

AN ANALYSIS OF THE FEDERAL GOVERNMENT'S PERTUSSIS IMMUNISATION POLICY

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ABBREVIATIONS

ABS	Australian Bureau of Statistics
ATP	Adult Diphtheria Tetanus vaccine
AAP	American Academy of Pediatrics
ACIR	Australian Childhood Immunisation Register
ACP	Australian College of Pediatricians
CDC	Centre for Disease Control (USA)
CDT	Combined Diphtheria – Tetanus
CDI	Communicable Diseases Intelligence
CSL	Commonwealth Serum Laboratories
DTPa	Diphtheria – Tetanus – Pertussis acellular vaccine
DTPw	Diphtheria – Tetanus – Pertussis whole-cell vaccine
dTpa	Diphtheria – Tetanus- Pertussis (adult pertussis vaccine)
EPA	Environmental Protection Agency
FDA	Food and Drug Association
GP	General Practitioner
HCP	Health Care Practitioners
IAP	Immunise Australia Program
ICD	International Classification of Diseases treaty
IOM	Institute Of Medicine
NCIRS	National Centre for Immunisation and Research Surveillance
NCES	British National Childhood Encephalopathy Study
NHMRC	National Health and Medical Research Council
NIS	National Immunisation Strategy
NNDSS	National Notification of Diseases Surveillance System
PHAA	Public Health Association of Australia
PPI	Primary Pertussis Immunisation
SIDS	Sudden Infant Death Syndrome
SIP	Service Incentive Payment
WHO	World Health Organisation

ABSTRACT

Pertussis immunisation in Australia is a Federal Government Public Health initiative implemented to reduce the mortality and morbidity from Pertussis disease. Pertussis or whooping cough is an infectious disease that is mainly serious in infants under one year of age. Since the pertussis vaccine was first introduced into mass immunisation programs in 1954 it has been questioned with respect to both safety and efficacy. This paper analyses the Government's Pertussis Immunisation Policy to test the claim that the pertussis vaccine is the most effective means of controlling the incidence, mortality and morbidity of pertussis disease in the Australian community. It also examines the scientific evidence that is used to evaluate the safety of the vaccine. The research involved a literature review of how the policy developed, the history of infectious diseases in Australia and immunological theories supporting vaccination. This information was then assessed with respect to current knowledge of adverse reactions to the pertussis vaccine. The paper finds that pertussis vaccine is not controlling the incidence of pertussis in the Australian community nor was it the most significant factor in reducing mortality and morbidity of pertussis disease. It concludes that recent knowledge of the influence of environmental toxins on gene expression and genetic disorders and the subsequent rise of these disorders in the population, should lead us to reassess the benefit of this vaccine to the Australian community.

1 INTRODUCTION

Controversy has surrounded the pertussis vaccine ever since it was introduced into mass immunisation programs in Australia in 1954. Throughout the twentieth century it was continually questioned with respect to both efficacy and safety and for this reason its use has been discontinued in some countries and is discretionary in many others. The Australian Government promotes immunisation programs as the main reason why infectious diseases such as pertussis are no longer causes of death and disability in Australia. Pertussis immunisation policies are based on the premise that the pertussis vaccine is the most effective means of controlling the incidence of pertussis in the Australian population.

Since 1993 the Australian Government has placed greater emphasis on increasing childhood vaccination rates. It began with the Immunise Australia Program (IAP) and was extended by the Seven-Point Plan in 1997. The Federal Government has linked the vaccination status of children to welfare benefits and entrance to schools. Parents who decide not to vaccinate must obtain a conscientious objector's form signed by their general practitioner. The Federal Government also pays General Practitioners for each child they vaccinate. This emphasis on immunisation has given the community the impression that vaccination is mandatory and consequently there has been an increase in vaccination rates.

In 2006, the Australian Government legislated for mandatory vaccination for all Health students completing practical work. This mandate included a list of ten vaccines, one of which is the pertussis vaccine. The mandate will be extended further in 2007 to include all health professionals and employees of the health system.

This research paper is a policy analysis to assess the effectiveness of the Federal Government's Pertussis Immunisation Program in controlling pertussis disease. Pertussis is another name for whooping cough, which is particularly serious in children under one year of age. The study aims to describe the reasons why the policy has been implemented and the evidence and theories that have been used in developing the policy. The information collected will be analysed to determine if the Federal Government's policy is effective in controlling the mortality, morbidity and incidence of pertussis disease in the community.

The purpose of this research is to provide supportive evidence for the Australian Government's Pertussis Immunisation Policy. Vaccination is a medical intervention that introduces a suspension of live (attenuated) or inactivated microorganisms and chemical substances into a healthy body to induce immunity to a particular disease (Stern A. and Markel H, 2005). The chemicals include preservatives, antibiotics and adjuvants that are contained in

a vaccine carrier. (NHMRC, 2003) Therefore it is important to consider the cumulative and synergistic effects of chemicals in vaccines and any other drugs taken at the same time. This policy applies to all individuals so consideration should also be given to the knowledge that exists on genetic factors that predispose some children to greater risks. This risk must be weighed against an accurate knowledge of the chances of harm being caused by the disease itself.

Pertussis vaccination is a health promotion intervention, which requires healthy babies to be injected with a treated pathogen (disease causing bacteria) before six months of age to induce immunity to pertussis disease. It is a procedure that carries a risk of injury or death for some individuals and is promoted by the Government as being for the good of the whole community (Dept. Health, 2004). Mandatory pertussis vaccination suggests that the medical profession has proven knowledge that this health intervention had a significant influence in reducing the risks of whooping cough disease in Australian children. It also suggests there is conclusive information indicating that pertussis vaccine is not causing mortality or disability to a significant proportion of the population.

The underlying ethical principle of the work of doctors is to avoid doing harm. However, it is sometimes necessary for doctors to adopt the utilitarian principle that accepts that an action can be taken if it is shown to produce more good than harm (Naidoo & Wills, 2000). This principle underpins the Government's policy on pertussis immunisation, as it is believed that the benefits of the vaccination to the community outweigh any harm caused to individuals through adverse reactions to vaccines. This may be an acceptable premise if it is based upon accurate knowledge of the risk of the disease and accurate knowledge of the harm that is caused to children by each vaccine plus the harm that is caused by combining these vaccines.

In assessing this public health policy, the researcher aims to illustrate the strength of the evidence supporting pertussis vaccination as a valuable public health intervention. It aims to determine whether the risks of the vaccine have been adequately weighed against the benefits of the vaccine for the Australian population. If genetics plays a role in human defence mechanisms and predisposition to disease then we must establish without question the value of immunisation procedures to all individuals.

The methodology will include a literature review of the development of the government's pertussis immunisation policy, the history of pertussis disease in Australia, relevant immunological theories and knowledge of the safety of the vaccine itself. It will then conclude whether the evidence supports the claim by the Government that pertussis immunisation is the most effective means of controlling the incidence of pertussis in the community and whether all

types of scientific evidence are being used to assess the risks of this vaccine. The search strategy is listed in **Appendix 1**.

Research Questions

1. How has the Federal Government's Pertussis Immunisation Policy developed?
2. What are the expected outcomes of this policy?
3. Is the Government's Pertussis Immunisation Policy achieving its outcomes?
4. What type of scientific evidence is being used to assess the risks and benefits of this vaccine?

2 BACKGROUND INFORMATION

2.1 CHARACTERISTICS OF THE DISEASE

Symptoms

Pertussis or whooping cough is a disease caused by the gram-negative bacteria *Bordetella pertussis* and is characterized by:

1. Paroxysmal coughing (sudden coughing attacks).
2. Bronchopneumonia (inflammation of the lung caused by bacteria) and
3. A distinctive 'whooping' intake of air when coughing (Behrman et al, 1998).

There are two other species of bacteria that produce this illness in humans but it is believed that the disease is less severe and of less duration than that caused by *B.pertussis* (Behrman et al, 1998). The two other species are *Bordetella parapertussis* and *Bordetella bronchoseptica*. Adenovirus is one of a group of DNA containing viruses, which is also known to cause pertussis like symptoms (Behrman et al, 1998). Humans are the only animal host of *B.pertussis*, however *B.parapertussis* and *B. bronchoseptica* are known to infect other mammal hosts (Smith A, 1999).

Pertussis is a highly contagious disease with an attack rate of ninety percent in susceptible populations (Behrman et al, 1998). However, it is not a serious disease in adolescents or adults (Adams A and Barron A, 1966; Kimura M, Kuno-Sakai H., 1990). The risk of this disease is highest in children under 5 years with most serious cases occurring in children under six months (Behrman et al, 1998). The mortality rate is 0.03% (NCIRS, 2005) and deaths usually result from pneumonia, pulmonary complications, asphyxia or encephalopathy (Behrman et al, 1998).

Transmission of the pertussis bacteria is by droplets released in the air during coughing episodes (Behrman et al, 1998). The incubation period is between 6 – 14 days and the most contagious period is the first stage or catarrhal stage (Behrman et al, 1998).

The catarrhal stage lasts for 1-2 weeks and has symptoms of a common cold. At this stage bacteria are at their greatest concentration but diagnosis of pertussis is usually not considered because of its similarities to the common cold (Behrman et al, 1998, p.364). Stage 2 is the paroxysmal coughing and vomiting, which lasts two to four weeks. It involves coughing episodes (paroxysms) of 5 –10 coughs with a whoop after each cough. The whoop is air being forcefully inhaled (Behrman et al, 1998). Paroxysms may cause anoxic brain damage or

encephalopathy (Behrman et al, 1998, p.363). The third stage is convalescence lasting one to two weeks and a chronic cough often persists for months (Behrman et al, 1998).

Diagnosis

The Communicable Diseases Intelligence (CDI) committee reported in 1986 that the diagnosis of pertussis is often delayed or missed. One reason given was that there may be an over-estimation of the degree of protection afforded by pertussis immunisation. Stewart (1977) also comments "it is clear that general practitioners are much less likely to notify whooping-cough in vaccinated children, even where the symptoms are typical. This is confirmed by Miller NZ, (1995), who claims that children who are vaccinated against pertussis and then contract pertussis are often diagnosed with bronchitis or parapertussis if no clinical test is performed (p.92).

B. pertussis disease often presents with atypical symptoms in younger children and adults. In these groups the whoop may be absent from the cough and babies under 6 months may also have apnea (temporary cessation of breathing) and cyanotic spells (a bluish discoloration of the skin resulting from an inadequate amount of oxygen in the blood). For this reason, diagnosis is problematic and requires culturing and staining of the bacteria for confirmation (Behrman et al, 1998: Burgess, M, 1994). It is believed that undiagnosed cases are frequently the source of infection for infants (Burgess, M, 1994).

The disease is rarely associated with asymptomatic individuals. That is, infected individuals will always display symptoms. There are rarely sub-clinical cases of pertussis (Behrman et al, 1998).

Morbidity and Immunity

Complications or morbidity from pertussis disease include:

- 1) Pneumonia - resulting from *B.pertussis* itself or secondary infections.
- 2) Atelectasis – a failure of part of the lung to expand due to mucus plugs.
- 3) Otitis media and sinusitis are common and usually due to *S.pneumoniae*.
- 4) Ruptured alveoli and emphysema.
- 5) Bronchiectasis – widening of the bronchi in which pus forms.
- 6) Convulsions and encephalopathy (Behrman et al, 1998).

Celermajer J, and Brown J, (1966) studied the morbidity due to pertussis over an eleven year period from 1953 – 1964 and concluded pertussis in the Sydney community appears to be only infrequently associated with neurological complications and these tend to be mild in nature.

Behrman et al, (1998) claim patients who have pertussis do not require further pertussis vaccinations because the disease produces lifelong immunity (p.365). This has been disputed by Wendelboe AM et al, (2005), who conclude immunity is not life-long but it is longer than the duration of immunity after pertussis vaccination. These authors state that the immunity induced after immunisation wanes between four to twelve years. The ACP stated in 1991 that the duration of immunity induced by the Australian whole-cell pertussis vaccines wanes after two to three years (Zeigler et al, 1991).

Wendelboe, AM et al, (2005) noted that adults in the pre-vaccine era rarely presented with typical forms of pertussis. The majority of reported cases occurred in children and it is estimated that 80% of the population suffered from pertussis during childhood (Gordan J, and Hood R, 1951 as cited in Wendelboe, AM et al, 2005). This would suggest that being infected with pertussis in childhood did confer long-term immunity as pertussis was not diagnosed in adults very often and it was not a serious disease in adults (Wendelboe AM et al, 2005). Although Wendelboe et al, (2005) question the length of duration of naturally acquired pertussis immunity they still conclude it is of longer duration than immunity after vaccination, possibly as long as twenty years.

2.2 THE HISTORY OF DISEASE IN AUSTRALIA 1900-1950

Infectious diseases were the main cause of infant deaths in the early nineteen hundreds. However, changes that occurred over the first half of the century significantly reduced the influence of these diseases on mortality. Strahan L., (1994) claims that by 1950 infectious diseases were something that Australians located in the outside world as a result of their high living standards and long life expectancy. It is believed that this was a result of changes in social conditions and the progress in medical science that occurred during the early twentieth century (Kaprio, (1984) as cited in Goldsmid, 1988, p.55).

Gandevia (1978) claimed that by 1950, out of every 100 children, 97 would be expected to survive to one year and 96 to five years of age (as cited in Goldsmid, 1988, p.57). It is also known that the under-five mortality rate in Australia in 1945, due to infectious diseases was very low (ABS, 2001). Lancaster HO, (1956a) confirmed this in his survey on Australian mortality for 1956. He stated, "as causes of infant mortality in Australia all the infective diseases have been overcome." (p.104) Infant refers to children less than one year of age. He continues by saying "only congenital malformations and causes peculiar to the first year of life now remain important."

The greater emphasis placed on preventative medicine in the nineteen-twenties resulted in changes in social conditions, which significantly affected mortality and morbidity statistics in children (Gillespie J, 1991, p.32). The Commonwealth Department of Health was established in 1921 (Gillespie J, 1991). At this time the aims of public health changed from an emphasis on sanitary reform to that of 'social medicine'.

Social medicine relates to the diseases that are caused by political, economic, and social factors (Gillespie J, 1991). For example, the funding of health infrastructure, living standards and lifestyle issues, all of which are associated with poor health in individuals. The belief by Public Health authorities at this time was that only action by the State, under the control of medical experts, could remedy diseases resulting from social causes (Gillespie J, 1991, p.34). The state was interested in the health of the population because officials believed the health of each individual is an asset to the State as well as the individual (Gillespie J, 1991, p.35). Authorities believed that widening the sphere of state and preventative medicine would eventually reduce the demand for curative services by eliminating much disease (Gillespie J, 1991, p.39).

The emphasis on social medicine was pushed strongly in the 1930's. The National Health and Medical Research Council (NHMRC) was established in 1936 and its purpose was to advise the Commonwealth Department of Health on Public Health Policies. It also assisted with research funding for medical practitioners. New research at this time demonstrated that many diseases resulted from nutritional deficiencies. Public health officials became aware that malnutrition increased the susceptibility of children to disease by weakening the immune system (Gillespie, J.1991). The medical profession increased its support for breastfeeding in 1929 and this measure along with new relief policies regarding the minimum nutritional requirements in food provisions for the unemployed, led to a marked reduction in mortality and morbidity in infants (O'Connor K, 1989).

At this time it was recognised that nutrition could provide the 'unifying key' to the prevention of disease and that the scope of public health must be widened from bacteriology to living standards, lifestyle and diet (Gillespie J, 1991, p.49). The State took control of community health centres with the aim of changing the focus on curative health to a more holistic approach focusing on preventative health (Gillespie J, 1991).

Health authorities realised the value of 'propaganda publicity' in achieving the success of social control through education (O'Connor K, 1989). The health department aimed to modify individual's behaviour through education using media such as films, radio programs and

newspaper campaigns. In this way parents were targeted with health information on the major initiatives recommended by the NHMRC, which were diet, national fitness, domestic hygiene and breastfeeding (Gillespie J, 1991). Mortality due to infectious diseases was reduced even further in the 1940's with the discovery of antibiotics (O'Connor K, 1989).

Lancaster HO, (1956a) notes that during the period from 1946-1954 'pertussis was an uncommon cause of death for children and there is a significant decline in mortality if the age of infection increases.' He also thought the 'Studies on Infant Mortality' published by the United Nations overemphasizes the importance of immunisation in reducing mortality due to pertussis in infants. This is consistent with the knowledge that pertussis is "very sensitive to general social conditions and hygiene" and its decline began before routine immunisation programs were implemented (Lancaster HO, 1956b). He continues by saying that "mortality rates due to pertussis are used as an index of hygiene or social wellbeing " (Lancaster, 1956b, p893).

In 1946 an amendment was made to the constitution, which gave the government power to provide a complete health service to the nation, including medical advice and treatment (Com. Yearbook, 1953). At this time provision existed in the Health Acts of all States for the compulsory notification of infectious diseases. Pertussis was placed on the nationally notifiable disease list in the 1930's. If a notifiable disease occurred, the local authority had to be informed at once and measures were taken to prevent the spread of the disease. Notification also had to be made to the Health Department (Com. Yearbook, 1953).

In 1950 the NHMRC altered the list of notifiable diseases and removed whooping cough, influenza and measles due to the reduction in mortality and morbidity that had occurred by this time (Com. Yearbook, 1953).

The Annual Report for the Department of Health for 1953-57 stated that whooping cough was causing mortality in aboriginal communities in NSW (O'Connor K, 1989). There was concern about the high infant mortality rates in aborigines in NSW in the early 1960's, despite immunisation clinics being held in these communities since 1958 (O'Connor K, 1989, p.74). The high mortality rate was being linked to malnutrition and unhygienic conditions, which were still rife in these communities (O'Connor K, 1989).

It is stated "changes in living conditions, particularly better nutrition (which increase host resistance to infection) and improved hygiene played a more important role in mortality decline than improved medical knowledge." (McKeown (1979) and Gordon (1976), as cited by the ABS 2001a)

2.3 IMMUNOLOGICAL THEORIES IN 1952

Prior to the implementation of mass vaccination programs, Burnet M, (1952) indicated that there were many gaps in scientist's knowledge about the functioning of the human immune system. At this time many public health experts, including Burnet, claimed it was 'possible' that the most physiological time for infants to have any type of infection is when maternal immunity has just begun to fade (Burnet M., 1952). The theory was that protection from disease could be provided to infants by introducing a modified infection into the individual. It was believed that only trivial symptoms would be experienced and this would be definite enough to produce lasting immunity (Burnet M., 1952). This was termed 'passive-active immunisation.'

The theory of active immunisation states that artificial immunity can be produced by injecting treated antigens (foreign protein) into the tissues of the body to stimulate it to produce its own antibodies to fight a particular disease (Martin E (ed), 2004). Antibody based immunity is called humoral immunity and is one part of an integrated disease defense system (Behrman et al, 1998). An assumption of this theory is that the immunity produced in this way would have the same effect and duration as that obtained by natural infection from the disease organism (Burnet M, 1952). The other assumption in this theory is that the 'treating' of the pathogens and the vaccine carrier itself will not result in harm to the individual that is vaccinated.

Questions such as the efficacy and duration of immunity obtained from the pertussis vaccine and whether the immunity induced by the vaccine affects the severity or incidence of re-infection at a later age, could not have been adequately determined until the vaccines were trialed in large numbers of individuals. This is because knowledge of human physiology and the complex immunological response to fighting disease is not complete (Burnet M, 1952).

This leads us to consider whether the theory of induced antibody production by vaccination covers all the elements involved in the human body's natural defense mechanisms against childhood diseases. That is, does the immunity from vaccination have the same duration and response to re-infection as that of natural infection?

Burnet M, (1952) considered that one of the main biological mysteries of the time was the unifying control involved in the development of an effective organism that is adapted to the environment. This control covers the three main aspects of development – morphological, neuro-mental and regulatory. He states that the pre-destined pattern or genes of the individual are behind the development of the organism and development occurs in conjunction with environmental factors (Burnet M, 1952). Burnet suggests that control of the internal environment must become progressively more efficient and therefore it must meet and deal with the type of events that can exercise the regulatory function. In other words the body

learns by contact with harmless or lowly virulent microorganisms what is needed to overcome more dangerous pathogens (Burnet M, 1952).

He concludes that a high mortality in infancy is attributed mainly to failure of an adequately developed regulatory function to compensate for the changes induced by infection. He defines a fatal infection as one that comes too early (Burnet M, 1952). In addition, he points out that many infectious diseases produce a short trivial illness in a young child which is associated with long-lasting immunity (often life-long), however in the non-immune adult it produces a serious clinical disease. Burnet M, (1952) states that a rising standard of living, the development of good hygienic practices in infancy and childhood, plus smaller family sizes all increase the age at which children come into first contact with infectious disease. Consequently mortality and morbidity due to diseases such as pertussis will fall naturally because the children are older at the time of first exposure (Burnet M, 1952).

Burnet M, (1952) believes genetic constitution is the most important hidden variable in disease statistics. He suggests that we may find genetics is the determining factor in the severity of many infections rather than sub-clinical infection that is assumed in vaccination procedures (p.106). In addition he says, "we know very little indeed about the genetic factors and the long-term influence of minor nutritional or psychological deviations from normality." In other words, infection or death from disease may be influenced more by the inborn genetic profile of the individual as well as the environment since birth, than exposure to the pathogen through vaccination procedures.

3 RESEARCH QUESTION 1: HOW HAS THE FEDERAL GOVERNMENT'S PERTUSSIS IMMUNISATION POLICY DEVELOPED?

3.1 RECOMMENDATIONS FOR A PERTUSSIS POLICY

Policy Development 1954

The Commonwealth Government's health policies from 1936 were determined by recommendations from researchers within the NHMRC. In the early nineteen hundreds infant mortality and morbidity due to pertussis was of concern and pertussis was classified as a notifiable disease in all Australian States and Territories from the 1930's (Com. Yearbook, 1953). Medical practitioners were expected to notify local authorities of cases of pertussis so public health measures could be used to reduce the incidence of this disease.

By 1950 there had been a significant decline in the mortality and morbidity due to pertussis and it was removed from the notifiable disease list (Com. Yearbook, 1953). The decline in mortality due to pertussis from 1950 – 1974 is shown in **Table 1** below. This decline is more significant if the rise in population numbers during this period is also considered.

Table 1 - The Mortality Figures Due to Pertussis from 1950 – 1974

Year	Mortality Due To Pertussis	Year	Mortality Due To Pertussis
1950	34	1962	4
1951	33	1963	3
1952	23	1964	4
1953	26	1965	4
1954	15	1966	4
1955	11	1967	1
1956	10	1968	4
1957	7	1969	4
1958	3	1970	0
1959	14	1971	1
1960	8	1972	4
1961	1	1973	2

Reference: Commonwealth Department of Health, Official Yearbook of the Commonwealth of Australia, Nos. 38 – 61.

Although vaccines for pertussis were developed in Australia in 1920, they were not used routinely or extensively until 1954 because of the variability in their efficacy and safety (Feery BJ, 1982; Smith A, 1999: CDI, 1997).

In 1953, District Health Officers in each state worked with local authorities to fight infectious diseases (Com. Yearbook, 1953, p.278). The Commonwealth government was offering free immunisation against pertussis in most States and Territories and if an outbreak of pertussis occurred immunisation programs were intensified (Com. Yearbook, 1954). Immunisation against pertussis was not as extensive as that for tetanus and diphtheria because “the incidence of whooping cough appears to have declined markedly in recent years” (Com. Yearbook, 1953, p.278). Immunisation programs were most extensive in Victoria and Queensland at this time (Com. Yearbook, 1954). This indicates immunization rates varied between States.

By 1954 mortality due to pertussis had declined to 15 deaths per year and the majority of these deaths were infants under one year of age (Com. Yearbook, 1950-1973). The National Health and Medical Research Council (NHMRC) decided pertussis was a vaccine preventable disease in 1954 and they recommended it be placed on the routine immunisation schedule for Australian children because a more effective vaccine was available, (CDI, 1997).

At this time it was recommended that pertussis be administered as a component of the triple antigen vaccine, a multicomponent vaccine containing diphtheria, tetanus and pertussis antigens (DTP) and given to infants at 3, 4, 5 and 11 months of age (NHMRC, session 38, 1954, p.18). It was given as a subcutaneous injection (under the skin) in the upper arm (NHMRC, session 38, 1954, p.18).

A summary of the changes that were made to the vaccination policy from 1954 to 2007 is given in **Table 2** below.

Table 2 - A Summary of Policy Developments from 1954-2007

1950	Pertussis removed from the Notifiable Diseases List
1954	NHMRC recommended routine pertussis immunisation *PPI given at 3,4,5 and 11 months of age. Given to children 2 years and under Subcutaneous injection Pertussis mainly serious in under one year olds
1979	NHMRC stated that provided that contraindications to immunisation were observed the risk of adverse reactions was minimal. CDT should be used instead if DTP is contraindicated. 18 month DTP booster dose removed
1981	PPI given at 2,4,6 months of age. Now only given to children under 1 year old.
1985	Pertussis immunisation levels greater than 90% in most States.
1986	18 month DTP booster dose re-instated.
1991	Pertussis became a Nationally Notifiable Disease again. Immunisation rates at 85-90%. Intramuscular injections not subcutaneous due to abscesses. Survey of Victorian doctors indicated 34% thought DTP was linked with brain damage and 32% unsure. (based on results of the NCES study from 1979) Immunise Australia Program to increase vaccination rates
1994	A re-analysis of the NCES study using follow up data concluded DTP was “rarely” associated with brain damage. Assessment based on epidemiological evidence only. Doctors were re-educated regarding the contraindications of the vaccine. There were now only 2 contraindications. A fifth booster dose was brought in at 5 years of age.
1997	Acellular vaccine (DTPa) given at 18m booster and 5-year booster. Seven-Point plan to increase vaccination rates
1999	DTPa recommended for PPI. IOM recommended the phasing out of thimerosal (mercury) from childhood vaccines.
2003	60% of pertussis cases now in adolescents and adults. Booster dose recommended for 10 year olds and above. 18 month and 5 year booster removed. Fourth dose now due at 4 years old.
2004	DTPa now replace DTPw.
2006	Mandatory vaccination for all health students completing practical work.
2007	Mandatory vaccination for all health professionals and employees of the health system.

*Primary Pertussis Immunisation – PPI (The first 3 doses).

Policy Development 1973-1978

Primary Pertussis Immunisation (PPI) refers to the first three doses of vaccine given to an infant. In 1973 this series of doses was not recommended for children over two years of age because older children were known to react more frequently to the vaccine. However, the need for the vaccine over this age was less because the disease was known to be most serious in children under one year of age (NHMRC, 78th session, 1974). The NHMRC claims that routine immunisation of children at 3-6 months with DTP has led to a marked reduction in cases and deaths from diphtheria, tetanus and pertussis (NHMRC, 78th session, 1974). Vaccination rates and changes in mortality and morbidity are not presented to support this statement.

The NHMRC reported in 1974 that the severity of whooping cough in small babies makes immunisation desirable even though it admits that the pertussis vaccine is not as effective as that for diphtheria and tetanus (NHMRC, 78th session, 1974). It claims, “the vaccine’s effects ‘appear’ favorable in reducing the symptoms and the incidence of complications.” **Table 1** above shows that by 1973 mortality due to pertussis was 2 deaths per year.

Pertussis became a notifiable disease again in some states prior to 1978 but confirmation of a pertussis case did not require a diagnostic test (NHMRC, 86th session, 1978, p.162). In 1977 the Council considered reports that outlined reactions to immunisation, particularly those following pertussis immunisation. These reports indicated that the incidence of side effects to the vaccine was higher than previously reported in the medical literature (NHMRC, 83rd session, April 1977). It also noted that there had been recent doubts expressed about the efficacy of the pertussis vaccine. However, the Council concluded immunisation was ‘important’ and decided to reaffirm the immunisation schedule that was outlined in 1974 (NHMRC, 83rd session, April 1977).

Again, no evidence was given to support this decision except a claim that “the benefits of immunisation for individual children and the community far outweigh the slight risk of side-effects associated with such procedures” (NHMRC, 83rd session, April 1977).

Policy Development 1978-1981

The incidence of pertussis was described as ‘epidemic’ in England, Wales, Sweden and Japan in 1975, 1978 and 1982 but epidemics in Australia were not mentioned (NHMRC, 1991, p.30). This evidence was used to emphasise the importance of pertussis immunisation despite an increase in reports about the safety of the vaccine (NHMRC, 86th session, 1978, p.162).

In 1978, the NHMRC recommended modification of the immunisation schedule to emphasise that combined diphtheria-tetanus (CDT) vaccine should be used in lieu of the triple antigen when children present with contraindications to the pertussis vaccine (NHMRC, 86th session, 1978). This was in response to concerns about adverse reactions. A contraindication is any factor in a person's condition that makes it unwise to use the vaccine (Martin E (ed), 2002).

The contraindications listed in 1978 included:

1. A previous history of neurological disease, including seizures, convulsions or cerebral irritation in the neonatal period.
2. A previous reaction to the vaccine other than minor local reactions and/or mild fever.
3. A family history of neurological disease other than that due to trauma and infections.

In 1979 the NHMRC claimed that pertussis was still a cause of significant mortality and morbidity amongst children in Australia (statistics were not provided to support this claim). The Council noted that in some parts of the community immunisation rates were not at a satisfactory level and it believed this was partly due to the recent publicity concerning adverse reactions to vaccines (NHMRC, 87th session, 1979).

The Council stated that the most effective preventative measure against pertussis outbreaks was a high level of immunisation (NHMRC, 87th session, 1979). It continued by saying that immunisation was not entirely without risk however, "provided that contraindications to immunisation were observed, the risk of severe adverse reactions was minimal." It advocated the promotion of active immunisation campaigns by all levels of government, the medical profession and by community groups to increase vaccination rates (NHMRC, 87th session, June 1979).

In 1981, the pertussis vaccination schedule was revised and the triple antigen was now administered at 2, 4, and 6 months of age (NHMRC, 91st session, June 1981). The fourth dose given at 18 months was removed due to global concerns of adverse reactions to pertussis vaccines (CDI, 1997). Prior to 1979 pertussis was given to infants 2 years and under. After this year it was recommended that it only be given to infants less than one year of age (Com. Yearbook, 1980). It was known in 1974 that pertussis immunisation was associated with more severe reactions in older children (NHMRC, 78th session, May, 1974).

Immunising children in the first year of life became a philosophy in 1980 (Moxen E.R, 1990). Prior to this the philosophy was to target children in schools. The reason given in developing countries for changing this philosophy is cost-effectiveness and in developed countries 'complacency' (Moxen ER, 1990). Resources and logistics of the immunisation programs are a limiting factor to immunisation rates (Moxen ER, 1990). Hence it was decided that infants are more accessible and more cost-effective in raising the immunisation level of the community in order to achieve the level of herd immunity thought necessary to prevent the persistence of the pathogenic microorganisms (Moxen ER, 1990).

Health officials believe the public is complacent about vaccination because the vaccines are so successful in controlling the infectious disease that we no longer see their devastating consequences (Moxen, 1990).

Policy Development 1982-1990

The NHMRC became concerned about the vaccination level of the population again in 1982 when an outbreak of pertussis occurred in Western Australia (NHMRC, 93rd session, June 1982). On this evidence, the Council recommended that Australia adopt the prevailing American system, which requires evidence of immunisation status prior to school entry. This requirement contains a provision for exemption from vaccination on defined medical, personal or religious grounds.

In 1984 the NHMRC established a Working Party on Pertussis due to the rising incidence in the community (97th session, June 1984). Its purpose was to determine why the incidence of pertussis was increasing.

Three possible explanations were investigated:

1. The current vaccine was not appropriate for the strains present in the community.
2. Young adults are not protected by natural immunity so they form a carrier group.
3. The level of immunisation uptake in the community was not high enough.

In 1985 the NHMRC reported that pertussis was seen as a continuing problem in Australia, especially in the cities of Sydney, Melbourne and Perth (NHMRC, 99th session, June 1985). It states that even though the estimated immunisation levels in the community are over 90% in most states, the disease is still occurring (NHMRC, 99th session, June 1985). Hence, the

Council recommended a two-part surveillance program on pertussis be established and reported upon.

The NHMRC also stated at this time that there was evidence from Australia and overseas to indicate that the withdrawal of the fourth dose of the pertussis vaccine at 18 months had resulted in an increased incidence of the disease (100th session, Nov. 1985). The fourth dose was withdrawn in 1979 due to concern about neurological side-effects but subsequent hospital data in Australia from 1980 onwards, suggested that the rate of pertussis had increased after this change (Ziegler et al, 1991). The NHMRC decided that 'as there was no evidence to suggest that the administration of the fourth vaccine significantly increased the risk of immunisation complications' then it recommends that the fourth dose of the pertussis vaccine be reinstated at eighteen months (NHMRC, 100th session, 1985, p.30).

These developments resulted in a revised version of the 1981 immunisation procedures and these were titled 'Immunisation Procedures 1986' (NHMRC, 100th session, 1985, p.30). Pertussis became a nationally notifiable disease again in 1991 with the requirement that both confirmed cases and probable cases of pertussis be notified (NNDSS, 2006).

3.2 THE NEUROLOGICAL COMPLICATIONS 1990

In the early 1990's, the NHMRC noticed there was an underuse of the pertussis vaccine in Victoria (Burgess M, 1994). A survey of health care practitioners (HCP), vaccine providers, general practitioners and pediatricians, revealed many had doubts about the safety of the pertussis vaccine. For example, 34% of respondents to the study believed that pertussis vaccine caused brain damage and 32% were unsure (MacIntyre P and Nolan T, 1994).

The fourth dose of the pertussis vaccine was removed from the Australian schedule during 1979 – 1985 because the vaccine was believed to cause serious neurological sequelae. Including encephalopathy and permanent brain damage in one in 310,000 doses as determined by the British National Childhood Encephalopathy Study in 1980 (Alderslade, R., Bellman M.N., Rawson NSB, et al, as cited in MacIntyre P and Nolan T, 1994). A 're-analysis' of the British National Childhood Encephalopathy study (NCES) and other case-control studies in 1991 by the Institute of Medicine (IOM) concluded that pertussis vaccine was 'very rarely' associated with encephalopathy or febrile seizures (Burgess M, 1994). MacIntyre P. and Nolan T, (1994) also state there was 'little' or no scientific evidence to support the claim that pertussis vaccine is a cause of neurological damage.

MacIntyre P. and Nolan T, (1994) indicate that the Victorian health practitioners were ‘misinformed’ about the contraindications of the pertussis vaccine (as determined by the survey) and this led to the update of the NHMRC ‘s guidelines on immunisation in 1994. The guidelines were brought in line with the UK and USA “where a more liberal approach was gradually being adopted to contraindications and to the upper age limit for pertussis vaccine” (Burgess M, 1994).

The more liberalised attitude was based upon epidemiological evidence and referred to changes to ‘what was considered’ a contraindication to pertussis vaccine as well as an increase in the upper-age limit for immunisation with pertussis, even though the components of the vaccine did not change (Burgess M, 1994).

The Australian College of Paediatrics (ACP) endorsed this liberalization of the contraindications and it was adopted in the immunisation guidelines by the NHMRC in 1994. However, there was no consensus within the medical profession about what the contraindications should be. This is illustrated in **Table 3** below.

Table 3 - The Conflict that exists about Contraindications between Medical Institutions

National Health and Medical Research Council (NHMRC).	Infants with a family history of neurological disease (ND), stable or progressive, should not have pertussis vaccines. Including recent convulsions. This is a contraindication to the pertussis vaccine.
American Academy of Pediatrics (AAP).	A family history of neurological illness (ND) is NOT a contraindication to pertussis vaccines. Infants with stable ND should be vaccinated (e.g. cerebral palsy and developmental delay) and those with progressive ND should not be vaccinated.
Australian College of Pediatrics (ACP).	The ACP has decided to adopt the AAP guidelines which disagree with the NHMRC
Vaccine Manufacturers Package Insert	These contraindications are in agreement with the NHMRC contraindications listed above and are the same as those listed by the NHMRC for 1981 and 1986.

Reference: Zeigler et al, 1991, The ACP, Pertussis Policy Committee, *Journal of Paediatrics and Child Health*, 27 (1): p.16-20.

A comparison of the changes made to the contraindications from 1954 to 1994 is given in **Appendix 2**.

The Contraindications to Pertussis Vaccine adopted in 1994

The two conditions that were now considered absolute contraindications to immunisation with pertussis vaccine were:

1. Encephalopathy without another cause within seven days of vaccination. This does not include febrile convulsions.
2. Immediate severe allergic reaction, for example, anaphylaxis occurring after pertussis-containing vaccines (NHMRC, 2003).

3.3 THE PREMISE FOR VACCINE ASSESSMENTS

Assessments about vaccines by the ACP are made from the perspective that the benefits of the pertussis vaccine greatly exceed the risks based on the evidence of a resurgence of whooping cough when immunisation rates fall and a claim that there is a far greater incidence of complications associated with natural disease (Zeigler et al, 1991). Therefore it was decided in 1991 that the best way to control pertussis disease in Australia was through measures to improve community acceptance of the current vaccine (Zeigler et al, 1991). The ACP admits there is a great deal of disagreement about the contraindications to pertussis vaccine amongst the medical profession (Zeigler et al, 1991).

3.4 THE IMMUNISE AUSTRALIA PROGRAM

Although Australia had long standing mass childhood immunisation programs prior to 1990 regular outbreaks of vaccine preventable diseases were still occurring at high levels in the 1990's (Dept. Health, 2004). The Department of Health and Aging implemented The Immunise Australia Program (IAP) in 1993 on the basis that higher levels of herd immunity were required to interrupt transmission of pathogenic organisms and therefore eliminate infectious diseases (Dept. Health, 2004). Hawe P, (1994) explains that highly contagious diseases such as whooping cough and measles require vaccination rates of 94 – 97% to eliminate them.

Therefore, the aim of the Immunise Australia Program, as stated by the Department of Health and Aging, was to reduce morbidity and mortality from vaccine preventable diseases by focusing on increasing national childhood immunisation rates. This program aimed to coordinate activities across many sectors in order to control epidemics through higher childhood vaccination rates (Hawe P, 1994).

The National Immunisation Strategy (NIS) of 1993 expanded previous campaigns against vaccine preventable diseases on the advice of the NHMRC in the early 1990's (Dept. Health, 2004). Studies quoted by the Department of Health indicated that the government "needed to get better at attracting parents to vaccination and making sure that their experience with vaccination keeps them committed." This evidence was used to design the Government's immunisation policy (Hawe P, 1994). The government believed that regular outbreaks of vaccine preventable diseases are still occurring because immunisation rates are not high enough due to the complacency of parents (Dept. Health, 2004).

The aim of the new strategy was to co-ordinate the States and Territories in a national vaccination campaign to reduce infectious childhood diseases. It stated, "immunisation is a simple, safe, and effective way of protecting children against certain diseases. The risks of these diseases are far greater than the very small risks of immunisation" (Dept. Health, 2004). Central features of the 1993 strategy included free childhood vaccines, improved standards for maintaining vaccine quality and increased surveillance and reporting of vaccine preventable diseases (Dept. Health, 2004). It was thought that immunisation levels would improve if the Commonwealth Government contributed to the access and delivery of health services as well as to improved health education, surveillance of disease and immunisation coverage (Hawe P, 1994). This would require greater cooperation between the public and private sector interests and the removal of financial barriers to vaccination (Hawe P, 1994).

The NIS was estimated to need a budget of \$53 million to operate. In the budget of 1994 an allocation of \$9.6 million was made (Hawe P, 1994). Hawe P (1994) concludes that the implication is "that the marginal benefit of extending vaccinations upwards of 95% of children is not felt to be worth the additional cost. As higher and higher levels of vaccination are reached, costs will increase as hard-to-reach groups are followed." Hawe P, (1994) states that the Commonwealth Government did not properly fund the NIS and that this required economic justification. The lack of funding, according to Hawe P, (1994) resulted in partial implementation of the strategy and hence the quality of practice and surveillance of vaccination was threatened. Hawe P, (1994) also makes the comment that as higher and higher levels of vaccination are reached, the assessments of personal risk and benefits made by parents may alter and these will require further investigation if immunisation programs are to be successful.

In 1994 a fifth dose of the pertussis vaccine was introduced into the Australian childhood schedule at 5 years of age. This was based on evidence of increased pertussis incidence in school-aged children and with reference to current American and Canadian practices (CDI, 1997). The belief was that this booster dose would reduce the transmission of pertussis to

younger siblings because immunity from four doses of pertussis vaccine was known to be of short duration (CDI, 1997) Zeigler et al, (1991) claim the immunity due to Australian whole-cell vaccines wanes after 2 to 3 years so extra booster shots have been included in the childhood schedule.

3.5 THE SEVEN POINT PLAN 1997-2002

As a consequence of the regular outbreaks of pertussis still occurring in 1997, a 'seven-point plan' was introduced to lift vaccination rates. The outbreaks were again blamed on low vaccination rates. This plan recommended combined strategies aimed at parents and infrastructure designed to target key childhood immunisation milestones (Dept. Health, 2004). The seven areas in which strategies were implemented included:

1. **Initiatives for parents** - In order to increase the coverage and timeliness of immunisation, a child's immunisation status was tied to eligibility for family assistance payments. Parents who do not wish to vaccinate are required to fill out a conscientious objectors form signed by a general practitioner in order to obtain the benefit.
2. **An expanded role for General Practitioner's** – a financial incentive scheme for general practitioners was implemented in July 1998 to encourage GP's to monitor, promote and provide age appropriate immunisation services to children less than seven years of age. The GPII Scheme aims to encourage at least 90% of practices to fully immunise 90% of children less than seven years of age attending their practices. It is made up of three components as described by the Department of Health:
 - A Service Incentive Payment (SIP) - an \$18.50 payment to GPs and Other Medical Practitioners, who notify the Australian Childhood Immunisation Register (ACIR) of a vaccination that completes an immunisation schedule according to the National Immunisation Program.
 - An Outcomes Payment - a payment to practices that achieve 90% or greater immunisation coverage of children less than seven years of age attending their practices.
 - Immunisation infrastructure funding - which provides funds to Divisions of General practice, State-Based Organizations and funding for a National GP Immunisation Coordinator to improve the proportion of children who are immunised at local, state and national levels.

3. **Monitoring and evaluation of immunisation targets** - The Australian Childhood Immunisation Register (ACIR) was established in 1996 to get a more accurate measure of immunisation rates. Quarterly reporting of these immunisation rates began in 1997 to encourage competition and improvements for areas of low coverage. These rates are published in Communicable Diseases Intelligence (CDI).
4. **Immunisation Days:** Mass immunisation days were arranged by the State and Territory governments in 1997 to increase immunisation coverage. Children aged 0 – 6 years old were targeted and in later years adolescents and adults have also been targeted.
5. **Measles Eradication**
6. **Education and Research** - Education activities for parents and providers were presented to improve knowledge and awareness of vaccination as well as to create acceptance for age appropriate childhood immunisation. Parents of children aged 0-6 were targeted in the campaign called 'Immunize Australia'. Education for service providers included an update of the NHMRC's policies and guidelines relating to immunisation delivery and clarification of the contraindications to vaccination. The National Center for Immunisation and Research Surveillance (NCIRS) was established by the Australian Government Department of Health and Aging, at the children's hospital at Westmead. Its purpose is to carry out research and give independent expert advice about all aspects of vaccine preventable diseases, particularly in children.
7. **School entry requirements** - This initiative requires that parents submit details of children's immunisation histories when they are enrolling at school. In the event of an outbreak of a vaccine preventable disease a non-immunized child will be asked to stay home from school to minimise the spread of the disease.

All initiatives of the seven-point plan were implemented and the medical profession believes this has created a framework for maintaining long-term high levels of immunisation in the Australian population (Dept. Health, 2004).

3.6 THE ACELLULAR PERTUSSIS VACCINE

In 1997, the NHMRC (2003) recommended the use of acellular pertussis vaccines (DTPa) and these were funded for use in booster vaccinations (18 months and 5 years of age). They were funded for the primary schedule in 1999 and had replaced the whole-cell pertussis vaccine by

2004. This was recommended by the NHMRC due to safety concerns regarding whole-cell vaccines (NHMRC, 2003). It is believed that acellular vaccines are significantly less reactogenic than whole-cell pertussis vaccines causing fewer local reactions and less fever and other systemic reactions (NHMRC, 2003). Whilst hypotonic-hyporesponsive episodes can still occur with acellular vaccines they are thought to be less common than with whole-cell vaccines (NHMRC, 2003, p.174).

The acellular vaccines contain three or more purified components of *B. pertussis* including pertussis toxin, filamentous haemagglutinin, pertactin and fimbrial antigens or agglutinogens (Dept. Health, 2004). It is claimed by the NHMRC (2003) that three or more antigens in acellular vaccines have similar efficacy to 'good quality' whole-cell vaccines. Zeigler et al, (1991) claim the immunity due to Australian whole-cell vaccine wanes after 2 to 3 years. This was the justification for adding the fifth dose of DTPw at five years of age in 1994.

3.7 POLICY DEVELOPMENT 2003-2006

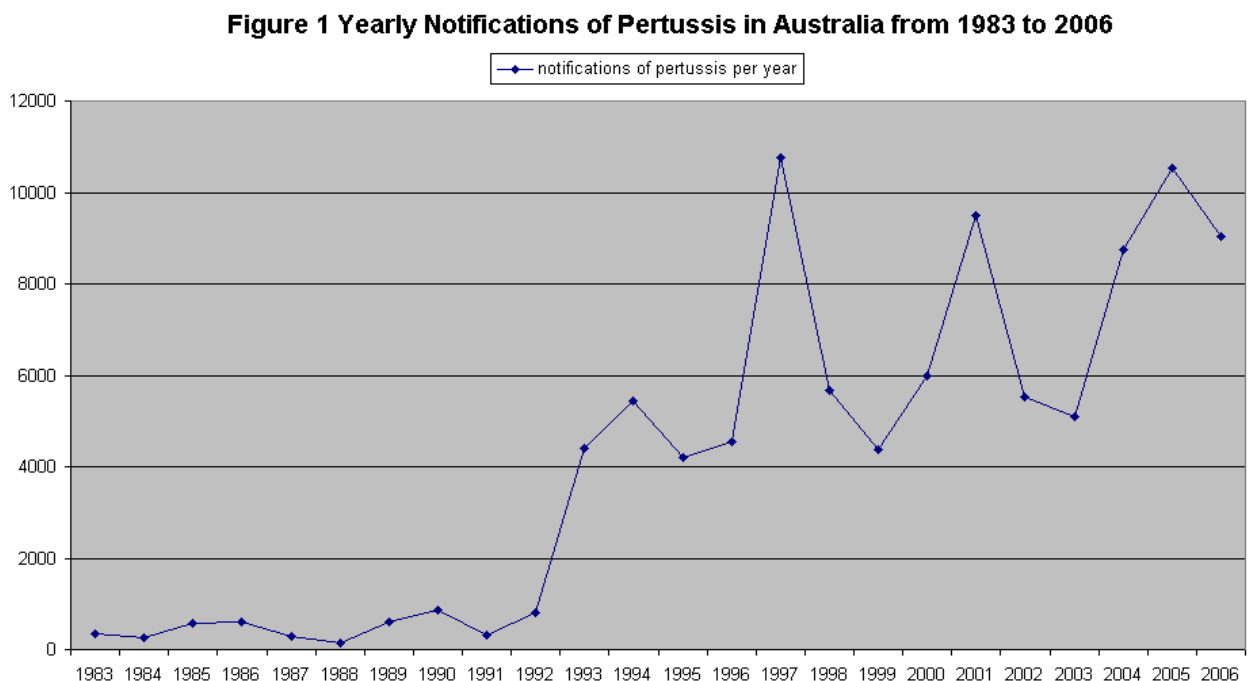
In 2003, the NHMRC claimed that outbreaks of pertussis still occur every three to four years in vaccinated populations but the outbreaks are smaller and have greatly reduced mortality and morbidity. This document does not support this statement with evidence of smaller outbreaks or the mortality and morbidity rates for different age groups of the Australian population. In fact, it states, "there are more cases of pertussis reported in the nineties than at any time since the 1960's" (p.173). The NHMRC (2003) uses global evidence to support its pertussis vaccination policy by stating 250,000 children are killed each year worldwide.

According to the NHMRC (2003) many cases of pertussis are now being recognized in adults and adolescents in highly immunized communities and this is said to be because of the waning immunity of the vaccine and increased availability of serological testing. Adolescents and adults are a significant reservoir of infection for babies too young to be vaccinated (NHMRC, 2003). It concludes that this increase in reporting may be largely due to increased serological diagnosis in older persons but there were nine deaths due to pertussis in children under one from 1993 to 1997.

Notification rates from 1993-1997 were highest amongst infants and school-aged children (CDI, 1997). Since 1991 notification rates in Australia have been ten times higher than those in the USA and three times higher than in England and Wales (Andrews R et al, 1997). The NHMRC (2003) suggests that despite this overall increase in notifications, the fifth dose of DTP introduced into the childhood schedule in 1994 is responsible for the decreased

notifications observed in the 5-9 year age group from 1999 onwards. The Council continues by saying Australia now has 60% of notifications in the over 10 year age group.

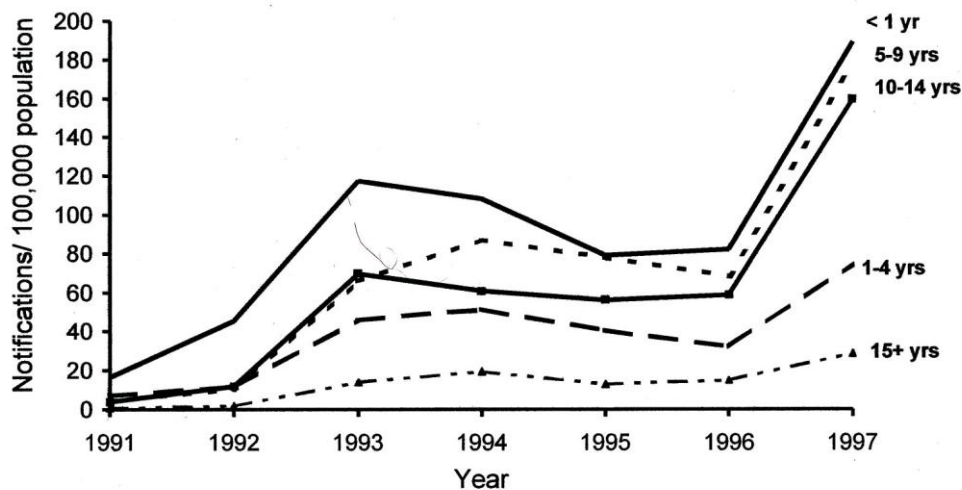
Pertussis became a nationally notifiable disease in 1991 and **Figure 1** below illustrates the change in notifications from the eighties to the nineties. It also illustrates the increasing incidence of pertussis in the nineties with a large peak in 1997-8 and another large peak in 2001 and 2005. Vaccination rates also increased in the nineties.



Reference: Commonwealth Department of Community Services and Health, The Official Commonwealth Yearbook of Australia, 1989: Department of Health and Ageing, NNDSS, 2006

Figure 2 below shows particularly high notifications in the 0-4 years and 5-9 year age groups from 1993 – 1998. Notifications remain high in the 0-4 age group from 1999 - 2005 and this is the age group of highest mortality and vaccination rates. **Figure 2** also shows an increase in notifications in the 10-14 year age group from 1999-2004.

Figure 2 Pertussis age specific notification rate 1991-97



Source: Andrews et al, 1997 and later data from NNDSS

The NHMRC (2003) claims this data on notifications supports the need for booster doses in individuals over the age of ten years in order to reduce morbidity in this age group and to reduce the transmission of pertussis to those most at risk - infants less than six months of age (p.174). Mortality and morbidity statistics in adolescents and adults are not given.

3.8 SCHEDULE FOR PERTUSSIS IMMUNISATION 2003

The NHMRC (2003) states that the primary course of the DTPa vaccine should be given at 2,4 and 6 months of age unless there is an absolute contraindication. In 2003, it was decided that the primary course of vaccines (2, 4 and 6 months of age) using DTPa produces prolonged immunity, so the 18-month dose is no longer recommended (NHMRC, 2003). The fourth dose is now due at four years of age (NHMRC, 2003).

The adult/adolescent booster vaccine for pertussis has lower antigen content (particularly diphtheria and pertussis antigens) therefore it is referred to as dTpa. Information on the duration of immunity of a single booster dose of dTpa is limited so no recommendation of further booster doses is being made at this time (NHMRC, 2003, p.177).

It is recommended by NHMRC (2003) that booster shots of dTpa be given to the following groups of individuals in the Australian population:

1. Adolescents at 15 to 17 years of age replacing the ADT (adult diphtheria and tetanus vaccine).
2. Before planning pregnancy or for both parents as soon as possible after delivery of an infant. Unless contraindicated by an expert opinion.
3. For adults working with young children. Immunisation is especially recommended for health-care workers and child-care workers in contact with the youngest infants. For example, maternity and nursery staff unless contraindicated.
4. An adult expressing an interest in receiving a booster dose of dTpa should be encouraged to do so provided the primary course of DTP vaccine has been given in the past. Otherwise ADT should be used.

3.9 ADVERSE EVENTS WITH ACELLULAR PERTUSSIS VACCINES

The following guidelines concerning reactions to the DTPa vaccine are the guidelines given to Healthcare Practitioners from the NHMRC Australian Immunisation Handbook (8th ed), 2003.

1. Studies have shown an increase in the incidence of local reactions in children boosted at 18 months with the acellular vaccine that they received for their primary series. The reactogenicity associated with the fifth dose of acellular vaccine in Australia is yet to be determined, as children who have received a full primary course of acellular vaccine have not yet received their booster at four years of age. It is currently recommended that the same acellular vaccine be used for this booster as was used for the primary course.
2. Paracetamol is not recommended routinely to reduce effects from adverse reactions for children receiving acellular pertussis vaccine.
3. A febrile convulsion after a DTPa injection can indicate an increased risk following the second dose. However, vaccination is still recommended as the risk can be minimized by appropriate measures to prevent fever.
4. Pertussis vaccine does not cause infantile spasms or epilepsy. Vaccine-induced fever 'may uncommonly' lead to a febrile convulsion. The risk is even lower in infants who complete their primary course by six months of age.
5. Sudden infant death syndrome (SIDS) is not associated with DTPa or any pertussis-containing vaccine.
6. It is noted that the incidence of acute neurological complications after pertussis disease in unvaccinated individuals (more than 1% of cases) is considerably higher than after vaccination (estimates range from 0 to 10 per million vaccinations).

7. There are only two absolute contraindications to the DTPa vaccine.

3.10 MANDATORY VACCINATION

The Federal Government implemented a new Policy Directive in 2006 requiring all health students to be fully vaccinated before commencing or completing their practical work (NSW Dept. Health, 2005). This policy directive is mandatory and the list of required shots consists of 10 vaccines, including pertussis (NSW Dept. Health, 2005). The Policy Directive for NSW states that all health students who are affiliated with the hospital system or with NSW Health are required to be vaccinated. The Initiative is called Policy Directive 2005_338. It will be extended in 2007 to include all health professionals and employees of the health system (NSW Dept. Health, 2005).

3.11 PHARMACEUTICAL FUNDING

Pharmaceutical companies are being allowed to fund health professionals to vaccinate. This initiative assists in raising vaccination rates. An example is the Infanrix Immunisation Awards (PHAA, 2006). Infanrix is a combination diphtheria, tetanus and acellular pertussis vaccine manufactured by the multinational pharmaceutical company GlaxoSmithKline (NHMRC, 2003). The awards of \$10,000 are offered to commend professionals that have implemented programs or initiatives over the past five years that have successfully achieved the following outcomes:

1. A significant increase in immunisation coverage in the four year-old cohort or
2. A significant increase in immunisation coverage rates in populations of hard-to-reach children and/or adolescents.

These awards were presented at the National PHAA Immunisation Conference in 2006 (PHAA, 2006).

4 RESEARCH QUESTION 2: WHAT ARE THE EXPECTED OUTCOMES OF THIS POLICY?

The aim of this policy in 1954 was to reduce mortality and morbidity associated with pertussis disease. In 1954 it was believed that lasting immunity could be produced in an individual by injecting a modified pathogen that would result in sub-clinical infection with only trivial symptoms of the disease. This is called passive-active immunisation (Burnet M, 1952). Another principle of this theory is that of Herd Immunity.

Herd immunity suggests that if a large percentage of the population is vaccinated then the unvaccinated group will benefit from some degree of protection because the pathogen is prevented from circulating (Collee G, 1984). The theory of Herd immunity applies to diseases that are transmitted from person to person (Collee G, 1984). This is because infectious diseases such as pertussis are more easily spread if there are large numbers of susceptible individuals to infect (Collee G, 1984). It was also believed at this time that diseases could be eradicated if the number of susceptible individuals was significantly reduced (Collee G, 1984). This is the underlying theory supporting the Government's pertussis vaccination policy (Dept. Health, 2004).

It is constantly stated in the Government's policy "immunisation is the most effective means of controlling the incidence of pertussis in our community". Hence, the aim of the policy changed from reducing the mortality and morbidity of pertussis in 1954 to an emphasis on increasing the vaccination rate of the population in 1993. The emphasis on increasing vaccination rates assumes that reducing the incidence of this disease will also reduce mortality and morbidity from pertussis. The push for higher vaccination rates began in 1980 when infant immunisation was strongly emphasized and this intensified in the 1990's with the Immunise Australia Program.

Policy Outcomes

1. To reduce mortality and morbidity due to pertussis
2. To increase vaccination rates in order to lower the incidence of pertussis in the community.

5 RESEARCH QUESTION 3: IS THE GOVERNMENT'S PERTUSSIS IMMUNISATION POLICY ACHIEVING ITS OBJECTIVES?

5.1 THE EFFECT OF PERTUSSIS VACCINE ON MORTALITY

The Australian Government's vaccination policy is founded upon the principle that pertussis vaccine was responsible for the reduction in pertussis disease that was observed throughout the twentieth century. This premise is not supported by the evidence presented in the development of this policy in Part 3.

Whilst it is possible to claim that the first vaccines were produced in Australia in 1920, there is no evidence that the uptake of this vaccine was extensive prior to 1954 (Com. Yearbook, 1953: Tinnion ON and Hanlon M, 1998). The pertussis vaccine was available to individual practitioners and local authorities in some states before 1954 and free immunisation was being offered but it was not used as extensively as the diphtheria vaccine because of the significant decline in whooping cough that had occurred before 1950 (Com. Yearbook, 1953, p.278).

The vaccine for pertussis has been questioned on grounds of both efficacy and safety ever since it was introduced into mass vaccination programs in Australia in 1953 (Goldsmid J, 1988, p65). Goldsmid (1988) also notes that the use of the triple antigen (DTP) in general has been queried particularly in light of the decreasing prevalence of the diseases themselves prior to immunisation.

The first Australian vaccines were very crude and there were many concerns about its safety and efficacy (Smith A, 1999). The CDI (1997) claims that the early vaccines reduced the incidence and severity of pertussis disease but they were not as efficacious as current vaccines. There is no evidence given to support this claim. It needs to be supported by an accurate knowledge of how widespread the use of this vaccine was in Australia before 1954 as well as studies that show the change in incidence and severity of the disease.

Available documents state that the vaccine was not used routinely or extensively until 1954. The decline in the mortality and morbidity of this disease occurred before 1950 and this is clarified by the fact that it was removed from the National Notifiable Disease list in 1950 (Com. Yearbook, 1953). **Table 1** (Part 1) clearly shows that pertussis mortality had declined significantly by this time.

The Government has presented the mortality figures due to pertussis in groups of years to support the claim that there was a significant drop in mortality from 1956 to the present time.

Table 4 illustrates this point:

Table 4 – Number of Deaths from Pertussis by Decade from 1926

Decade	Mortality
1926 - 1935	2,808
1936 - 1945	1,693
1946 - 1955	429
1956 – 1965	58
1966 – 1975	22
1976 – 1985	14
1986 - 1995	9
1996 - 2002	15

Reference - Feery B, One Hundred years of Vaccination. *Public Health Bull* 1997 as cited in CDI, 2002, Vol 28 suppl 2.

However, if the data is examined on an annual basis from 1946, the extent of the decline prior to 1950 is easily observed. This is illustrated in **Table 5** below:

Table 5 – Deaths due to Pertussis from 1946-1950

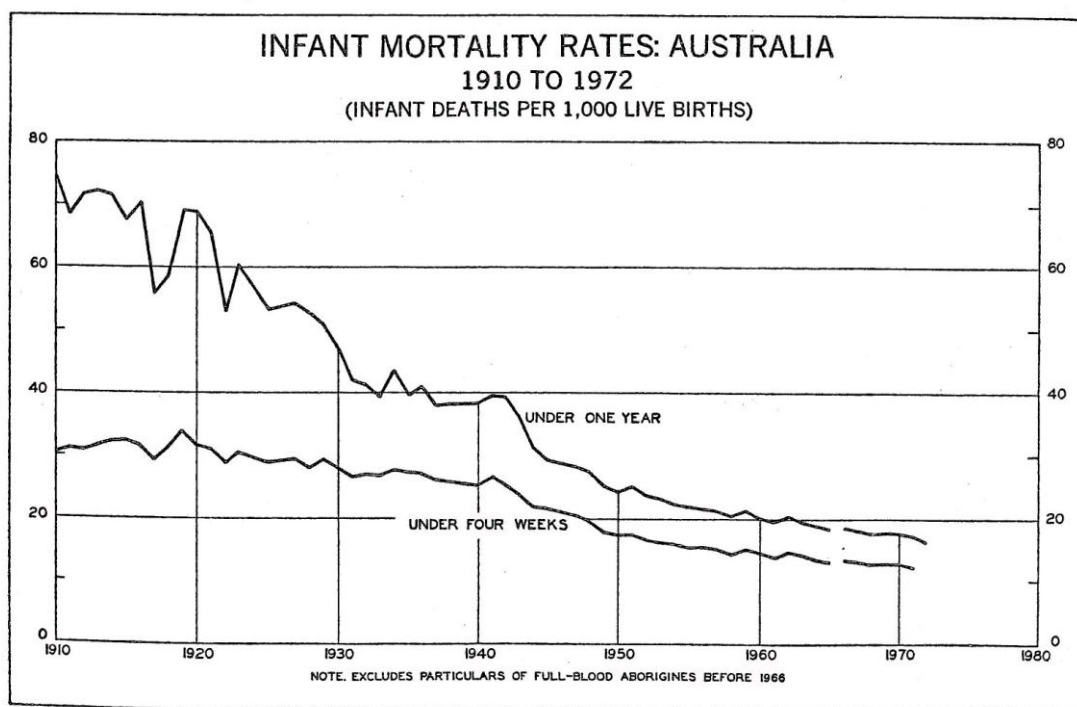
Year 1946-1950	Deaths due Pertussis
1946	74
1947	75
1948	65
1949	73
1950	34

Reference: Official Commonwealth Yearbook of Australia, 1945-1946.

There has been a steady decline in pertussis disease from 1926 onwards, despite the increase in population size that was occurring. As a suitable pertussis vaccine was not introduced into a routine immunisation schedule in infants until 1954, it would appear the decline was due to other factors.

The infant mortality rate also declined steadily throughout the twentieth century and there was no significant drop in mortality in the 1950's when routine vaccination for many diseases was introduced. This is illustrated in **Figure 3** below.

Figure 3: Infant Mortality Rates in Australia



Reference - Official Commonwealth Yearbook of Australia, 1973, No. 59, p.183

It is clear from this graph that the most significant decline in infant mortality occurred prior to 1950 and as the graph shows a steady continual decline that began early in the twentieth century it cannot be a result of immunisation programs implemented in the late 1950's. However, there may be hidden effects due to the vaccine and these could have been determined if information regarding the vaccination status of cases of pertussis disease had been recorded. This data has not been provided.

These statistics support the beliefs of Public Health officials in 1950, such as Lancaster HO, Cumpston JHL and Burnet M, who state that social medicine including improvements in living

standards, fitness, nutrition, breast-feeding, family size and sanitary reform were the most significant factors in reducing mortality due to pertussis in Australia (Refer Part 2.2).

Lancaster H.O, (1956b) states that the infant death rate due to pertussis declined from 1.735/1000 live births in 1908 to 0.091/1000 live births in the period 1951-1953. The vaccine cannot be held responsible, as immunisation programs with pertussis vaccine did not begin until 1954 (Lancaster HO, 1956a). He suggests that improved medical care cannot be responsible either as no special therapy was available for pertussis.

Stewart GT, (1977) made similar observations on the reasons for the decline of pertussis in the United Kingdom. He reported that calculations based on the mortality of whooping cough in Scotland before 1943 predict accurately the decline and present low mortality of this disease. Stewart GT, (1977) claims the decline was unaffected either by small-scale vaccination beginning about 1948 or by nationwide vaccination beginning in 1957 in the United Kingdom. This decline in pertussis mortality and morbidity was being observed in many developed countries before the introduction of national immunisation programs (Lewis M (ed), 1989).

Aboriginal populations in Australia provide further evidence of the significance of social conditions in disease prevention. These populations have had vaccination programs since 1958 yet infant mortality and morbidity rates are still high in 2006. Living conditions, sanitation and nutrition are still a problem in these communities today. The Aboriginal childhood mortality rate in 1994 -1996 was 18.6/1000 live births (3 times higher than the non-indigenous rate) (ABS, 2001) and similar to the infant mortality rate for non-indigenous Australian's in 1953. Non-indigenous Australians had an infant mortality rate of 23.3/1000 live births in 1953 (Lancaster HO, 1956a).

These statistics indicate social conditions and nutrition may have more influence on mortality and morbidity rates than immunisation for many childhood diseases. Particularly, mortality and morbidity due to pertussis, as this disease is considered "an index of hygiene or social wellbeing" (Lancaster, 1956b).

5.2 THE EFFICACY OF THE PERTUSSIS VACCINE

Behrman et al, (1998) state the efficacy of pertussis whole-cell vaccine to be 70 – 90 percent. They claim the vaccine does not stimulate antibody production in one hundred percent of individuals therefore they remain unprotected from infection. In addition, it is known that outbreaks of pertussis have been common in urban areas in fully immunized children

(Behrman et al, 1998, p.363). It leads us to question whether this is because the bacteria revert to virulence or because uptake of the vaccine was unsuccessful. Refer **Appendix 3**.

The Australian college of Paediatrics (ACP) (1991) admits that there are wide variations in the estimates for the efficacy of pertussis vaccine and there are many potential biases in ascertaining cases of pertussis and immunisation status. Efficacy estimates from different studies indicate a range of 40 – 90% (Zeigler et al, 1991). This range is a result of the significant differences in the design of the different studies (Zeigler et al, 1991). In fact, the effectiveness of the Australian whole-cell pertussis vaccine has never been tested (NHMRC, (1997) as cited in Andrews R, Herceg A, and Roberts C, 1997).

It is known that the efficacy of the vaccine may also vary according to the prevalent strains of pertussis and the ability of different vaccines to induce immunity against specific strains (Zeigler et al, 1991). The symptoms of pertussis disease can be produced in humans by several bacteria (Part 1). However, the vaccine only protects against *B.pertussis* bacteria (Khelef N et al, 1993). The claim is often made that pertussis is increasing in frequency in areas where immunisation has declined (Behrman et al, 1998, p. 364). This is an unsupported statement and contradicts the fact that outbreaks are occurring in fully immunized children and in countries where immunisation rates have been high for the last two decades (Wendleboe et al, 2005; Burgess M et al, 1998).

In a study by the Communicable Diseases Intelligence in 1985, it was found that 73 percent of the 15 patients of vaccine age (19 months) who got infected with whooping cough had 2 or more doses of vaccine. This evidence does not support a case for vaccinating children under six months of age, as they do not receive the third dose until six months. Statements from the ACP also indicate there is no benefit under six months of age. They say, with regard to the schedule of doses, there is clear evidence that “two doses are inadequate and suggestive evidence that four or five doses are more effective than three” (Zeigler et al, 1991, p.16).

Stewart GT, (1977) claims that precise information about the efficacy and safety of this vaccine is lacking due to the existing provision of national and international epidemiological surveillance.

In 1966, Adams I. and Barron A, reported “Pertussis is a disease which in the public mind does not carry with it a fear of high mortality or lifelong morbidity. The vaccine, which gives a high degree of protection, (although not complete) has been in use for many years. It is therefore of interest to note that pertussis epidemics continue to occur in Australian communities with considerable regularity.”

Pertussis was considered at this time to be a disease of low morbidity and mortality despite the epidemics. **Table 1** (Part 1) indicates that mortality due to pertussis in 1966 was 4 deaths per year. This article reports that pertussis was occurring largely in unimmunised children in the Sydney community. The information to support this statement is given in **Table 6**.

Table 6 - Immunisation Status of a Group of Children Admitted to Sydney Metropolitan Hospitals in 1964 with Pertussis

Immunisation Status	Number	Percent
Unimmunised	81	59
Partly Immunised	19	14
Immunised	37	27
Total	137	100

Reference: Adams I. and Barron A, 1966, MJA, Vol. 1, No.2.

The authors concluded from the information in **Table 6**, that the majority of patients had received no immunisation or if they had commenced their immunisation, they had failed to complete it (Adams I. and Barron A, 1966).

It is interesting to examine this table from a different perspective. It is possible to say 41% of these children were fully or partially immunised and 59% of them were unimmunised. If the 6.5% fewer than two months are not included because they are ineligible for immunisation, this leaves 52.5% of the cases unimmunised. These figures are compared in **Table 7**.

Table 7 - Immunisation Status of a Group of Children Admitted to Sydney Metropolitan Hospitals in 1964 with Pertussis

Immunisation Status	Number	Percent
Under two months	9	6.5
Fully or partially immunised	56	41
Unimmunised	72	52.5
Total	137	100

Nearly half of the children who got pertussis had some immunisation status. The reason for immunizing is to gain some protection from the disease. The statistics indicate that one-third of fully vaccinated children still got infected with pertussis. This does not support the earlier statement that 'the vaccine gives a high degree of protection.' The ACP (1991) agrees that two doses are inadequate yet infants are vaccinated at two months of age.

Sweden and Japan both stopped vaccinating with DTPw in 1975 because of the low efficacy and high potential risk of the vaccine (Sato Yet al, 1984). Vaccination recommenced in Japan in late 1975 but only in children older than two years of age (Kimura M and Kuno-Sakai H, 1990). Acceptance rates for the whole cell vaccine had dropped and incidence of pertussis disease increased, so Japan changed to the acellular vaccine in 1981 in older children (Sato Y et al, 1984) and in infants from three months of age in 1989 (CDI, 1997).

To assess the true situation in these countries it is necessary to know the changes in mortality and morbidity rates that have occurred and not the changes in incidence of pertussis that is given in these articles. This is because the disease is caused by several bacteria species and also because the incidence of the disease does not indicate the severity of the disease, as the disease is not of significance in all age groups (Burnet M, 1952: Stewart GT, 1977).

In addition, we need to know whether vaccination in Japan is compulsory or discretionary, as it is in many European countries. If the pertussis vaccination policy is based upon the incidence of pertussis then we would expect to see a lower incidence of pertussis disease in countries with high vaccination rates. This is not the case. Epidemics of pertussis are being described in the United Kingdom, Australia and America where vaccination rates have been above 90% since 1995 (Wendleboe et al, 2005: Burgess M et al, 1998: Tinnion ON and Hanlon M, 1998) This is similar to the incidence of pertussis in European countries, such as Sweden, Germany and Italy, where immunisation with DTP vaccine is discretionary and vaccination rates are around forty percent (Tinnion ON and Hanlon M, 1998).

Stewart GT, (1977) investigated the efficacy of the pertussis vaccine in a study in Scotland in 1976. Stewart's (1977) study of incidence and severity of pertussis in family contacts found that 68% of children who were infected with pertussis were fully vaccinated (47 of 69 cases). Observations of the unvaccinated group in his study showed that a significantly higher proportion came from overcrowded homes in social classes (iv) and (v). These classes indicated lower socioeconomic status.

In Stewart's (1977) school study he found that 61% of pertussis cases were in fully vaccinated children (36 of 59 cases). He also completed a hospital study, which showed that from 1935-1953 less than half the children admitted to hospital for pertussis were infants younger than one year. However, in 1974-1975 infants formed 82% and 81% of admissions respectively. Of the 203 infants admitted to hospital most of them were partially vaccinated and they were mostly from social classes (iii), (iv) and (v).

Stewart GT, (1977) claims the only variable that differed in his study of vaccinated and unvaccinated cases was socioeconomic status. He states there was no difference in other variables such as incidence, duration or severity of illness. He concluded that no protection by vaccination is demonstrable in infants.

In 1977, Stewart described pertussis as an uncommon disease and the only group seriously at risk from pertussis was infants from crowded homes. To justify using the vaccine, he suggested it would need to be shown that it confers at least partial immunity to children 1-10 years of age and that it is not responsible for significant risk in itself (Stewart, GT, 1977).

These comments suggesting pertussis was an uncommon disease also applied to Australia in the seventies. **Table 1** indicates the mortality due to pertussis in 1973 was two deaths per year. The hidden variables of this statistic are socioeconomic status and whether the cases were vaccinated or unvaccinated. The government has not supported its policy documents with studies indicating the vaccination status of cases of pertussis (similar to Stewart's study), in order to demonstrate the protective effect of the vaccine.

The ACP states that there are two undisputed facts: 1) disease is less severe in vaccinated individuals and 2) vaccine efficacy becomes higher when more severe categories of disease are examined (Zeigler et al, 1991).

The first fact is disputed by the evidence given above from Stewart's study in 1977 and the second fact is irrelevant if a baby under six-month's of age is subjected to the 'treated' pathogen and chemicals in the vaccine carrier but cannot be guaranteed protection from the disease.

In 1974 the NHMRC stated that they knew the pertussis vaccine was not as effective as other vaccines but its effects 'appear' favourable in reducing the symptoms and incidence of complications. This is not a definitive statement and it is not supported by studies indicating how the vaccine has influenced the number or severity of complications due to pertussis. Although Stewart's study was small it has not been refuted with contrary evidence.

By 1991 the ACP admitted that the theory suggesting pertussis disease could be eradicated by achieving a vaccine uptake of 95% was 'probably' wrong (Zeigler et al, 1991,p.16). This is because the vaccine is thought to protect better against disease than infection (disease is classified as a severe infection), which allows the pertussis bacteria to continue to circulate (Zeigler et al, 1991). In addition, there are other bacteria causing pertussis disease that the

vaccine does not protect against and these cases are also included in notification statistics of pertussis (Khelef N et al, 1993).

5.3 SOCIOECONOMIC STATUS AND PERTUSSIS INCIDENCE

In 1966, the Public Health Department believed one factor preventing some parents from vaccinating was complacency (Adams I. and Barron A, 1966). Parents were thought to be complacent because they couldn't see the effects of infectious diseases in the community so they weren't frightened enough to have their children vaccinated (Adams I. and Barron A, 1966). The public health officers in 1966 believed that it was the community members with higher educational achievements that could be expected to cooperate with vaccination programs for diseases that were no longer obvious in the population (Adams I. and Barron A, 1966).

The aim of the study designed by Adams I. and Barron A, (1966) was to test the hypothesis that mothers in the Sydney community with a higher educational achievement were more likely to vaccinate their children. The authors concluded from their results that this hypothesis was correct. However, another consequence of lower educational attainment can be inadequate hygiene and nutrition in the home. If we accept that pertussis disease is associated with lower living standards (Burnet M, 1952: Lancaster HO, 1956a) then we could also conclude that there would be a greater susceptibility to pertussis in these households.

The study found that "41% of the unimmunised group lived under less than optimal conditions as compared to only 18% of the immunised children." A comparison of the father's occupation showed that the majority of the cases with pertussis had fathers with professions classified as 'skilled' or 'semi-skilled and unskilled' (Adams I. and Barron A, 1966). Profession is used as a proxy for indicating the socioeconomic status of the family.

The authors concluded that mothers with lower educational achievement are more likely to have unimmunised children. But we could also conclude children in these households will be more likely to get pertussis because of a lower standard of living not because they are unvaccinated. This study did not account for this confounder in the results.

5.4 HIDDEN VARIABLES AND STATISTICS

Three of the hidden variables in pertussis incidence statistics include vaccination status, socioeconomic status and the pathogen responsible for causing the disease. If these variables

are not recorded then it is impossible to determine what effect the vaccine is having in reducing mortality due to this disease.

Pertussis is endemic in Australia despite vaccination rates of 85-90% since 1991 (NHMRC, 1991). It became a nationally notifiable disease in Australia in 1990 (CDI, 1997). Prior to this it was only notifiable in some states and case definitions varied between the states (Com. Year, 1953-1986: NHMRC, 1978). Notification figures for pertussis disease in Australia include both probable and confirmed cases of pertussis (Dept. Health, NNDSS, 2005). The definitions for confirmed and probable cases of pertussis are:

1. **Confirmed** cases are those that identify the *B.pertussis* bacteria by culturing techniques or cases that are confirmed by seroconversion (blood antibody levels for *B.pertussis*) in conjunction with clinical evidence (Dept. Health, NNDSS, 2005).
2. **Probable** cases of pertussis are those defined on clinical evidence of the disease alone. Clinical evidence includes coughing that lasts for two weeks or more and paroxysms of coughing or inspiratory whoop or post-tussive vomiting (Dept. Health, NNDSS, 2005).

It is known that three or more microorganisms can cause this disease yet the requirements for pertussis notification do not include confirmation that *B.pertussis* is the causative bacteria. Therefore notification statistics are not a true indicator for the incidence of *B.pertussis* disease in the Australian population.

The increase in notifications of pertussis disease in Australia has been affected by the introduction of laboratory reporting techniques and serological testing as well as an increase in the awareness of the disease and the requirement to notify the disease on a clinical basis (CDI, 1997). The inclusion of cases on a clinical diagnosis means that cases caused by other species of bacteria will also be included (Scheil W et al, 1998).

As a result of these variables it is not possible to compare the incidence of pertussis in or between countries. A comparison of pertussis incidence between countries also requires knowledge of whether vaccination is mandatory or discretionary. In Australia it is discretionary, however it is perceived to be mandatory because it is tied to welfare benefits and school entry. This places a strong emphasis on the importance of vaccination and encourages parents to vaccinate. Hence the vaccination rate is much higher in Australia than in many European countries where vaccination is truly discretionary.

Government documents constantly discuss the epidemics that have occurred in Australia since pertussis became a notifiable disease in 1990 (NHMRC, 1991: CDI, 1997: Burgess M et al, 1998). Coinciding with this large increase in the incidence of pertussis in Australia in the nineties is the increase in the vaccination rates in Australian children (NCIRS, 2005). This began with the implementation of the Immunise Australia Program in 1993 and continued with the seven-point plan in 1997.

There has also been a particular increase in the incidence of pertussis in children ten to fourteen years old over this time (NCIRS, 2005). Interestingly, the vaccination status of notified cases of pertussis since 1990 has not been recorded (Andrews R et al, 1997). Therefore, it is not possible to know what influence the vaccine is having in controlling this disease.

The evidence suggests that it is having no effect in controlling the incidence of pertussis in populations as the incidence is the same in countries with high and low vaccination rates. If the vaccine controls pertussis incidence there would be fewer cases of pertussis in countries with high vaccination rates.

Burgess M et al, (1998) claim that 1997 had “the greatest number of deaths and notifications (in Australia) in decades” These authors place the blame on the anti-vaccination lobby yet Australia had a vaccination rate of 90% plus for pertussis vaccine at this time. Some benefit from the vaccine should be observable. Mortality figures were not given in the policy document until 1997 when a large number of deaths occurred. There were 21 deaths in the 20 years from 1976 – 1995 and nine deaths in the year 1997-1998 (Burgess M et al, 1998). This increase in deaths occurred as vaccination rates were increasing and they were described as significant (Burgess M et al, 1998).

Comparing the mortality rate over the years is not accurate unless the case definition of the disease is known. In order to make international comparisons, diseases have been defined by the International Classification of Diseases Treaty (ICD) since the early nineteen hundreds Refer **Appendix 4**. Many revisions have occurred since this time resulting in changes to the descriptions of diseases. An accurate comparison of deaths due to pertussis and other respiratory diseases can only be made if the case definitions for that year are known.

The classification of pertussis (whooping cough) as a cause of death in 1953 was in accordance with the sixth edition of the International Treaty on causes of death (Com.Year, 1953, p.617). This edition made fundamental changes to the selection of the main cause of death when more than one cause is listed on the death certificate. For this reason, deaths

from 1951 onwards are not strictly comparable with previous years. Yet the government has presented mortality figures from 1926 in a manner that suggests they are comparable. Shown in **Table 4**.

It is also to be noted that government documents concentrate on the notifications of pertussis disease and not the mortality of the disease. This leaves the public and medical professionals to assume that notifications are an indicator of the incidence of *B.pertussis* and that a lower incidence of pertussis disease will result in lower mortality. Burnet M, (1952), Stewart GT (1977) and Cumpston JHL, (1927) all state this is not the case and this is explained in the following section.

Disease Statistics

Burnet M., (1952) makes the comparison between the medical statistician's approach to disease and the practicing doctor. He observes that statistics hide many variables and focusing on the overall incidence of pertussis is not of any significance. The overall incidence of pertussis in the population does not inform us of the age-incidence of the disease nor the age-incidence of mortality and morbidity from the disease (Burnet M., 1952). Clinical severity of pertussis disease can only be determined by comparing the age-incidence in the population with the age-incidence of mortality and morbidity, because this disease is mainly severe in children under one (Burnet M., 1952).

He also states that case-fatality rates will vary greatly in different investigations because of the different criteria that can be used in diagnosing and reporting diseases (Burnet M., 1952). Stewart GT, (1977) states that notifications are incomplete indicators of prevalence and are in no way indicators of the severity of the disease. This leads us to question the significance of reporting the overall incidence of whooping cough in the population. In order for this statistic to be of any significance there needs to be a standard case-definition of the disease and its complications.

Pertussis Case-Definition

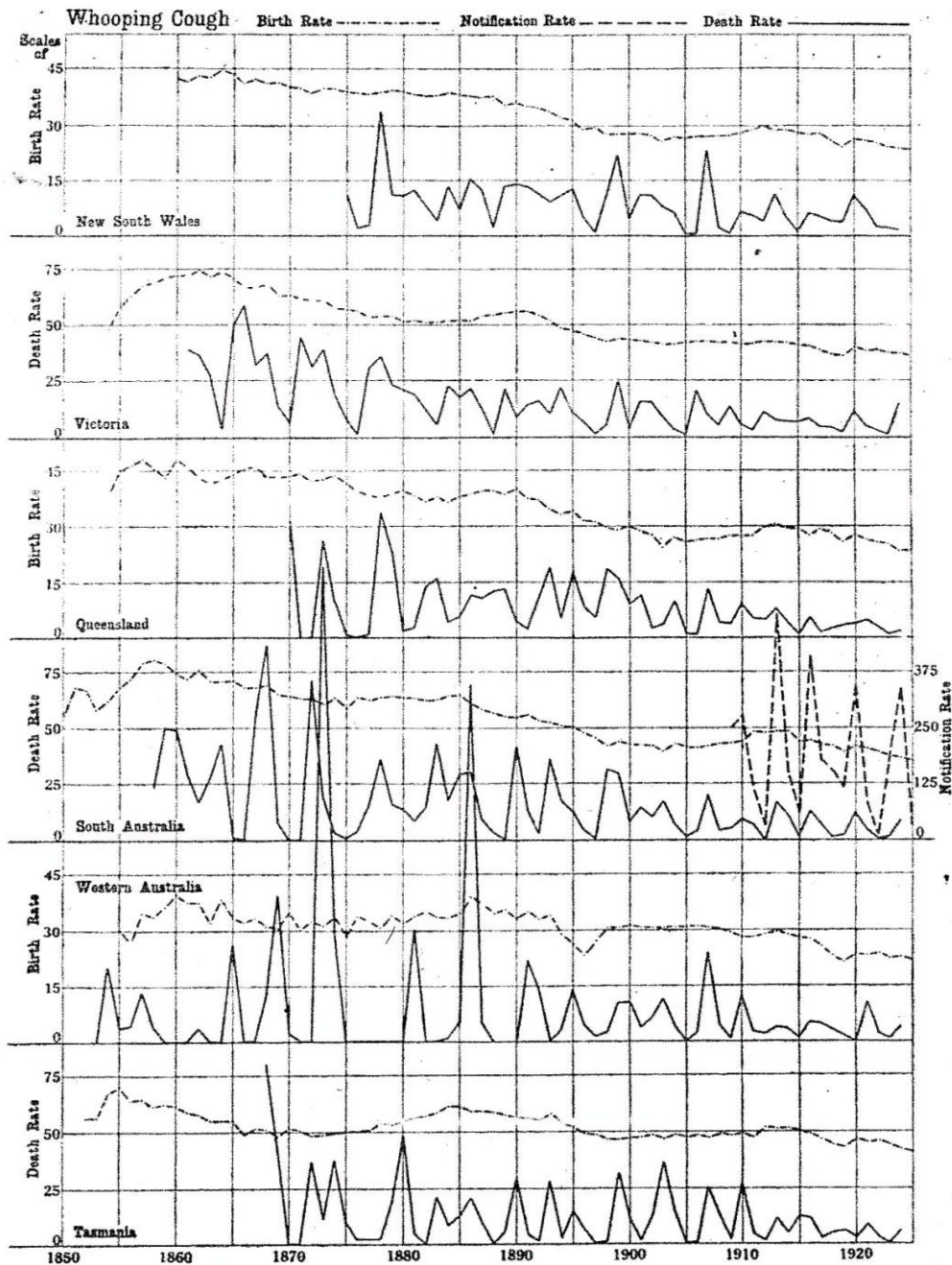
The World Health Organisation (WHO) described a case-definition for pertussis in 1991. (Smith A, 1999) It states that reported cases of pertussis must be culture or serologically confirmed, as it is known that the diagnosis is problematic with other respiratory infections (WHO as cited in Smith A, 1999). Once confirmed, the length of paroxysmal coughing indicates mild or severe cases and it must be decided which of these cases should be included in the reporting of the overall incidence.

The WHO decided cases would include those with paroxysmal coughing of twenty-one days or more. (Smith A, 1999). This definition was necessary for determining the efficacy of vaccines (Smith A, 1999). Pertussis vaccines are found to be more effective against pertussis with paroxysmal coughing of 21 days or more than cases with coughing of less than 21 days. Hence, the vaccine protects better against disease than it does against infection (Smith A, 1999: CDI, 1997). Are we to assume that infection refers to mild cases that are not associated with complications therefore we don't need to be protected by the vaccine? Or should we conclude that the vaccine is not effective in many cases of pertussis?

Even with this case-definition, publication of the overall incidence does not indicate the severity of this disease in the community because it is known that this disease is generally not of concern in adolescents and adults, particularly in the pre-vaccine era (Wendelboe A, et al, 2005). This is because most children (approximately eighty percent) were exposed to natural infection by pertussis and this confers long-term immunity (Gordan J, and Hood R, 1951 as cited in Wendelboe, AM, et al, 2005). It is thought that subsequent mild, unrecognised pertussis infection maintains a high level of immunity in adolescents and adults who have been infected in childhood (Wendleboe et al, 2005: NHMRC, 1991). However, the severity of this disease is also dependent upon the age of first contact with natural infection (Burnet M, 1952).

The reason for reporting the incidence of pertussis in all age groups is if lower incidence of the disease overall correlates to less mortality and morbidity from this disease (Cumpston J, 1927, p. 291). Cumpston J, (1989) comments that there is no evidence that notification of pertussis has affected the case-mortality of this disease (Lewis M, (ed.) 1989, p.312). He made this observation after examining the statistics on pertussis mortality in South Australia from 1909 to 1924. At this time South Australia was the only state to have compulsory notification of pertussis and he compared the reduction in mortality in South Australia to the reduction in mortality that occurred in the other States. This is illustrated in **Figure 4** below.

Figure 4 - Graphs illustrating the Birth Rates and Death Rates from Pertussis in all States in Australia. Including the Notification Rates of Pertussis per 100,000 of the South Australian Population from 1910-1924



Graph VIII.—Birth-rates, death-rates from whooping-cough for the various States; and, in South Australia, notification rates per 100,000 of cases of whooping cough.

Reference: Cumpston JHL, 1927, p.269.

The graphs indicate that there was no significant change in mortality in South Australia with respect to the other States. Mortality declined at the same rate in all States, so he concluded that notification of the overall incidence of pertussis disease had no effect on the reduction in mortality that occurred. Cumpston J, (1928) also mentions the fact that the decline in mortality from whooping cough, like measles, diphtheria and scarlet fever, occurred simultaneously to the period of sanitary reform (Lewis M., (ed.), 1989, p.312).

Cumpston J, (1989) states that whooping cough has been fatal almost entirely in the under-five age group and largely within the first year of life. Therefore, he concludes that fluctuations in the proportion of children under five and the variations in birth-rate, should be considered in relation to the death-rate from whooping cough. In other words, the death-rate will correspond to changes in the number of the susceptible population when observed over a long time interval (Lewis (ed.), 1989).

Scheil et al, (1998) claims that despite the high incidence rates of pertussis in South Australia over the nineties there has been no increase in the mortality nor hospitalisation (morbidity) for pertussis in South Australia. This suggests morbidity and mortality rates fluctuate together. Cumpston JHL, (1927) states "Whooping cough has been notifiable in South Australia since 1909. The morbidity rate has varied with the death rate and shows no feature not shown also by the death rate." (p.276).

As government documents do not give any statistics on the morbidity of pertussis from the nineteen fifties onwards we must assume that the morbidity and the mortality have been low since the 1950's as indicated in **Table 1**.

Morbidity due to Pertussis

Celermajer, J.M. and Brown J., (1966) carried out an eleven year study from 1953 – 1964 in Sydney and concluded that pertussis in the community they studied was only infrequently associated with neurological complications. They observed that these tended to be mild in nature and very rarely followed by residual neurological damage.

To determine if this observation was linked to vaccine use it would be necessary to know the immunisation rate in the population in 1953 - 1966, the vaccination status of the patients admitted with pertussis and their socioeconomic background.

Celermajer J, and Brown J, (1966) investigated 632 patients who were admitted to the children's hospital in Sydney with pertussis infection over an eleven-year period. Twelve of these patients suffered neurological complications and one patient died. The only neurological complications observed in this study of 11 years were convulsions and meningoencephalitis. These complications occurred mostly in children under two, between two days and three weeks after infection with pertussis and were most common in the second and third weeks.

Pertussigen (pertussis toxin) is the protein antigen in *B. pertussis*, which is thought to be responsible for some of the clinical symptoms of pertussis and possibly for the adverse effects of pertussis immunization (as it is also a component of the vaccine) (Feery BJ, 1982; Blumberg et al, 1993). Therefore, it would be reasonable to assume that the adverse reactions to the vaccine will be similar to the complications produced by natural infection with *B.pertussis*. Particularly as the vaccine does not induce immunity in all individuals and it is known that the pertussis bacteria can revert to virulence. Refer **Appendix 3**.

For this reason, studies of adverse reactions to the pertussis vaccine should include all reactions associated with infection and observed within a three-week time period after immunisation. The same time period that is associated with complications from natural infection.

Celermajer, J.M, and Brown J, (1966) described some of the neurological complications that other studies have found to be associated with pertussis infection. These include:

1. Paralysis of spastic or flaccid type involving one or more limbs.
2. Peripheral neuropathy (a group of disorders affecting the sensory or motor nerves in the peripheral nervous system).
3. Epilepsy.
4. Various mental changes including intellectual impairment, psychological disturbances etc (Sears, 1929; Levy and Perry, 1948; Byers and Rizzo, 1950; Annell, 1953; Berg, 1959 as cited in Celermajer, J.M., Brown J., 1966).

The NHMRC (1991) also lists the following complications

5. Death due to hypoxia following severe prolonged cough.
6. Apnoea.
7. Pneumonia.

The estimates of mortality and morbidity given by the NHMRC (1991) guidelines indicate, "The risk of the vaccine is less than the incidence of hypoxic encephalopathy and death due to natural infection". This is supported by the claim that the death rate in infants due to pertussis

infection is estimated from one in 300 to one in 2000. Data to support this statistic is not given. Morbidity data associated with the vaccine at this time was largely based on the British National Encephalopathy Study. (NCES) (NHMRC, 1991)

6 RESEARCH QUESTION 4: WHAT TYPE OF SCIENTIFIC EVIDENCE IS BEING USED TO ASSESS THE RISKS AND BENEFITS OF THIS VACCINE?

6.1 THE VACCINE INGREDIENTS

Parents are told that the chemicals and virus's/bacteria in vaccines will not overload a baby's immature immune system nor will it harm their developing neurological systems (Immunise Australia Program, 2004: Ada and Isaacs, 2000). This is not the evidence from animal studies and adverse reactions to the vaccines. Refer **Appendix 5**.

The Australian whole-cell DTP vaccine is made using heat inactivated *B.pertussis* bacteria and then strengthened with the adjuvant, aluminium phosphate and other stabilisers (CDI, 1997: Informed Choice, 2005). All vaccines contain quantities of preservatives, antibiotics and stabilisers and examples of these found in the DTP vaccine include thimerosal (a mercury compound), sodium chloride, sodium hydroxide, aluminium hydroxide, aluminium hydrochloride, sorbitol, hydrolyzed gelatin and formaldehyde (Informed Choice, 2006). Aluminium and mercury are heavy metals linked with neurological damage (Needleman H, 2000: Kirby D, 2005) and formaldehyde is a brain carcinogen (FDA as cited in Kirby D, 2005: Miller NZ, 1995).

Prior to 2003 government documents did not present the ingredients in vaccines. The synergistic and cumulative effect of the chemicals in each vaccine needs to be considered as new vaccines are added to the childhood schedule. It is known that toxicity of mercury is increased when combined with other ingredients such as aluminium and formaldehyde (Informed Choice, 2006: Kirby D, 2005). The manufacturing processes of different brands of pertussis vaccines will result in variations in the efficacy and safety of these vaccines between countries.

Thimerosal is a mercury compound that has been used as a preservative in vaccines since 1939 (Cook M, 2006: Kirby D, 2005). It contains nearly 50% ethylmercury by weight and is a nerve cell poison causing death and brain damage (FDA and CDC as cited in Kirby D, 2005). It is present in the DPTw vaccine, which is given to children before the age of six months.

The infant blood-brain barrier is not developed until six months of age so its possible that even miniscule amounts of toxin can cause harm if injected before this age (Cook M, 2006: Kirby D, 2005). Each dose of the whole-cell DTP vaccine contains approximately twenty-five micrograms of ethylmercury (Kirby D, 2005, p.81). This may vary between brands.

Prior to 1987 this was the only vaccine containing mercury given to children. In 1987 the Hepatitis B vaccine was introduced for infants in Australia and the Hib vaccine in 1992 (Vic

Dept. Health, 2006). Both of these vaccines also contain ethylmercury - approximately twelve micrograms in the hepatitis B vaccine and twenty-five micrograms in the Hib vaccine (Kirby D, 2005, p.81). Other sources of mercury in infants include the Rho (D) immunoglobulin injection (65 micrograms of mercury) which is administered to mothers prenatally and also the flu vaccine (Kirby D, 2005, p.65).

Governments first became concerned about the cumulative effects of mercury in vaccines in 1999, when parents (who had observed their infants development change after vaccination) linked the symptoms of autism to mercury poisoning (Kirby D, 2005). The Environmental Protection Agency's (EPA) daily standard for mercury in adults is 0.1 micrograms per kilogram (Kirby D, 2005). Mercury is known to be more toxic in infants than in adults (Kirby, 2005, p.311). It is estimated that children in the nineties were receiving many times more than the daily limit of mercury with each vaccination (Kirby D, 2005, p.82).

There is evidence from America and Australia that doctors were not informed of the amount of mercury in vaccines (Kirby D, 2005). Halsey N, (1999) the Director of Vaccine Safety in America, is quoted as saying in an American Academy of Pediatrics (AAP) committee report "doctors should be told soon about the amount of mercury in vaccines and the conflict with a federal health guideline." (Kirby D, 2005, p.70). Halsey N, (1999) also stated "no-one knows what dose of mercury, if any is safe, and we can claim there is no evidence of harm but the truth is no-one has looked." (Kirby D, 2005, p.71).

It is a scientific fact that neurodevelopment disorders such as autism have similar symptoms to those of mercury poisoning (Coulter H., 1990: Kirby D, 2005, p. 73). The Institute of Medicine (IOM) stated in 1999 that an association between mercury and autistic behaviours is biologically plausible (Kirby D, 2005). Researchers have linked heavy metals with affecting the neurotransmitters – chemical substances needed for the proper functioning of the nervous system (Needleman H, 2000). Alteration of the prefrontal lobes affects decision-making, choices, resisting impulses and behaviour (Needleman H, 2000).

This is consistent with research on the causes of autism, which indicates autism is a result of immature development and organization of the brain, in particular of the frontal and temporal lobes (Coulter, 1990, p.25: Kirby D, 2005). Mercury and Aluminium are examples of heavy metals and these with other metals are found in vaccines.

There are several causes of Autism of which one is genetics (Autism Association NSW). The rate of autism spectrum disorders in developed countries was 1 in 10,000 a decade ago, today they are 1 in 166 (Autism Association NSW). As it is unlikely there has been an increase in the percentage of people with the autism gene in such a short time period, it is plausible to suggest that an environmental toxin is causing the observed increase in autism (Kirby D, 2005)

Children with autism have very different immune profiles from normal children. They are found to have increased autoimmunity and an imbalance of the normal immune response (Kirby D, 2005, p.465). Environmental triggers can cause the immune system to dysfunction (Behrman et al, 1998). An FDA memo in the American Register in 1982, claimed thimerosal was among the most toxic of mercury compounds and an unreliable preservative (Kirby D, 2005, p.83). It is also highly allergenic with symptoms often not appearing until well after exposure (Kirby D, 2005, p.83). Evidence suggests some children have a genetic problem with expelling mercury from the body and these predisposed children are more at risk of permanent neurological damage particularly when exposed to the live-virus MMR vaccine at eighteen months of age (Kirby D, 2005). This genetic predisposition appears to be four times more common in boys than girls (Kirby D, 2005, p.143). Refer **Appendix 6**.

The neurological theory of autism is described in Coulter H, (1990, p.1-51). It illustrates the relationship between autism, palsies and vaccine-induced encephalitis as well as the link with Sudden Infant Death syndrome (SIDS). Coulter H, (1990) also states that the medical profession has known for a long time that “encephalitis, especially from vaccination can give rise to an allergic state, while conversely the existence of an allergic state predisposes to the development of encephalitis after vaccination.” (p. 152-155).

In the NHMRC 1994 guidelines doctors are informed that pertussis vaccine does not cause infantile spasms, epilepsy, or Sudden Infant Death syndrome. Yet vaccine induced brain injuries in children are on a scale from those who completely recover to mild forms of ADD or ADHD, learning difficulties to autism, seizures and death (Fisher B, 2004). Coulter and Fisher (1985) noted that allergic children react more strongly to the DPT shot and that vaccines seem to heighten existing allergic sensitivities (Coulter, 1990, p151).

6.2 IMMUNOLOGICAL THEORIES AND BIOLOGICAL EVIDENCE.

Collee G, (1984) claims that the initial dose of vaccine primes the immune system but does not confer protection. In the case of pertussis vaccine, three doses are required before protection is conferred (Zeigler et al, 1991). This suggests that even if vaccination starts at two months of age, a baby under six months will not have protection (Scheil W et al, 1998). Mortality due to pertussis is highest in babies under six months (Behrman et al, 1998). This knowledge combined with the fact pertussis occurs commonly in fully immunized children (Behrman et al, 1998: Stewart GT, 1977: Burgess M et al, 1998) should prompt us to question whether we are exposing infants to the antigens too early.

In addition, maternal antibodies protect babies for several months after birth (particularly when breastfed) and the introduction of vaccines at this stage, may interfere with the protection obtained from maternal antibodies (Burnet M, 1952). Burnet M (1952) stated that it was “possible that the most physiological time for infants to have any type of infection is when maternal immunity has just begun to fade.”

Whilst it is observed that babies receive little protection from maternal antibodies against pertussis in the vaccine era (Grigor W, 1965), this may have been different in the pre-vaccine era, when most children were exposed to natural infection from *Bordetella pertussis* and re-infection at a later age was less severe and immunity longer lasting (Wendelboe et al, 2005: Behrman et al, 1998). Therefore mothers would have had some immunity to pass on.

Burnet M, (1952) explains that three factors are observable in the general mortality pattern that occurs in humans:

1. The diminishing susceptibility of infants to death from infective diseases with age. This is related to the changing capacity of the human body to compensate for disturbances in homeostasis in the internal environment.
2. The young adult peak of mortality that occurs at adolescence (10-14 years of age)
3. The rise in mortality with age.

Factor (1) is explained by suggesting that control of the internal environment by an infant must become progressively more efficient and therefore it must meet and deal with the type of events that can exercise the regulatory function of body systems (Burnet M, 1952). In other words, the immature immune system of a newborn baby is stimulated, strengthened and matured by responding to natural infections and this results in the capacity to control the internal environment and overcome more dangerous invasions later in life (Burnet M, 1952). It

is important for children to be exposed to endemic diseases such as pertussis when young so immunity is established before puberty (Burnet M, 1952). This is because many infectious diseases produce a short trivial illness in a young child but in the non-immune adult it produces a serious clinical illness.

Factor (2) refers to the more intense inflammatory reaction that occurs in young adults when exposed to infections from microorganisms. Burnet M, (1952) states this is beneficial in superficial infections, such as wounds or abrasions, but very dangerous when generalized infections from pathogens, such as pertussis occur in non-immune adults (Burnet M, 1952). He says this phenomenon is very real and more obvious in males than females. It results in increased tissue reactivity possibly due to the liberation of histamine and other pharmacologically active substances from damaged cells and produces severe health risks. This includes allergies and anaphylactic shock because it was known in 1952 that pathogenic microorganisms could also cause allergic reactions in individuals with genetic or acquired conditions (Burnet M, 1952).

It is known that the immunity due to vaccination is not the same as that of infection. The duration of the immunity is shorter hence it is possible that the immunological response is not identical. We are only assuming that sub-clinical infection induces the same response as that of natural infection and thus develops the regulatory mechanism that allows us to control homeostasis. Whilst our current knowledge of immunology is more sophisticated than in 1952, scientists admit that one of the hindrances in developing improved vaccines is the limited understanding of the mechanisms involved in either natural infection based immunity or that conferred by vaccination. (Smith A, 1999) There is also controversy over which components of the pertussis vaccines are protective and which are toxic (Sato et al, 1984).

Smith A (1999) states that vaccine trials of the acellular pertussis vaccine show no correlation between antibody responses and vaccine efficacy. (Smith A, 1999) That is, the people that are protected against pertussis by the vaccine do not always show a greater antibody response from the vaccine than individuals that get pertussis even though they are vaccinated. Therefore, we might conclude that some other part of the immune system, other than antibody response, is responsible for the protection against disease in these individuals.

It is known that the age at which individuals meet pathogens and how they are exposed to them, is significant to their ability to overcome them (Burnet M, 1952). Burnet M, (1952) suggests that if the age of first contact with the infection is adolescence then infection can be very severe. It is also known that pertussis is most serious in children under six months of age.

Therefore, it would be unwise to expose babies to the pertussis pathogen and the preservatives and adjuvants in the vaccine, if protection by the vaccine is not assured.

The data from the National Centre for Immunisation, Research and Surveillance (NCIRS), 2005, claims pertussis is now a problem in two age groups in Australia – those under six months and those older than ten years. Prior to immunisation pertussis was considered a problem in children less than five years of age and mostly less than six months (Cumpston JHL, 1927: Wendelboe et al, 2005: Behrman et al, 1998).

It is possible that in the pre-vaccine era women were passing on a higher degree of protection to babies under six months of age through maternal antibodies due to a longer lasting immunity from natural infection. We must consider whether natural infection in childhood and the longer lasting immunity conferred is more beneficial to the community than the short-term immunity from the vaccine. This has resulted in numerous booster doses of DTP and a more severe disease in adolescents and adults. Particularly as the evidence suggests the vaccine was not the most significant factor in the decline of mortality and morbidity due to pertussis.

Burnet M, (1952) suggests that disease prevention may be a result of the interaction between genetic, nutritional, psychological and environmental factors. This is in contrast to the theory of vaccination, which is based on the premise that if a microorganism is present the body produces antibodies that protect the individual from this pathogen (Burnet M, 1952).

By introducing vaccines as the major form of protection against disease we are making assumptions about which components of the human immune system become primed to fight infection. Available research suggests that if the unified immune system response is bypassed then both immediate and long-term protection is likely to be compromised (Miller NZ, 1995). Behrman et al, (1998) informs that the body resists infection by a number of integrated systems including barriers that filter the organisms and a system of serum proteins and cells derived from bone marrow that are collectively known as the immune system.

Microorganisms are complex antigens and many of their toxic products will cause reactions in the host (Collee G, 1984: Blumberg et al, 1993). They upset the internal equilibrium by being injected directly into the tissues (Miller NZ, 1995). When a child gets a disease naturally the virus or germ travels through the nasopharynx, into the lungs, into the circulation and to all the lymph tissues of the body, thereby providing antibody and cellular protection (Behrman et al, 1998). Injections of vaccines into the main tissues and organs, avoids filtering by the skin,

respiratory secretions, sneezing, tears, fever, intestinal flora and other elements of immunity (Behrman et al, 1998).

Vaccines introduce foreign proteins directly into the blood without digestion or processing by the liver and these are known to be one of the chief causes of allergies (James W, 1988). In bypassing much of the natural defense system vaccines are not providing full protection (Miller NZ, 1995: James W, 1988: Behrman et al, 1998). Allergies are disorders in which the body becomes hypersensitive to particular antigens. They result when the allergens provoke the release of IgE antibodies that stimulate histamine and serotonin production causing the allergic symptoms (Martin E (ed), 2004). Autoimmune or allergic disease results when the immune system develops inappropriate or deleterious responses (Behrman et al, 1998).

Burnet M and Mackay I (1965) comment that “there is no doubt that conditions basically resembling certain human autoimmune diseases can be produced in originally healthy experimental animals by injections of normally inaccessible autologous antigens.” They state that these experiments use Freund’s adjuvants. “It has been postulated that the changes induced by adjuvants may render the lymphoid system of the animal hyperergic, making it similar to that of humans predisposed to autoimmune disease” (as cited in Grigor W, 1965, p. 83).

Autologous antigens are foreign proteins that are very similar to human proteins, for example, the calf serum, monkey kidney tissue or human diploid cells that are used in the manufacturing process of some vaccines (La Rosa W, 2002). These animal proteins (and human protein) are similar in structure to human proteins, hence the antibodies that are produced in the vaccinated animal may cross-react with its own tissue proteins in a process similar to autoimmunity (La Rosa W, 2002). These foreign proteins as well as the preservatives, adjuvants and antibiotics in vaccines are potential allergens and can produce anaphylactic shock (James W, 1988).

Ford RM, (1984) noted in 1984 that one theory for the high incidence of common allergic diseases in developed countries could be immunisation. He said this is supported by the fact that a single injection of *Bordetella pertussis* “renders rats anaphylaxis-prone and highly histamine-sensitive – ideal models for allergy experimentation” (p.47).

Molina and Shoenfeld (2005) state “many environmental factors are known to affect the immune system and may play a role as triggers of the autoimmune mosaic.” They claim vaccines in several reports were found to be temporally followed by a new onset of autoimmune diseases. The same mechanisms that act in infectious invasion of the host (to

cause autoimmune diseases) apply equally to the host response to vaccination” (Molina and Shoenfeld, 2005).

Ravel G et al, (2004) state that vaccination could enhance the risk of autoimmunity in genetically susceptible individuals when exposed to certain environmental chemicals. They confirm that genetic predisposition and environmental factors are largely accepted as risk factors for autoimmune diseases, even though the mechanisms by which they are induced are not fully known.

In addition, it has been theorized that T-lymphocytes that mature in the thymus gland and protect against intracellular disorders such as cancer, virus infection and transplants, become committed to specific antigens after the routine series of vaccines in children and become immunologically inert (James W, 1988, p.16). This results in reduced ability to defend against other antigens, infections or diseases. The research supporting this theory is also showing that vaccines can cause abnormalities in the production of the hormone thymosin, produced in the thymus gland, which is necessary for the maturation of T-lymphocyte cells (James W, 1988, p.16). Abnormalities in the thymus secretory function are associated with autoimmune, neoplastic (tumors) and immuno-deficiency diseases (James W, 1988, p.16).

Stewart GT, (1977) says that the pertussis vaccine more than any other is known pharmacologically to provoke increased sensitivity to histamine, a decreased response to adrenaline (epinephrine), hypoglycaemia due to increased production of insulin and alterations in heart-rate among other effects. In addition, he states “the vaccine also has powerful adjuvant effects (enhancing effects) on certain other antigens and allergens.

Blumberg et al, (1993) states that “many reactions occur following whole-cell DTP immunisation and the pertussis component is responsible for most of the reactogenicity.” However, there are many virulent factors in the whole-cell vaccine and with the exception of endotoxin it is not known whether one or more of these factors are responsible for any DTP vaccine reactions (Blumberg et al, 1993). Possible toxic factors include pertussis toxin, which is also known as lymphocytosis-promoting factor -a known cause of leukaemia (Morse SI, (1965) as cited in Blumberg et al, 1993). It is also known to have pancreatic islet-activating properties, which are associated with diabetes mellitus (Blumberg et al, 1993: Feery BJ, 1982: Stewart GT, 1977).

Studies in mice show that large doses of pertussis toxin also cause hyperinsulinemia, an excessive secretion of the hormone insulin which, if severe will lead to hypoglycaemic coma

(Blumberg et al, 1993). Hypoglycaemia (a deficiency of glucose in the bloodstream) in mice, results in muscular weakness, in-coordination, mental confusion and sweating. In humans this is a condition of juvenile diabetes mellitus (Type 1 diabetes). Symptoms of this condition are similar to the hypotonic-hyporesponsive episodes and collapse or shock-like states that are experienced in infants who have a severe reaction to the pertussis vaccine.

Blumberg et al, (1993) quotes studies that have concluded there is sufficient experimental data to implicate both endotoxin and pertussis toxin in adverse neurological reactions to pertussis vaccine (Menkes JH, Kinsbourne M., 1990, as cited in Blumberg et al, 1993). Other quoted studies say “pertussis toxin is the causative agent in pertussis vaccine encephalopathy” (Goh JW, Pennefather PS 1989, as cited in Blumberg et al, 1993). Refer **Appendix 7**.

6.3 EPIDEMIOLOGICAL EVIDENCE

Epidemiological studies result in a statistical analysis of the disease incidence within a community (Friis, R.H., and Sellers, T.A., 2004). They are designed using specific case definitions with inclusion and exclusion criteria that are selected by the researchers (Friis, R.H., and Sellers, T.A., 2004). Hence, the perspective of the researcher can influence the outcome of the study by the selection criteria that are used. Case-definitions of disease and the variables and controls that are used are fundamental to the conclusion reached. There are many variables and confounders in a study of adverse reactions to vaccines and hence there will be disagreement on the parameters in different study designs (Kirby D, 2005). An example of the way in which parameters of vaccine studies affect the conclusion is given in **Appendix 7**.

The British National Childhood Encephalopathy Study (NCES) also illustrates how the conclusion can change using different case-definitions. This study was a large case control, population-based study carried out from 1976 – 1979 in Britain (AAP, 2001). It examined 1,182 cases of acute neurological illnesses in children 2 to 36 months of age who were admitted to hospitals. The researchers concluded from the study in 1979 that a significant association exists between the occurrence of acute neurological illness (excluding infantile spasms) and vaccination with DTP (within 7days) (AAP, 2001). The relative risk of DTP immunisation resulting in neurological illness in the vaccines, as determined by this study in 1979 was 3.3 (95% confidence interval, 1.7 to 6.5) (AAP, 2001). Refer **Appendix 7**.

A reassessment of this study ten years later by the AAP led to the conclusion “the whole-cell pertussis vaccine ‘may on rare’ occasions be associated with the development of severe acute neurological illness that can have serious sequelae” (AAP, 2001). The conclusion depended upon the definition of encephalopathy that was used. (McIntyre P and Nolan T, 1994) The ‘rare occasions’ was the researchers interpretation based upon a narrower definition of encephalopathy. The re-assessment only included encephalopathy associated with long-term brain damage as defined by the study (McIntyre P and Nolan T, 1994). A different conclusion could also have been obtained if this study had included all acute neurological illness and immune dysfunction associated with thimerosal and other vaccine toxins that occurred within a three-week period of immunisation (similar to the time period associated with infection with *B.pertussis* itself).

McIntyre P. and Nolan T, (1994) discuss how the definition of encephalopathy can cause confusion. It can be altered to include or exclude a spectrum of clinical symptoms (McIntyre P. and Nolan T, 1994). Therefore, they claim that as the definitions of encephalopathy have varied between different studies, then the results for these studies will not be comparable (McIntyre P, and Nolan T, 1994).

In Stewart’s (1977) study, 24 children who reacted to the vaccine were given a second or third injection and the reaction syndrome was observed in an exaggerated form with signs of brain damage ensuing shortly afterwards. When parents questioned their doctors about the safety of the vaccine doctors assured them there was no connection between the child’s condition and the vaccine but no alternative diagnosis was given (Stewart GT, 1977). Stewart’s (1977) study of children injured by pertussis vaccine indicates that a number of children and toddlers can be identified as likely victims of the toxic effects. He calls this “Pertussis Reaction Syndrome” and the signs for this syndrome are listed in **Appendix 5**.

Feery’s 1982 study of adverse reactions to the pertussis whole-cell vaccine also found a significant result between DTPw vaccine and neurological illness. Refer **Appendix 7**. Despite these significant findings of disability associated with DTPw vaccine he adopted the same conclusion as the British NCES study because “it must also be applicable in Australia”. He concluded that the benefits of pertussis vaccine exceed the risks of its use. This conclusion did not state what the benefits of the vaccine were in 1982 (with respect to pertussis mortality) and nor did the NHMRC policy recommendation documents at this time.

6.4 BIOLOGICAL AND CLINICAL EVIDENCE

The Department of Health in 1966, stated that many of the antigens a person receives in a vaccine produce no protective response, but may result in a sensitizing response, a local reaction, anaphylaxis or a delayed serum type of reaction (Greville RW, 1966: Sato Y, Fukumi H, Kimura M, 1984). The use of mineral carriers (adjuvants) to enhance the potency of immunizing agents also has disadvantages (Greville RW, 1966). This includes alum, aluminium phosphate or aluminium hydroxide. These agents cause the sensitizing antigens in vaccines (foreign proteins) to become more serious in their effects. It was stated in 1966, that there are hazards and complications arising from the use of vaccines and the incidence of some of these hazards becomes more frequent with the increased number of immunisations that the individual receives (Greville RW, 1966). This is a significant statement considering Australia's Childhood Vaccination schedule in 2007 recommends twelve vaccines. Refer **Appendix 8**.

Due to the inherent reactogenicity of whole-cell vaccines a new acellular vaccine was developed in the 1980's (Sato Y, Fukumi H, Kimura M, 1984). Japan was the first country to use these vaccines in 1981. These component vaccines were practically free of endotoxin (but still had pertussis toxin) and were treated with formalin to destroy its ability to induce leucocytosis and to cause histamine sensitization (Sato Y, Fukumi H, Kimura M, 1984). Formalin itself is a toxin (Martin E (ed), 2002). Sato et al, (1984) state that there is no consensus on which antibodies protect against whooping cough and how they do so. It says a long-term survey of the acellular pertussis vaccine with respect to its efficacy and side effects, especially on the nervous system, will be necessary (Sato Y, Fukumi H, Kimura M, 1984). This is stated after the vaccine has already been implemented.

Studies in mice have shown that rats with an autoimmune genetic predisposition will develop autistic-like behaviours after thimerosal-containing vaccines are injected into them (Hornig M, (2004) as cited in Kirby D, 2005, p.311). Infant rats showed hyperactivity, and a range of social disturbances and communication problems that are similar to children with autism. The rocking movements of autistic children were displayed in rats that were unable to turn their bodies over in the normal corkscrew manner (Kirby D, 2005, p.311). Hornig M, (2004) concluded from this study that it shows how genes, environment and timing all interact together in the occurrence of disease (Kirby D, 2005, p.311).

The majority of adverse reactions to vaccines result in dysfunction of the neurological and immunological systems (Dept. Health, 2004:Coulter, H., 1990: Fisher, B, 2004: Wilson, G, 2000: Kirby, D., 2005). Immunological conditions that result are often similar to those of

autoimmune diseases (Blumberg et al, 1993: Stewart GT, 1977: Coulter H, 1990: La Rosa, 2000). Autoimmune diseases include diseases of the pancreas (diabetes), thyroid, collagen and fibronectin (scleroderma, lupis), cardiolipin (cardiomyopathy) (La Rosa W, 2002). The body produces autoantibodies and attacks itself to cause the autoimmune disease (La Rosa W, 2002).

The Hayward Foundation study on vaccines examines vaccine safety in dogs and concludes vaccines are a possible cause of autoimmune diseases observed in dogs (La Rosa W., 2002). It states that “autoimmune diseases in dogs are clinically similar to those in humans” and it concludes that current vaccines induce autoantibodies and that contaminants (the fetal calf serum on which viruses are grown or preservatives/antibiotics) may be part of the problem (La Rosa WR, 2002).

Kirby (2005) claims that government-sponsored studies of vaccine reactions are exclusively statistical and epidemiological in nature and the expanding volume of biological and clinical evidence is being ignored (p.332). It can be seen that if doctors are re-educated about contraindications to vaccines on epidemiological studies alone, then they are not presented with a balanced perspective. There are many animal studies showing harmful effects from the chemicals found in vaccines (Kirby D, 2005: Needleman H, 2000: La Rosa WR, 2002).

Prior to human use vaccines are trialed on animals to determine the degree of harm they may cause. If we ignore this evidence, vaccination becomes a large experiment on children and one that can manipulate statistics to show inconclusive results. In addition, if the vaccines have only been trialed separately and not in conjunction with all the other vaccines listed in the recommended childhood schedule then we are also experimenting on children. The synergistic and cumulative effects of these chemicals could be extremely important to children's health. Morbidity in children has risen significantly over the past fifty years particularly with respect to immune and neurological dysfunction. Refer **Appendix 6**.

Clinical trials and epidemiological studies in human populations will not detect the adverse reactions that will occur in a sub-set of the population that have a genetic pre-disposition to characteristics such as expelling mercury from the body (Kirby, 2005). The harm from vaccines will also be enhanced by other genetic pre-dispositions that have not been identified.

Our estimates of harm as measured by general practitioners reports to the Adverse Reaction Committee are not complete because it is known that only reactions with a strong temporal association to vaccines are being reported (Miller NZ, 1995). Environmental triggers that

cause allergies are known to have a delayed response so a temporal association will not be found and these cases will not be picked up. (Kirby D, 2005) The FDA recently acknowledged that 90% of doctors do not report vaccine damage (Miller NZ, 1995). This is in agreement with Feery BJ, (1982) who claimed family physicians are not generally consulted regarding reactions to vaccines and so are unaware of the level of reactions after vaccinations. Therefore, the majority of reports of serious neurological complications from pertussis vaccination are from parents, which is regarded as non-scientific or anecdotal evidence (Feery BJ, 1982).

In 2007 general practitioners are being paid to maintain high vaccination rates. Doctors are no longer unbiased observers in vaccination decisions because pharmaceutical companies are directly marketing to doctors and governments. (Dept. Health, 2004: PHAA, 2006: Fitzgerald, P.D., 2001). Refer **Appendix 9**. This influences the information they receive and the decisions they make regarding adverse reactions to vaccines and can lead to an inaccurate measure of the harm caused by vaccines.

The ecological evidence is showing a significant increase in chronic illness in children. This includes the increasing incidence of diabetes mellitus, leukaemia, food allergies, asthma, epilepsy, behavioural and intellectual disabilities and autism (AIHW, 2004). Refer **Appendix 6**. Whilst this increase in disease has occurred in children at the same time as vaccination use has increased it is not evidence for a causal link. However, the biological plausibility of vaccines as a cause of these diseases is demonstrated in animal studies, the clinical evidence from adverse reactions to vaccines and the volume of reports from parents claiming their child's development changed after vaccination (Kirby D, 2005).

This study is illustrating that it is possible for the medical profession to be educated with unbalanced information on adverse reactions to vaccines. In 1994, the medical profession was 're-educated' about contraindications to the pertussis vaccine with information based largely on epidemiological studies. These studies are dependent upon case definitions and statistics.

Epidemiological information about the pertussis vaccine is summarised to general practitioners as:

"The major disadvantages of pertussis vaccination are:

1. A high rate of short-lived, unpleasant side effects that are of no consequence
2. More serious side effects that are extremely rare; the probability of permanent brain damage is virtually zero." (NHMRC, 1991).

This ignores the historical experience of use of the DTPw vaccine as well as the biological, clinical and ecological evidence that is indicating the possibility that harm is being caused from vaccines.

7 CONCLUSION

In developing this pertussis immunisation policy the NHMRC has not supported its policy recommendations with evidence. An examination of the annual mortality data for pertussis indicates it was significantly reduced prior to routine pertussis vaccination. The mortality rate for pertussis in 1954 when the vaccine was introduced was 15 deaths per year and was showing continual decline each year. Public Health officials stated in the 1950's that pertussis was an index for 'hygiene and social well-being' and pertussis was observed to fall significantly as living standards improved. The evidence presented in this paper shows that morbidity from pertussis infection also decreases with mortality. Hence, the low mortality of this disease in the fifties and sixties would also indicate low morbidity. The government has not provided contrary evidence on morbidity.

The NHMRC has presented misleading information by representing the mortality data from 1926 – 2002 in decades. Illustrating the data in this grouping showed a significant drop in mortality after 1955. However, the annual mortality data clearly shows that a significant drop in mortality occurred prior to 1950 and this was the reason for the removal of pertussis from the National Notifiable Diseases List in 1950. In addition, infant mortality was showing a continual steady decline from early in the twentieth century. There was no significant drop in infant mortality during the 1950's when mass vaccination programs were introduced. The decline in infant mortality was expected to continue steadily as living standards continued to improve from the 1950's onwards. These facts are strongly supported by prominent Australian public health officials of the time.

The protective effect of the vaccine in controlling pertussis could have been demonstrated if vaccination status and socioeconomic status of cases was recorded. This data was not recorded prior to 1997. Hence many of the Government's policy statements remain unsupported. It is also known that mortality data prior to 1951 cannot be strictly compared with data after this date because of revisions made to the ICD list and Principle Causes of Death Series. The benefits of this vaccine in NHMRC documents were promoted on incidence figures only with statements such as "the mortality and morbidity of pertussis is of serious concern." The first mention of mortality figures in the NHMRC documents was in 1997 when vaccination rates were high and they had seven deaths from pertussis in one year.

The ACP claims that assessments regarding the benefits of the pertussis vaccine are based on the evidence that "a re-surgence of whooping cough occurs when immunization rates fall and a claim that there is a far greater incidence of complications associated with natural disease." Evidence for a re-surgence of whooping cough provided by the government consists

of increases in notification rates in different countries. This paper described why notifications are not an accurate indicator of incidence, mortality or morbidity of this disease. In addition, it is well documented that pertussis is endemic and is considered a public health problem in countries which have had high vaccination rates for decades. This includes Australia. The ACP also did not provide evidence to support its claim that there is a greater incidence of disease associated with natural infection in Australia.

Mortality figures presented in this policy analysis were obtained from the Official Commonwealth Yearbook of Australia. The annual mortality of pertussis was not presented after 1973 because it was no longer a cause of significant death. However, the NHMRC claimed "pertussis was a cause of significant mortality and morbidity amongst Australian children in 1979." No statistics were provided.

The development of this policy indicates there was trial and error in determining the appropriate schedule. This is because the efficacy of the Australian whole-cell pertussis vaccine has never been tested. The ACP admitted in 1991 that the duration of immunity from the vaccine was probably two to three years instead of four to twelve years. Hence extra booster doses were added to the schedule. In addition, the contraindications and age-limits for the vaccine changed several times before the components of the vaccine changed in 1999.

The contraindications to the DTPw vaccine were changed in 1994 on the basis of epidemiological evidence that concluded there was only a 'slight risk' of side-effects from the pertussis vaccine. This was despite the same study concluding there was a significant risk of acute neurological damage ten years prior to this. Medical professionals were re-educated with the new contraindications at this time in order to increase vaccination rates. Therefore, conditions that were thought to be a contraindication prior to 1994 were ignored after this date even though the vaccine did not change and there was no consensus amongst the medical profession about which neurological conditions should be considered a contraindication.

In 1979, the Council stated, "provided that contraindications to immunisation were observed, the risk of severe adverse reactions was minimal." This advice was ignored in the nineties, as many conditions were no longer considered contraindications. It was known in the seventies and eighties that the vaccine was associated with brain damage, allergies and death but the exact figures were unknown.

The highest notifications of pertussis are now occurring in 0-4 year olds and 10-14 year olds. Hence the need for more booster doses. Prior to vaccination the disease was mainly a problem in under one year olds. Medical professionals and the public are told the vaccine is

needed because of the increasing notifications. However, this statistic includes cases of pertussis caused by bacteria other than *B.pertussis*, which are not controlled by the vaccine and it does not give an indication of the case-fatality of the disease. Notifications are not an indication of the incidence of *B.pertussis* in the community and National notifications were not recorded in the sixties and seventies when mortality rates were very low. This indicates it is irrelevant to the control of mortality and morbidity of pertussis in the community as was stated by Cumpston J, (1927) and Burnet M, (1952).

The ACP admitted in 1991 that the theory suggesting pertussis could be eradicated with vaccination rates of 95% and above was probably wrong. This dispels the herd immunity theory because it was known that the vaccine was only effective against cases of pertussis, which had prolonged symptoms of coughing (twenty-one days or more) and against one species of *Bordetella*. Therefore the bacteria will continue to circulate in the population even with vaccination rates at 95%.

It is known that pertussis occurs in fully immunized children and communities yet when outbreaks occur they are blamed on the anti-vaccination lobby group. Pertussis bacteria are known to revert to virulence under certain environmental conditions and this cannot be ruled out as a possible cause of immunized children getting infected with pertussis. The vaccine is also known to vary in efficacy so it will not protect all immunized children. This vaccine is introduced into babies at two months of age – the time they are most at risk from pertussis – and will not be protected by the vaccine until they have completed three doses of vaccine after six months of age. This paper leads us to question whether introducing the vaccines into infant's bodies at the most vulnerable time in their neurological and immunological development, without guaranteeing protection is the best protective measure. In addition, the list of vaccines for babies continues to increase even though the synergistic and cumulative effects of the chemicals have not been tested.

Knowledge of immunology in the 1950's indicates there was no certainty that inducing sub-clinical infection into individuals would provide long lasting immunity. At the time Burnet said it was 'believed' that vaccination would only produce trivial symptoms and that it would be enough to produce lasting immunity. In fact, Burnet uses the term it is 'possible' that it may be beneficial to do this when maternal antibodies begin to fade. Maternal antibodies do not begin to fade for several months after birth yet we are vaccinating infants at two months of age.

It is known that the duration of immunity from the vaccine is short term. Hence, in the vaccine era it is observed that mothers are not passing on significant protection to infants against pertussis. Immunity from natural infection is longer lasting so it is likely that mothers passed on

maternal antibodies in the pre-vaccine era, particularly as re-infection in adults was known to be mild and to enhance the natural immunity. In 2006 re-infection is now a problem in adults and adolescents. This is the justification for the adult booster dose at 15-17 years of age.

Prior to the implementation of mass vaccination programs, Burnet M, (1952) indicated that there were many gaps in scientist's knowledge about the functioning of the human immune system. Fifty years on it is known that vaccination doesn't provide lasting immunity and a 'modified infection' means bacteria or virus's that are treated with preservatives, antibiotics and stabilizers that parents are not informed about. These chemicals are known allergens and neurotoxins such as mercury, formaldehyde and aluminium. In the twenty-first century the effects of these chemicals on biological cells are well known and parents are trying to avoid them in their children's diet. Yet parents are not being told they are injecting them into their babies bodies at the most vulnerable stage in their development. Evidence suggests that doctors are also unaware of the quantities of these chemicals in each vaccine.

Animal studies are showing there is overwhelming evidence supporting the link of autoimmune diseases with vaccines. In addition, it is stated that genetic predisposition and environmental factors are accepted as risk factors for immune and neurological diseases. Yet the medical profession is using epidemiological studies with narrow parameters to claim that because we do not know the mechanism by which vaccines can cause neurological and immunological diseases then there is 'no evidence' that the vaccines are causing significant harm. Epidemiological studies will not detect conditions that are produced in children with a genetic predisposition to certain conditions. Yet this is the information that is used to promote vaccination to health professionals and the government. Health professionals are also paid to vaccinate which is not an incentive to investigate or promote risks of vaccines. Scientists admit that one of the hindrances in developing improved vaccines is the limited understanding of the mechanisms involved in either natural infection based immunity or that conferred by vaccination.

In other words, despite the fact that we do not know all the mechanisms involved in the human defense system, we will claim that vaccines do not overload a baby's immature immune system nor will it harm their developing neurological systems. Scientists have not provided conclusive evidence that harm is not being caused to other vital parts of the immune system by vaccinating against an increasing number of diseases.

This study has shown that the Federal Government's Pertussis Vaccination Policy is not achieving its objectives. It was also not the most significant factor in reducing the mortality and morbidity associated with this disease. The study has shown that the policy is not controlling

the incidence of pertussis in the Australian population. Immunological knowledge regarding human defense mechanisms of disease is shown to be incomplete and all types of scientific evidence are not being used to evaluate the risks and benefits of the pertussis vaccine.

The implications of this research are significant not only to the governments pertussis immunization policy but to all vaccines being made available to the public. The pertussis vaccine must be reassessed with respect to the risks and benefits of the vaccine to the community and to individuals. Improved social conditions in Australia have increased the age of pertussis infection in children and this reduces the risk associated with natural infection. There are also benefits to the community from longer lasting immunity due to natural infection. This should be considered particularly as pertussis is now observed to be a more serious disease in adults and adolescents in the vaccine era and also because there are serious concerns about the risk of the vaccine.

Vaccines cause adverse reactions, which will vary in severity amongst individuals due to genetic factors. Genetic and environmental factors are seen to influence the incidence of disease in communities. Therefore it is important that vaccines are promoted to the public because of a real threat of disease to the individual and the community. It is known that the hazards of vaccination increase with each vaccine that an individual uses, so it is important to consider how many vaccines are safe to combine in an infant's body. Etiological studies of chronic illness in children must also investigate vaccines as a possible cause for these diseases as they are a biologically plausible trigger for these diseases. This is the scientific evidence that is needed to ensure we are not removing one risk and replacing it with another.

Fifty years ago Burnet (1952) suggested that genetics, nutrition, psychological and environmental factors may play a more important role in the mechanisms for disease defense than those of sub-clinical infection produced by vaccination procedures. He claimed that in future years "we may find that we have some hard thinking to do. It may be that we shall have to recognize that mortality in infancy and childhood in the past has been the necessary price that had to be paid to prevent genetic deterioration, and that some of our modern successes in preventative and curative medicine may on the longest view be against the best interests of the state." (p107).

These words were very prophetic at a time when Burnet admits the picture of immunology was very superficial. It is also consistent with the ecological evidence in children and recent animal studies where scientists have concluded that the studies show how genes, environment and timing all interact together in the occurrence of disease.

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A P P E N D I X

1

SEARCH STRATEGY

The motivation for this project has been a concern for children's health in 2006. The researcher has vaccinated her children and first observed some of this information on non-government websites. Originally the ethics of mandatory vaccination seemed to be the obvious starting point for the project but it became obvious that the pertussis vaccination policy itself needed to be analysed to ensure it was responsible for controlling pertussis disease.

Recent policy documents for this project were obtained from the Australian Government Health Department websites. Including:

- 1) Department of Health and Ageing, Immunise Australia website
- 2) Communicable Diseases Intelligence
- 3) National Notification of Diseases Surveillance System (NNDSS)
- 4) Australian Bureau of Statistics
- 5) Australian Institute of Health and Welfare, National Mortality Database. This website had information on the health of the Australian population and trends in diseases in children and adults.
- 6) NSW and Victorian Government documents were also used to find information on the history of use of vaccines in Australia.

Policy documents from 1950 to 1990 were obtained from the National Health and Medical Research Council (NHMRC) Session Reports and the Official Commonwealth Yearbook of Australia. Annual mortality data for pertussis was hard to find and not presented in the NHMRC policy recommendations. Government sites such as the ABS and the CDI gave pertussis mortality figures in irregular groups of years and one document gave it for each decade from 1926. The Commonwealth Yearbook of Australia published annual mortality statistics for pertussis up to 1973.

The Medical Journal of Australia and the Communicable Diseases Intelligence were used to find supportive evidence for the pertussis vaccination policy.

The search included books on the history of infectious diseases in Australia, which gave comments from prominent public health officials throughout the twentieth century. It also included books on vaccination.

The databases used to collect information included:

- 1) APAFT
- 2) Meditext
- 3) Proquest
- 4) Science Direct
- 5) APAIS
- 6) OVID
- 7) Cochrane Database of Systematic Reviews
- 8) Australian Digital Thesis

The search terms used were –

- 1) immunisation (immuni*) + policy
- 2) vaccination + government
- 3) pertussis vaccine + policy
- 4) pertussis + etiology
- 5) pertussis + incidence/mortality/morbidity
- 6) pertussis vaccine + adverse reactions
- 7) chemicals + autoimmune diseases
- 8) vaccine ingredients
- 9) vaccines + other environmental triggers of autoimmune diseases

References were also obtained from veterinary scientists and general practitioners.

There is a voluminous amount of material on this topic so the search strategy focused on policy documents published by the NHMRC, CDI and the ACP because they are involved in advising the government on public health policy. In order to get background information on the knowledge scientists had of immunology at the time vaccinations were introduced I quoted from Sir MacFarlane Burnet a prominent immunologist from 1950. His comments on the gaps in immunological knowledge that scientists had in the 1950's have been supported in recent research papers that are also quoted in this investigation. Background information on the history of infectious disease in Australia was obtained from prominent public health officials of the early twentieth century. These references were obtained from the bibliographies of government department health reports. In selecting data on the safety of vaccines animal studies were selected to show the biological plausibility of a connection between vaccines and the diseases of concern. Epidemiological studies were chosen to illustrate how design can affect the conclusions that are reached.

Most of the literature obtained in this search was from government documents and peer-reviewed scientific journals. It is therefore of high scientific value. In most cases primary sources of information have been used. The researcher only used books that were fully referenced from scientific studies.

The literature showed consistent data supporting the fact that the government's policy was not controlling the incidence, mortality and morbidity of pertussis disease from 1966 – 2006. Public health officials were in agreement about the factors most responsible for causing pertussis mortality decline and the effect of incidence statistics on mortality and morbidity. There was also consistent data indicating the lack of accurate knowledge on the extent of adverse reactions to pertussis vaccine and mechanisms involved in the human defense system.

Limitations of this research include obtaining policy documents with supportive evidence for the policy. The NHMRC gave recommendations for the development of the policy without supporting their conclusions with specific mortality, morbidity and adverse reaction data. It may be possible that other policy documents exist that provide the supportive evidence. However, the evidence from medical journals, the Australian College of Pediatrics, the Communicable Diseases Intelligence, prominent public health officials, government documents, and other countries does not indicate pertussis vaccine is controlling pertussis incidence.

**COMPARISON OF
CONTRAINDICATIONS**

CONTRAINDICATIONS TO PERTUSSIS VACCINE IN 1991 AND 1994

The NHMRC recommended contraindications as listed in the 1991 Immunisation Guidelines (p.24) include:

- 1) Immunisation should not be carried out during the course of a significant acute illness.
- 2) Any major reaction is likely to be due to the pertussis component and any further DTP or monovalent pertussis vaccine is contraindicated. In this situation there is no indication to use a smaller dose of any pertussis vaccine. Major reactions include:
 - Fever above 40.5 Degrees Celsius
 - Convulsions
 - Hypotonic / hyporesponsive episodes
 - Shock, anaphylaxis, thrombocytopenia and encephalopathy
 - Severe local reactions
 - Persistent screaming (more than three hours)
- 3) Sterile abscesses are observed rarely but they are believed to be more likely to occur when the vaccine is given subcutaneously.
- 4) Infant's known to have active or progressive neurological disease (including recent convulsions) should not be given pertussis-containing vaccines. For infants with stable neurological disease (including controlled epilepsy) or family history of idiopathic or other familial neurological disorder, the risks of pertussis infection still greatly outweigh the risks of pertussis immunization, so that routine immunization including DTP should be commenced, subject to normal precautions. If there is doubt in individual cases, consultation with a pediatrician or pediatric neurologist may be appropriate.
- 5) A history of allergic symptoms is NOT a contraindication to childhood immunization. Other misconceptions relevant to childhood immunization are listed on p.18. In particular, eczema, hay fever, asthma and 'snuffles' are not valid reasons for deferring immunization.
- 6) The use of paracetamol is effective in reducing febrile reactions following DTP.

These contraindications are compared to those listed by the NHMRC in 1994 (Zeigler et al, 1994)

There are only two absolute contraindications to pertussis vaccination after 1994 and these are:

- 1) Immediate severe allergic reaction, for example, anaphylaxis occurring after pertussis-containing vaccines.
- 2) Unexplained encephalopathy following within seven days of pertussis vaccination. This does not include febrile convulsions.

A P P E N D I X

GENETIC CONTROL OF VIRULENCE

3

GENETIC CONTROL OF VIRULENCE

Reference – Smith A (1999)

Bacteria that are members of the genus *Bordetella* are known to have two very different phenotypic (physical) states. These states can be switched on and off according to the surrounding environment and it enables the bacteria to survive harsh conditions.

It is thought that the bacteria have a genetic locus, which encodes a type of 'biological switch' enabling the bacteria to oscillate between the two states. In harsh conditions, outside the host environment, pathogenic *Bordetella* bacteria switch to an avirulent phase. In this phase the proteins required for host invasion are not produced, instead a set of genes, which allow the organism to deal with difficult conditions are expressed. A lot of energy is saved by not producing virulence factors. A different sub-set of genes is expressed in the warm, moist surroundings of the human respiratory tract.

In the laboratory the virulence control switch can be manipulated into an avirulent phase by the addition of sulphate ions or nicotinic acid to the culture medium. This can also be achieved by reducing the culture temperature from 37 degrees Celsius to 25 degrees Celsius. The gene locus encodes two proteins that enable the bacterium to 'sense' the environmental conditions and then 'act' accordingly by controlling the expression of specific genes and gene loci.

A P P E N D I X

INTERNATIONAL CLASSIFICATION OF DISEASES

4

DESCRIPTION OF THE INTERNATIONAL CLASSIFICATION OF DISEASES TREATY

The classification of pertussis (whooping cough) as a cause of death in 1953 was in accordance with the sixth edition of the International Treaty on causes of death signed in London in 1934. (Com.Year, 1953, p.617) This treaty described the classification of 87 main causes of death for the purpose of making international comparisons and it became known as the International Classification of Diseases (ICD) (Com.Year, 1946/47).

The sixth edition was the first time that there were international rules for a uniform method of selecting the main cause of death when more than one cause is listed on the death certificate (Com.Year, 1953, p.617). In Australia this resulted in a fundamental change to the cause of death statistics as the emphasis was now placed on the underlying cause of death as indicated by the certifying practitioner (Com.Year, 1953, p.617). This means deaths from 1951 onwards are not strictly comparable with previous years. In Australia comparability of diseases over the years also varies according to the revised edition of the ICD that is used and the requirements of notification issued by each State or Territory (Com.Year, 1968).

The ICD has been revised in the following years

1909	Second edition
1920	Third edition
1929	Fourth edition
1938	Fifth edition
1948	Sixth edition
1955	Seventh edition
1968	Eighth edition
1979	Ninth edition
1999	Tenth edition

It is thought that because death rates are subject to continual fluctuation it is unsafe to base deductions on the figures relating to a single year. Therefore, it is thought that a valid comparison is 3 five-yearly periods (Com.Year, 1953, Vol.39). The sixth revision was used for deaths registered from 1950 – 1957 in Australia and the seventh revision used from 1958 onwards (Com.Year, 1968, Vol.54).

The ABS back coded 1997 –1998 deaths to the ICD tenth revision in order to compare the underlying causes of death from 1997-2000. This is referenced with alpha-numeric ICD-10 (AIHW, 2004).

The Automated Coding System was adopted from the USA in 1996. This has resulted in a break in the underlying causes of death series between 1996 (and earlier years) and 1997. There are significant differences for a number of causes of death between these years (AIHW, 1999, p.120). Another break occurred in 1999 as some codes were reversed back because they were not in line with the ICD coding rules (AIHW, 1999, 120). So data between 1998 and 1999 are not strictly comparable.

A P P E N D I X

**ADVERSE REACTIONS TO THE
VACCINE**

5

ADVERSE REACTIONS TO THE WHOLECELL PERTUSSIS VACCINE

LOCAL SIDE EFFECTS

Erythema or dilated blood vessels at the site of injection, tenderness and swelling. About 50% of vaccinated children have local reaction (Feery BJ et al, 1985 as cited in Burgess M, 1994). These common reactions do not 'appear' to be allergic in nature (NHMRC 1991 guidelines, p.12).

SYSTEMIC REACTIONS

Fever, vomiting, diarrhoea and general irritability are common (Cherry et al, 1988). 20% of children become febrile and 30% will cry and become irritable (Feery BJ et al, 1985 as cited in Burgess M, 1994).

SEVERE SIDE- EFFECTS

Febrile seizures, atypical high pitched crying and persistent screaming (0.1%), convulsions (0.06%) and hypotonic-hyporesponsive episodes (0.06%) (Cody CI, 1981 as cited in Burgess M, 1994). Burgess M, (1994) cites Cherry et al, (1989), Beal SM, (1991) and Howson CP and Fineberg HV, (1992) to state that the pertussis vaccine does not cause infantile spasms, sudden infant death syndrome or epilepsy.

The NHMRC immunisation guidelines for 1991 state that patients may be hypersensitive to the preservatives and antibiotics in the vaccines. The public is informed that the number of individuals who would be hypersensitive are 'rare' and the preservatives and antibiotics are described as being in 'trace' amounts in the vaccines.

NCES STATISTICS

The 1991 NHMRC immunization guidelines state that the major controversy over the DTP vaccine relates to concern over the occurrence of adverse neurological events including brain damage. It quotes the conclusions of the British National Childhood Encephalopathy Study (NCES), which is claimed to be the most rigorous study measuring vaccine brain damage due to pertussis, and concludes that acute encephalopathy occurs in 1:110,000 cases and encephalopathy with residual sequelae occurs in 1:310,000 cases. The authors stated these figures were 'provisional'. DTP is plausibly associated with a large number of neurological conditions.

The authors of the NCES have used their study to claim that on 'further analysis' the risk of encephalopathy with permanent brain damage is close to zero and very much less than the

original estimate (NHMRC, 1991). They state that this is less than the incidence of hypoxic encephalopathy and death due to natural infection. This is supported by the claim that the death rate in infants due to pertussis infection is estimated from one in 300 to one in 2000. There is no indication of what data this statistic is based upon.

STEWART'S (1977) STUDY

For example, Stewart's (1977) study of children injured by pertussis vaccine claims to indicate that a number of children and toddlers can be identified as likely victims of the toxic effects. He calls this "**Pertussis Reaction Syndrome**" and it includes the following signs:

1. Persistent crying or fits of screaming 4-48 hours after injection.
 2. Marble pallor, rigidity, unresponsiveness, and shock of sudden onset within 48 hours of injection, usually within 6-12 hours.
 3. Irritability and interrupted sleep for a few days or longer.
 4. Refusal or vomiting of feeds.
 5. Altered response to the parents.
 6. Paresis or localized paralysis.
 7. One or more convulsions with or without pyrexia and cyanotic episodes (blue fits).
- In some cases these signs subside within a few weeks but in other cases further signs appear:
8. Hyperkinesis (ADD/ADHD).
 9. Infantile spasms extending into convulsions, epilepsy, or salaam fits.
 10. Progressive unresponsiveness to parents.
 11. Flaccid paralysis.
 12. Partial or complete amentia (failure of development of the intellectual capacities).

Stewart (1977) studied 5 known cases of encephalopathy that occurred immediately after DTP vaccination. Two became mentally retarded and the other three partially recovered. He claims that damage from the vaccine is unlikely to be lower than 1 in 60,000 and if it is 1 in 20,000 it means that 30 children would suffer brain damage in the U.K. each year and many more with damage that may not appear until later in their life. In this case the risk of the vaccine far outweighs the risk of damage from whooping cough itself.

He concluded that the present schedule of pertussis vaccination was ineffective and information on efficacy and adverse reactions was incomplete.

STUDY 2

Stewart GT, (1979) reported eight SIDS cases in 1978-1979 that occurred following routine vaccination of infants with DTP vaccine in Tennessee. He continues “Excluding fatalities, I have investigated some hundreds of severe reactions, most of which are also known to the Committee on the Safety of Medicines. These reactions are mainly neurotoxic in nature and some are life-threatening. They cannot be explained by a random distribution or frequency and show a consistent symptomatology long associated with pertussis vaccine.”

Notification of Adverse Reactions

Stewart (1977) states that whilst reactions to vaccines are required to be reported to the Committee on Safety of Medicines, it is known that many are not. He informs us that whilst some deaths and many non-fatal reactions were reported to the board between 1964 and 1975, no information was available on the exact number or circumstances (living conditions, vaccination status) of the cases reported. In addition, he explains that the adverse effects of pertussis vaccine cannot be separated from the immunizing effect of the vaccine because potency is related to the toxins. Stewart (1977) says that potency levels of the pertussis vaccine were increased during the 1970's by international agreement and this also increased the toxicity.

RE-EDUCATING MEDICAL PROFESSIONALS

Doctors are told that pertussis vaccine does not cause infantile spasms, epilepsy, or sudden infant death syndrome. (NCIRS, 2005)

A P P E N D I X

**THE HEALTH OF AUSTRALIAN
CHILDREN**

6

THE HEALTH OF AUSTRALIAN CHILDREN

Whilst mortality rates in children 0-4 years have dropped to low levels in 2006 the morbidity rates for many chronic diseases are high and increasing (AIHW3). In Australia chronic disease affected 44% of 0-14 year olds in 2001 (AIHW3). One-third of chronic illness in this age group is due to asthma, allergies, eczema and hayfever (AIHW3). Diabetes and cancer also contribute significantly to the burden of illness in Australian children today (AIHW3). Many of these conditions require a large amount of time and resources to manage and they have a significant impact on the emotional stress, mental health and financial resources of the families. (AIHW1)

In 2003 the infant mortality rate (0-1 year) was 4.8/1000 births (AIHW3). Diseases of the nervous system and Sudden Infant Death Syndrome (SIDS) were two main causes of death. SIDS became a notifiable condition in the 1970's and increased to high levels in Australia until 1991 (AIHW3). SIDS represented 17% of postneonatal deaths in 2003 and 10% of infant deaths (AIHW3).

The child mortality rate 1-14 years was 15.4/100,000 children in 2003 (AIHW3). The major causes of death include neoplasms, congenital malformations, and diseases of the nervous system (AIHW3). Forty-seven percent of childhood deaths occur at 1-4 years of age (AIHW3).

Morbidity due to chronic disease has been steadily increasing in all developed nations since the early 1980's (AIHW2, 3). Autoimmune diseases in children 0-14 yrs have increased significantly over the last two decades and these include: autism, asthma, allergies (particularly food allergies and anaphylactic hypersensitivity), diabetes 1 and 2, chronic sinusitis and eczema and hayfever (AIHW3).

- In Australia Autism now affects 1 in 150 children (Autism Spectrum Australia. Autism results in impaired social interaction, communication and behaviour (Autism Spectrum Australia).
- Asthma affected 13.3% of Australian children 0-14 years of age in 2001 (AIHW1). It is the most common cause of hospitalisations and days absent from school (AIHW).
- Type 1 diabetes is the most common diabetes found in children (98%) and the prevalence is increasing at a rate of 3% per year (AIHW1). This is the fastest growing chronic disease in Australian children (AIHW1). The incidence of Type 2 diabetes is now found to be increasing in children as well (AIHW1).
- In 2003 16% of deaths among children 1-14 years were due to cancer (AIHW1). Incidence rates for cancer have been increasing and were highest for children 0-4

years – 22.1 cases per 100,000 children (AIHW1). The most common types of new cancers were leukaemia and cancer of the brain and central nervous system. They accounted for 57% of all cancers diagnosed in children in 2001 (AIHW1).

- Although deaths due to chronic disease in children 0-14 years are low, the 6 main causes of death were cancer, cerebral palsy, epilepsy, asthma, diabetes, and cystic fibrosis (AIHW1). Deaths from cancer accounted for more than twice the number of all other deaths from chronic disease added together (AIHW1). Most children who get these diseases live a life of disability requiring constant care and management (AIHW1).

Coulter H, (1990) notes that a study in 1954 of the “neurologic sequelae of prophylactic inoculation” (vaccination) showed that a common factor in the pathology of encephalitis from vaccination is “anaphylactic hypersensitivity”. (p. 152)

Anaphylactic hypersensitivity has reached such high levels in Australian children (6% of children are affected (AIHW3) that guidelines are now being put in place to ensure teachers are trained to deal with this syndrome (Anaphylaxis Australia).

The occurrence of many of these conditions is observed to be four times greater in boys than girls which is the same ratio observed in children with a dysfunctional gene (metallothionein) known to bind with heavy metals to enable them to cross the blood brain barrier and be eliminated from the body (Walsh W, (2000) as cited in Kirby D, 2005).

A P P E N D I X

EPIDEMIOLOGICAL STUDIES

7

EPIDEMIOLOGICAL STUDIES

STUDY 1

Feery BJ, (1982) describes the toxic effects of pertussigen (pertussis toxin) as having histamine-sensitising (allergies), lymphocytosis-promoting (leukaemia) and pancreatic islet-activating properties (diabetes mellitus). He designed a study in 1982 to determine the incidence and type of reactions associated with the use of DTP vaccine. It involved interviewing parents and completing a questionnaire about reactions observed in infants after immunization. However, the parameters of the study were limited and had a significant effect on the conclusions that could be drawn. The limitations included:

- 1) It only included reactions that occurred within three days of immunization.
- 2) Parents to be interviewed were selected according to the workload of the Health Centre sisters.
- 3) It was not a controlled study and it did not compare vaccinated children with unvaccinated children.
- 4) It only examined the presence or absence of local (mild) or general reactions (severe). It did not include allergies, asthma, diabetes, leukaemia, developmental delay, intellectual or behavioural disabilities
- 5) The 18 months booster was removed from the schedule at this time.
- 6) Parents were invited to comment on the 'condition' of the child. It is not clear what this term means. Does it include development of the child over the five-year period with respect to behavioural and intellectual abilities or appearance of the child in terms of comfort and well-being?
- 7) The researchers admit that the wording of the questions in the pilot study produced a different result in the actual study when the wording of the question was changed.
- 8) In this study any child who reacted unduly to an earlier dose or who was contraindicated to the vaccine was given DT vaccine. At this time contraindications of the vaccine included a family history of specific allergies to vaccine components or a family history of neurological disease. (Part 1) Establishing these contraindications in a two-month old baby is difficult therefore most babies are vaccinated.
- 9) The DTP vaccine is manufactured by the Commonwealth Serum Laboratories (CSL) and the Data Processing was performed by the CSL
- 10) The study claims there was no neurological sequelae after any reactions but it doesn't indicate how long the period of follow up was for each child nor what 'sequelae' were monitored.

STUDY 2

THE BRITISH CHILDHOOD ENCEPHALOPATHIC STUDY (NCES)

This study was a large case control, population-based study carried out from 1976 – 1979 in Britain (AAP, 2001). It examined cases of acute neurological illnesses in children 2 to 36 months of age who were admitted to hospitals. The study population consisted of 1182 cases with two matched controls for each case. The researchers concluded from the study that a significant association exists between the occurrence of acute neurological illness (excluding infantile spasms) within 7 days of vaccination with DTP. The relative risk of DTP immunization resulting in neurological illness in the vaccines, as determined by this study was 3.3 (95% confidence interval, 1.7 to 6.5) (AAP, 2001)

Yet in 1991 the American Academy of Pediatrics (AAP) re-assessed the conclusions after a ten-year follow up period and concluded the whole-cell pertussis vaccine had not been proven to be a cause of permanent brain damage. This is despite the 1991 Institute Of Medicine (IOM) review committee concluding that the evidence was consistent with a causal relationship between DTP vaccine and acute encephalopathy as defined in the NCES study (AAP, 2001). The IOM had established that the attributable risk in the NCES study for serious acute neurological illness (most commonly prolonged febrile convulsions) in the week after DTP immunization was 6.8 per million doses. The estimated risk for encephalopathy was 2.7 per million doses (AAP, 2001).

However, the IOM review committee also changed its conclusion to “the whole-cell pertussis vaccine ‘may on rare’ occasions be associated with the development of severe acute neurological illness that can have serious sequelae” (AAP, 2001).

STUDY 3

BLUMBERG et al, 1993

Blumberg et al, (1993) hypothesized that pertussis toxin may retain some of its biological activity in DTP vaccine or even revert from an inactive form to an active form. They designed a study to test the suggestion that reversion to virulence may cause histamine sensitization or alterations in insulin and glucose metabolism resulting in serious adverse reactions such as seizures, hypotonic-hyporesponsive episodes or persistent crying, which have been observed after pertussis vaccination (Blumberg et al, 1993).

This study was inconclusive in its results and limited because of the small number of children studied (60), the inadequacy of the test used to identify pertussis toxin activity and the fact that it did not examine the role of the other numerous toxic factors in the pertussis vaccine (Blumberg et al, 1993) Other possible toxic factors include endotoxin – a poison contained in gram-negative bacteria, that is generally harmful to all body tissues and released when the cell dies or disintegrates (Martin E (ed), 2004), agglutinogens (cause clumping of red blood cells), filamentous hemagglutinin, pertactin, tracheal cytotoxin, dermonecrotic toxin and adenylate cyclase toxin (Blumberg et al, 1993).

Yet the authors conclude “ we have found no evidence that pertussis toxin in DTP vaccine plays a role in severe DTP vaccine reactions.” This is not an accurate conclusion. There is evidence that pertussis plays a role in DTP vaccine reactions (as seen in animal studies and adverse reactions to the vaccine) but this small study did not find evidence of the mechanism by which this might happen.

A P P E N D I X

NATIONAL IMMUNISATION SCHEDULE 2006

8



National Immunisation Program Schedule

(VALID FROM 1 NOVEMBER 2005)

Age	Vaccine
Birth	<ul style="list-style-type: none">Hepatitis B (hepB) ^a
2 months	<ul style="list-style-type: none">Hepatitis B (hepB) ^bDiphtheria, tetanus and acellular pertussis (DTPa)<i>Haemophilus influenzae type b (Hib)</i> ^{c,d}Inactivated poliomyelitis (IPV)Pneumococcal conjugate (7vPCV)
4 months	<ul style="list-style-type: none">Hepatitis B (hepB) ^bDiphtheria, tetanus and acellular pertussis (DTPa)<i>Haemophilus influenzae type b (Hib)</i> ^{c,d}Inactivated poliomyelitis (IPV)Pneumococcal conjugate (7vPCV)
6 months	<ul style="list-style-type: none">Hepatitis B (hepB) ^bDiphtheria, tetanus and acellular pertussis (DTPa)<i>Haemophilus influenzae type b (Hib)</i> ^cInactivated poliomyelitis (IPV)Pneumococcal conjugate (7vPCV) ^e
12 months	<ul style="list-style-type: none">Hepatitis B (hepB) ^b<i>Haemophilus influenzae type b (Hib)</i> ^dMeasles, mumps and rubella (MMR)Meningococcal C (MenCCV)
12-24 months	<ul style="list-style-type: none">Hepatitis A (Aboriginal and Torres Strait Islander children in high risk areas) ^f
18 months	<ul style="list-style-type: none">Varicella (VZV)
18-24 months	<ul style="list-style-type: none">Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander children in high risk areas) ^gHepatitis A (Aboriginal and Torres Strait Islander children in high risk areas)
4 years	<ul style="list-style-type: none">Diphtheria, tetanus and acellular pertussis (DTPa)Measles, mumps and rubella (MMR)Inactivated poliomyelitis (IPV)
10-13 years ^h	<ul style="list-style-type: none">Hepatitis BVaricella (VZV)
15-17 years ⁱ	<ul style="list-style-type: none">Diphtheria, tetanus and acellular pertussis (dTPa)
15-49 years	<ul style="list-style-type: none">Influenza (Aboriginal and Torres Strait Islander people medically at-risk)Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people medically at-risk)
50 years and over	<ul style="list-style-type: none">Influenza (Aboriginal and Torres Strait Islander people)Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people)
65 years and over	<ul style="list-style-type: none">InfluenzaPneumococcal polysaccharide (23vPPV)

* Please refer to reverse for footnotes

IMMUNISATION

Footnotes to National Immunisation Program Schedule

- a Hepatitis B vaccine should be given to all infants as soon as practicable after birth. The greatest benefit is if given within 24 hours, and must be given within 7 days.
- b Total of three doses of hepB required following the birth dose, at either 2m, 4m and 6m or at 2m, 4m and 12m.
- c Give a total of 4 doses of Hib vaccine (2m, 4m, 6m and 12m) if using PRP-T Hib containing vaccines.
- d Use PRP-OMP Hib containing vaccines in Aboriginal and Torres Strait Islander children in areas of higher risk (Queensland, Northern Territory, Western Australia and South Australia) with a dose at 2m, 4m and 12m.
- e Medical at-risk children require a fourth dose of 7vPCV at 12 months of age, and a booster dose of 23vPPV at 4 years of age.
- f Two doses of hepatitis A vaccine are required for Aboriginal and Torres Strait Islander children living in areas of higher risk (Queensland, Northern Territory, Western Australia and South Australia). Contact your State or Territory Health Department for details.
- g Contact your State or Territory Health Department for details.
- h These vaccines are for one cohort only within this age range, and should only be given if there is no prior history of disease or vaccination. Dose schedules may vary between jurisdictions. Contact your State or Territory Health Department for details.
- i This vaccine is for one cohort only within this age range. Contact your State or Territory Health Department for details.

Further information

Please refer to the *Australian Immunisation Handbook 8th Edition*, available at www1.health.gov.au/immhandbook, for detailed information on vaccine scheduling and administration. Further information and immunisation resources are available from the Immunise Australia Program website at www.immunise.health.gov.au or by contacting the infoline on 1800 671 811.

You should contact your State or Territory health department for further information on the program specific to your State or Territory:

State/Territory	Contact Number
Australian Capital Territory	02 6205 2300
New South Wales	Public Health Unit (look under 'Health' in the White Pages)
Northern Territory	08 8922 8044
Queensland	07 3234 1500
South Australia	08 8226 7177
Tasmania	1800 671 738 (Tasmania only)
Victoria	1300 882 008
Western Australia	08 9321 1312

IMMUNISE
AUSTRALIA PROGRAM
An Australian, State and Territory
Governments Initiative

CONFLICT OF INTEREST

Conflict of Interest

Kleinman et al, (2005) claim the pharmaceutical industry sells drugs to the community without randomised clinical trials and down plays the effects (p.13). This is the possibility that is presented when pharmaceutical companies are allowed to promote drugs/vaccines to the medical profession by offering awards to medical practitioners. An example of this is the Infanrix Awards of \$10,000, which are offered to health Professionals to increase vaccination rates. Pharmaceutical companies are driven by profits and doctors are induced to sell the vaccine for profit. This can result in a disregard for medical ethics and the public interest. (Fitzgerald PD, 2001) In this way the pharmaceutical companies are determining what is best for the public interest and undermines health professionals as a credible source of health information.

Fitzgerald PD, (2001) states that Australian governments have encouraged the transition of the Australian health system to a “free market” model, with little understanding of the role general practitioners play in protecting the public interest.

Kirby D, (2005) has documented the conflict of interest that exists within the Centre for Disease Control (CDC) and the Food and Drug Administration (FDA) in America. The following is a list of some of the conflicts of interest in these organizations:

- Members of the FDA and CDC advisory committees who make these decisions own stock in drug companies that make vaccines.
- Individuals on both advisory committees own patents for vaccines under consideration or affected by the decisions of the committee.
- Three out of five of the members of the FDA’s advisory committee who voted for the rotavirus vaccine had conflicts of interest that were waived.
- The CDC grants conflict of interest waivers to every member of their advisory committee a year at a time and allows full participation in the discussions leading up to a vote by every member, whether they have a financial stake in the decision or not.
- CDC’s advisory committee has no public members – no parents have a vote on whether a vaccine belongs on the childhood immunization or not. The FDA’s committee has only one public member (p.124).