which extend beyond the risks and benefits of immunisation. It is a debate which tests our ability to discuss important and controversial issues openly, which tests medicine's ability to maintain an objective and scientifically supported stand, which tests doctors ability to fully inform their patients of risks as well as benefits, and tests our profession's honesty in reporting adverse outcomes from vaccine preventable illness and immunisation adverse reactions.

It also tests our ability as a society to accept the informed decisions of those who choose to hold a contrary viewpoint without prejudice or vilification.

I wish to state my own position on the subject up front. I am in no way "anti-vaccination" or "pro-vaccination". These labels are media constructs, and do a disservice to any thinking person in issues as complex as this. My personal belief is that the informed decisions of an educated public and profession lead to the best choices in medical care. Whether a person so informed decides to vaccinate or not to vaccinate, I am of the opinion that it is not my right to interfere. In my own practice, I have tended to see more iatrogenic problems than are seen in most medical practices. I see many people who believe their own or their children's health has suffered as a result of vaccination, in which adverse effects had not been reported by their own doctors.

The debate, if it continues to be conducted at the extremes, will worsen matters, and may lead to a fall in vaccination rates. It is already confusing parents, who cannot determine a sensible path from the extreme views presented.

It also risks causing alienation and vilification of those who decide not to vaccinate. Some, including a few of my medical colleagues, believe that this is an acceptable tactic, in that it will apply social pressure making it difficult or impossible for parents to choose not to vaccinate. It is a tactic which I find reprehensible and profoundly anti-scientific, especially when the alternative is improved education, and gaining an understanding of the reasons people oppose vaccination.

Enforcing one's opinion, no matter how passionately held to be true, by accusing dissenters of negligence, by stifling free speech, by inducing social outrage and indignation, and by manipulating and distorting statistics, are anti-scientific practices which medicine would do well to eschew.

## **II. Flawed methods of assessing adverse outcomes**

Immunisations cause beneficial and adverse outcomes<sup>2,3,4,5</sup>. To pretend otherwise demonstrates ignorance or deceit. Most adverse reactions are self-limiting and mild, while occasional reactions are serious and may be fatal. That there are major benefits to be gained by the community from immunisation is, to my mind, not in doubt.

There is a problem inherent to defining potential adverse reactions to procedures such as immunisation. As doctors, we are dependent upon the medical literature and adverse reactions registers to identify cases where poor outcomes could be attributed to the procedure. This causes something of a dilemma, as can be seen in the recent Coroners Case. A child died about three hours after being vaccinated from sudden infant death syndrome. The coroner looked to the medical literature to see if such reactions were reported, and to see if evidence exists to support a causal link. Finding no proven association, he determined that there was unlikely to be any association in this case.

This particular case is then lost from the literature as a *potential* adverse reaction, and is not recorded in adverse reaction registers. If the same problem was seen by a thousand coroners around the world in the course of a year, and all went through the same rigorous process, they would all come to the same conclusion. None of the cases would be likely to enter the medical literature or adverse reactions registers, perpetuating the view that such reactions do not occur.

The additional, more subtle problem is that the community may hold a different view regarding these associations, so that children identified at risk of a medical condition (such as infant death syndrome) may remain unvaccinated because the parents fear an adverse outcome. Thus, a pool of children “at risk” for other illnesses are removed from the vaccination pool, skewing the statistics regarding any association. This type of confounding leads to a potentially serious underestimation of the likelihood of a real association, and may even lead to the paradoxical result that vaccination “protects” against such unrelated illness <sup>6</sup>.

The problem here is that we have no method of holding “possible but unlikely” adverse reactions in such a way that they are available worldwide to the profession for further review. One fear is that such information may be misused by anti-vaccination groups to perpetuate their perceived goals, further reducing vaccination rates and placing the community at an intolerable risk.

The view that each individual event must be decided on a frequentist probabilistic basis, and then assigned to one of two outcomes (ie “adverse reaction” or “not adverse reaction”) is at odds with current thinking on statistical approaches and inference. This “all or none” approach also contributes to an escalation of the bitter disagreement between the profession and the so-called anti-vaccination lobby, leading the latter to perceive such decisions as part of a conspiracy to suppress information on adverse outcomes.

There is urgent need for Australia to adopt a mechanism of reporting which captures “possible” adverse reactions, and accumulates them in an organised way which is reviewed regularly and openly using Bayesian statistical methods <sup>7</sup>, which have been shown effective in incorporating data progressively over time. These data would be “out of bounds” for discussion until analyses are completed (a process open to all interested parties), whereupon a summarised report of findings to date would be prepared for publication in the peer reviewed medical literature. This publication would be regular, and independent of whether adverse reactions were found or not (avoiding the bias of publishing positive results only).

The involvement of all interested parties, the accumulation of experience and evidence over time, and the ability to hold as “undecided” information which does not fit the current understanding of a process or illness, should all do much to improve the quality of science, while reducing the bitterness and polarisation surrounding the debate. Further, it would effectively separate those who seek a better system in recording adverse outcomes from those whose opposition to immunisation is irrational and vindictive.

### **III. The current epidemic**

There has recently been claims in the media that Australia is suffering a whooping cough “epidemic”. Curiously, media reports appear to be the only source of this information, and I could find no data in peer reviewed medical literature to support such claims.

The Benenson definition of epidemic (kindly provided to me by Dr Gavin Frost), appears reasonable, although it is almost impossible to quantify.

*Epidemic - the occurrence in a community or region of cases of an illness (or an outbreak) with a frequency clearly in excess of normal expectancy. The number of cases indicating presence of an epidemic will vary according to the infectious agent, size and type of population exposed, previous experience or lack of exposure to the disease, and time or place of occurrence; epidemicity is thus relative to usual frequency of the disease in the same area, among the specified population, at the same season of the year.*

Do the data support this definition? Are we currently suffering an epidemic in vaccine preventable diseases?

The current national statistics on disease notification suggest not <sup>8</sup>. Notifications for every vaccine preventable disease was lower in 1996 than in 1995, with the exception of diphtheria and polio (which were zero in both years). Decreases ranged from over 60% for measles to 1% for pertussis (whooping cough). Interestingly, only one case of pertussis was reported in New South Wales in the December 1996 reporting period, at the time when NSW Health was announcing the epidemic.

As well, three infant deaths have recently been attributed to pertussis (whooping cough) in media reports. Because the information was not released through normal medical channels, it is impossible to determine if these deaths were due to pertussis. The US statistics <sup>9</sup> suggest that in such young infants, premature birth and sickness are the major risk factors for contracting and dying from pertussis. There is no evidence that exposure is from unvaccinated contacts, although there is evidence that adult hospital staff can be asymptomatic carriers of pertussis, and would therefore be the most likely source of infection.

The point should be made that these tragic deaths were in no way related to poor vaccination rates. Such deaths occur even where vaccination is compulsory and complete <sup>9</sup>. The babies themselves were too young to have been immunised, the infection was most likely from an adult carrier <sup>3</sup>, and other factors in their medical history most likely predisposed them to a poor outcome <sup>9</sup>.

#### **IV. ABS 1995 Study**

The 1995 Australian Bureau of Statistics immunisation report <sup>10</sup> has been widely quoted as demonstrating Australia's appallingly low immunisation rate, suggested to be 52.1%. The report suffers severe shortcomings, most admitted in disclaimers within the body of the report, to the extent that it is virtually useless in assessing rates or effectiveness of immunisation in Australia. One can only assume that it has not been read by those quoting it, including the Health Minister.

The report shows apparent improvement in immunisation rates since 1989-1990, rather than worsening. The report does warn, however, that the two ABS reports (1989-90 and 1995) are not comparable because of important differences in data collection methodologies.

The report was constructed from interviews of parents and based on their recall of immunisation. Where possible, records were consulted to verify the parents' recollection. Most importantly, in the 60% of interviews in which records were consulted, the actual immunisation rate was almost twice as high as the recalled immunisation rate.

To suggest that Australia's immunisation record is worse than third world countries is absurd. Australia's complex immunisation schedule (15 separate immunisations in at least 6 episodes over 5 years) is compared to schedules in countries where a single injection is considered evidence of immunisation. In fact, the complexity, changes and additions to the Australian Schedule makes the 52.1% fully immunised rate remarkable. To quote the report,

*"Only those children who have received all the vaccinations appropriate to their age for all conditions covered by the schedule are considered fully immunised".*

Given the strict criteria, and the underestimations admitted in the report, the fully immunised rates for individual vaccines were surprisingly good:

Diphtheria / tetanus	.68.6%
Pertussis	.....59.9%
Polio	.....82.6%
Measles	.....91.6%
Mumps	.....89.6%
Rubella	.....75.5%
Hib	.....50.2%

This accords with the findings of Skinner et al <sup>11</sup> regarding children in the northern suburbs of Sydney that,

*"The full immunisation rate was 86 per cent, 14 per cent were partially immunised and only four children had received no immunisations."*

The Minister for Health has stated, in his new immunisation policy <sup>12</sup>, that he intends to raise Australia's immunisation rate to 90%. This, from these figures, smacks of political opportunism, and could most probably be achieved today in a properly constructed study.

Changes in the schedule in 1993 and 1994 were the main reasons for the apparent drops in some rates. The problem was not with the parents, but with the doctors who failed to administer the correct vaccine at the contact. In such a case, increased effort in education of doctors, rather than coercion of parents, would seem to be appropriate.

When the reasons for not immunising were assessed, some very interesting results emerged. One point of note was that the failure of the doctor to administer the correct vaccine was not provided as an option in answering.

Between 50% and 70% (depending on the particular vaccine) either had not heard of the vaccine, had not got around to it, or mistakenly thought their child was too young to have the vaccine. Around 15% to 20% either opposed immunisation or were concerned about side effects, and about 13% had medical reasons for failing to immunise, or the vaccine was unavailable.

The recent political announcements (withholding of part of the Maternity Allowance and Childcare Cash rebates) <sup>12</sup> do not address these problems. They *will* defer government payments, increase popularity of a Health Minister, and cause distress and financial hardship for all Australians, especially the poor who most need the Maternity Allowance at the time of the birth. They also divert attention from the current crisis in Australia's health system with a proposal which can only further stress that system.

## **V. Use of the media on medical issues**

In fact, this "science-by-media-release" seems to be the current fashion in medicine. In this case, the release of misinformation seems to have been for "motivational" purposes, in support of a more general campaign to increase vaccination rates.

It would appear to be part of a deliberate process, foreshadowed by Levy and Bridges-Webb in the Medical Journal of Australia in 1990 (9), when they wrote, "*In order to maximize the impact of immunisation programmes, the social and cultural contexts within which immunisation occurs should receive greater consideration*". The current actions would seem to be an attempt to counter what was perceived to be successful media manipulation by the anti-immunisation radicals. The goal of higher immunisation rates was set, and a strategy was created to achieve the goal, irrespective of the facts. The 1995 ABS survey was coopted into the issue, apparently without anyone actually reading it.

The result is that trusted professors, doctors and scientists have now descended to the level of their perceived opponents. Truth is the victim, and unimmunised children and their parents are being portrayed as perpetrators, a modern resurrection of a type of “typhoid Mary”.

One would think we would have learned from our past experience with HIV. Labelled the “gay plague”, misinformation led to the vilification of the perceived perpetrators, namely the male homosexual community. Now, a decade later, bashings and hatred remain a legacy of that ignorance, and the homosexual community is still regarded as pariahs by a significant minority of Australians.

What is going on? Many parents do not immunise because of passionate religious beliefs. Many parents do not immunise because they have too little information, and too little community support. These people need access to information, resources and education.

Many parents, however, do not immunise because they have looked carefully at the pros and cons, and have decided against. They have taken *more* care than parents who accept immunisation without thinking, and have made their informed choice on behalf of their child. Railing against these parents does far more harm than good. It drives a wedge through communities, creates an atmosphere of fear and mistrust, and paradoxically strengthens the influence of those who oppose immunisation. Jack-booted enforcement, even when the cause is good, inevitably leads to the entrenchment of opposition, and over time can lead to community resentment. When lies or exaggeration are the currency of both sides of a debate, the average parent is left more confused, not less.

## **VI. Doctors and reporting**

There is another, more subtle consequence of such an emotional and polarised debate, one which should concern all doctors. This may cause a knee-jerk reaction of denial and outrage on the part of my colleagues, but it is my experience gained from those patients who have sought my care in the past.

Doctors are responsible for reporting both cases of vaccine-preventable disease, and adverse reactions to immunisations. Both of these actions are subject to the biases and beliefs of those doctors. I would predict, for example, a significant increase in reporting of

vaccine preventable disease given the current media focus. I would predict also a fall in the reporting of adverse reactions for the same reason.

In the current climate, when adverse reactions do occur, doctors seem less likely to attribute them to immunisation, and less likely to report them. Why is this? Because doctors are human. Nearly all have been forced to “take a side” in the debate, and have consequently had to become proselytes for vaccination. They have cajoled, advised and persuaded vacillating parents about the benefits of immunisation. There has been a tendency to play down the likelihood of common adverse reactions and not provide information on rare but important risks. Immunisations are thus commonly given without the informed consent of the parents.

When problems arise after vaccination, these doctors tend to play down the severity of the complaints, and will often deny a connection with the vaccination. The reasons for this are unclear, but may be a misplaced fear that such an admission may lead to the parents avoiding future vaccinations. There are other possible reasons. The adverse reaction reporting rate in Canada <sup>2</sup> is just under one in four thousand doses, while an active surveillance system <sup>4</sup> for serious adverse reactions picked up five times as many reactions as did the passive reporting system, such as that employed in Australia.

This is a problem. If there is a systematic error in the under-reporting of adverse reactions, leading politicians, professors and doctors to deny the existence of adverse outcomes, then suffering is increased. The victims of immunisations become an embarrassment, and are denied recognition and compensation. Essential research needed to make immunisation safer and more effective is forgotten. We make do with second rate vaccines, putting the health of all who choose to immunise at unnecessary risk.

If we stifle debate and vilify those who choose not to immunise, then we divide the community. Those who choose not to immunise become pariahs, and are incorrectly blamed for almost any illness which does occur. When parents see their child suffer from an unexpected adverse effect, and are told that what they experienced is just not true, they seek information. If the issue is not open for discussion, then they may seek that information from less reputable sources. Litigation increases when people believe they have been lied to by their doctor and by health authorities, and the increased costs of medical insurance will be passed back to the public in increased fees for their medical care.

These are paths I, for one, do not wish to pass down. They are complex issues, requiring openness, debate, information and honesty on the part of all. They are not issues which are resolved by inflammatory proclamations or complex, punitive schemes.

We have wasted millions of dollars already in futile attempts to increase vaccination rates by media campaigns, threats, and name-calling. We now face a complex system of withholding of entitlements, which will most hurt the uneducated, the poor and those who speak little English. No one can be proud of the gutter tactics which are being employed by either side, because the real victims are the ordinary Australians who simply want to do what is best for their children.

It is now time to end the battle. A neutral forum is needed, where such language and tactics are discarded, and where there is an honest desire to reach consensus. All share a common goal, to ensure the best possible health and outcomes for all Australian children. They simply interpret the facts differently. Those differences can and must be resolved, before they divide the Australian community any further.

Signed

Dr Mark Donohoe MB BS

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