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IMMUNISATION — BENEFITS OUTWEIGH RISKS

Immunisation programs in NSW have been extremely effective in reducing the risk of disease. Diphtheria and poliomyelitis have been eliminated, tetanus is rare, and measles and whooping cough occur far less frequently than before immunisation became universally available.

However, as the risks of disease have lessened, concerns about the side effects and complications of immunisation have increased.

Despite the safety and efficacy of modern vaccines, complications do occur. Although their rates are difficult to estimate, it is known that side effects of immunisation are far less frequent than the complications caused by the diseases themselves.

Fever and neurological conditions occur spontaneously in children whether immunised or not. Against this background, it is sometimes difficult to determine if a recent immunisation is causally, or merely coincidentally, related to a child's illness.

DIPHTHERIA

Diphtheria, caused by *Corynebacterium diphtheriae*, is an acute infectious disease which mainly affects the upper respiratory tract. It is characterised by an inflammatory exudate which forms a membrane that causes acute respiratory obstruction. The major complications of diphtheria are cardiac dysfunction and neuropathy. For complication rates from diphtheria, see Table 1.

TABLE 1

COMPLICATION RATES FROM DIPHTHERIA

COMPLICATION	RATE/100,000 CASES
Cardiac dysfunction	10,000 - 25,000
Neuropathy	75,000
Death	3500 - 12,000

(Source: Reference 2)

Diphtheria has been effectively controlled in NSW. Since 1982, only one case of diphtheria has been notified to the NSW Health Department (1987).

For vaccine adverse reactions, see Table 3.

TETANUS

Tetanus is an acute, often fatal, disease caused by the toxin produced by the bacterium, *Clostridium tetani*. Muscle rigidity with superimposed painful spasms occurs. Complications of tetanus include respiratory failure, pneumonia, pulmonary embolus, hypertension, hypotension and myocarditis.

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In NSW, tetanus has become a rare condition (see Table 2). All recent cases have occurred in unimmunised adults. Severe cases of tetanus have a case fatality rate of 44 per cent[2].

TABLE 2

NOTIFICATIONS OF TETANUS IN NSW 1982-1990

YEAR	NOTIFICATIONS
1982	0
1983	0
1984	4
1985	1
1986	0
1987	1
1988	1
1989	0
1990	2
1991	1

(Source: Epidemiology and Health Services Evaluation Branch)

For vaccine adverse reactions, see Table 3.

PERTUSSIS (WHOOPING COUGH)

Pertussis, caused by *Bordetella pertussis*, is a highly infectious disease which involves the respiratory system. It causes distressing spasms of repeated violent coughing over a prolonged period. Even minor episodes of whooping cough can last for 6-8 weeks before coughing abates. Hospitalisation is often required for the treatment of children.

Complications of the condition include malnutrition caused by excessive vomiting, pneumonia, encephalitis, convulsions, coma and permanent brain damage (see Table 3). The death rate from whooping cough in Australia before the availability of a vaccine was 41.3/100,000 (1927-1936). This dropped to 0.13/100,000 (1967-1976) as a direct result of routine infant immunisation[3].

TABLE 3

ESTIMATED RATES OF ADVERSE REACTIONS FOLLOWING DTP IMMUNISATION COMPARED TO COMPLICATIONS OF PERTUSSIS

ADVERSE REACTION	WHOOPING COUGH COMPLICATIONS/ 100,000 CASES	DTP VACCINE REACTIONS/ 100,000 DOSES
Encephalitis	90 - 4000	0.1 - 3.0
Convulsions	600 - 8000	0.3 - 90
Permanent brain damage	600 - 2000	0.2 - 0.6
Death	100 - 4000	0.2
Hypersensitivity		0.5 - 30

(Source: Reference 5)

Epidemics occur when immunisation rates fall. Pertussis continues to occur in NSW, as demonstrated by the 1989/1990 figures (see Table 4). In the UK, due to adverse publicity in 1974-1978, whooping cough immunisation levels fell from 80 per cent to 31 per cent. In 1977-1979, there were 102,500 cases of whooping cough and 300 reported deaths[4]. This represents a case fatality rate of 293/100,000.

TABLE 4

NOTIFICATIONS OF PERTUSSIS IN NSW 1982-1990

YEAR	NOTIFICATIONS
1982	39
1983	137
1984	117
1985	303
1986	227
1987	43
1988	25
1989	202
1990	151

(Source: Epidemiology and Health Services Evaluation Branch)

TRIPLE ANTIGEN (DIPHTHERIA TETANUS PERTUSSIS) VACCINE

Although the pertussis component of triple antigen is more likely to cause side effects and adverse reactions than any other vaccine, the benefits of immunisation far outweigh the risks associated with the disease (see Table 3). Moderate local and systemic reactions can occur but are usually transient and minor in nature (see Table 5).

The National Childhood Encephalopathy Study examined the issue of vaccine safety. This large study conducted in the UK in 1976-1979 concluded that the estimated attributable risk of serious neurological disorders occurring within seven days of immunisation with DTP in previously normal children and persisting for one year was 1:310,000.

That conclusion has recently been criticised as being imprecise and excessive. In a landmark UK judgement in which evidence included that from the National Childhood Encephalopathy Study, Lord Justice Stewart Smith said he was not satisfied that pertussis vaccine caused permanent brain damage[7,8].

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TABLE 5

SIDE EFFECTS OF TRIPLE ANTIGEN IN AUSTRALIA

SIDE EFFECTS	%
Redness, bruising at the injection site	48
Irritability or vomiting	24
Fever	16
Persistent screaming	7
Drowsiness	5
Pallor	1
Convulsions	0.03

(Source: Reference 6)

This was supported by another large study conducted in the US. No evidence was found to support claims that in the three days following DTP immunisation, the risk of afebrile seizures or acute symptomatic seizures was increased. The report concluded that "serious neurological events are rarely, if ever, caused by DTP immunisation"[9].

MEASLES

Measles is an acute viral illness characterised by fever, rash, coryza, cough and conjunctivitis. The most common complications of measles involve the respiratory tract and the central nervous system. Pneumonia, encephalitis, convulsions, Subacute Sclerosing Panencephalitis (SSPE) and death can occur.

SSPE is a rare, fatal, degenerative disease of the central nervous system, which affects children and adolescents who have contracted measles (see Table 6).

TABLE 6

RATES OF SERIOUS ADVERSE REACTIONS FOLLOWING MEASLES IMMUNISATION COMPARED TO COMPLICATIONS OF MEASLES INFECTION

ADVERSE REACTION	MEASLES COMPLICATIONS/ 100,000 CASES	MEASLES VACCINE REACTIONS/ 100,000 DOSES
Pneumonia	3800 - 7300	0
Encephalitis	50 - 400	0.1
Convulsions	500 - 1000	0.02 - 190
SSPE	0.5 - 2.0	0.05 - 0.1
Death	10 - 10,000	0.02 - 0.3

(Source: Reference 5)

Epidemics of measles continue to occur at three-yearly intervals (see Table 7).

TABLE 7

NOTIFICATIONS OF MEASLES IN NSW 1982-1990

YEAR	NOTIFICATIONS
1982	96
1983	47
1984	236
1985	46
1986	140
1987	246
1988	43
1989	76
1990	388

(Source: Epidemiology and Health Services Evaluation Branch)

Since 1983, there have been 120 cases of SSPE reported in Australia. There have been 36 cases reported in NSW since 1985.

MUMPS

Mumps is an acute viral disease characterised by fever, swelling and tenderness of one or more salivary glands, usually the parotid gland. Signs of meningeal irritation appear in up to 15 per cent of cases, but permanent sequelae are rare.

Nerve deafness is one of the more serious of the rare complications (one in 500 hospitalised cases). Testicular inflammation has been reported in up to 20 per cent of clinical mumps cases in post-pubertal males, but sterility is rare. Inflammation of other organs has been observed less frequently (pancreas, ovaries, liver, heart and thyroid). Mumps is not a notifiable disease in NSW at present.

RUBELLA

Rubella (German measles) is a mild disease, causing a rash, enlarged lymph nodes and, occasionally, arthritis.

The most important complication is maternal rubella, where infection during the first trimester is the period of greatest risk for the foetus. Congenital rubella syndrome (CRS) can occur. Congenital defects include deafness, blindness, cardiac defects and mental retardation.

Rubella is not a notifiable disease in NSW. However, since 1982, five cases of congenital rubella syndrome have been reported in NSW.

In the US in 1985, the reported incidence of CRS was 0.05/100,000 live births[10].

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TABLE 8

NOTIFICATIONS OF CONGENITAL RUBELLA SYNDROME IN NSW 1982-1990

YEAR	NOTIFICATIONS
1982	0
1983	0
1984	1
1985	1
1986	2
1987	1
1988	0
1989	0
1990	0

(Source: Epidemiology and Health Services Evaluation Branch)

MEASLES, MUMPS, RUBELLA VACCINE

Reactions to the measles component of the combined measles/mumps/rubella vaccine are significantly less frequent than complications of natural measles[11].

The most common reaction is malaise and fever, with or without a rash (5 per cent). Up to 15 per cent of those vaccinated will develop a fever which may last several days. Febrile convulsions may occur during these episodes.

Severe reactions following measles immunisation are rare. In the US, neurological disorders, including encephalitis and encephalopathy, have been reported with a frequency of less than one per million doses administered (see Table 6)[12]. The incidence of encephalitis after measles immunisation of healthy children is lower than the observed incidence of encephalitis of unknown cause.

Hypersensitivity reactions to the measles vaccine have been reported. It is a National Health and Medical Research Council recommendation that children be observed for an adequate period after receiving the vaccine[11].

Reactions to the mumps component of the combined measles/mumps/rubella vaccine are uncommon and usually mild and of brief duration.

Reactions to the rubella component of the combined measles/mumps/rubella vaccine include fever, sore throat, enlarged lymph nodes, rash and arthritis.

POLIOMYELITIS

Poliomyelitis is an acute illness resulting from the invasion of the gastrointestinal tract by poliovirus. The infection may be clinically unapparent or range in severity from a fever to aseptic meningitis or paralysis and possible death. Symptoms include headache, gastrointestinal disturbance, malaise and stiffness of the neck and back, with or without paralysis.

The most important complications of polio are respiratory failure caused by paralysis of the chest muscles, pneumonia and pulmonary embolus. Gastrointestinal complications include haemorrhage and paralytic ileus. The overall case mortality of paralytic polio in epidemics in the past was 5000-10,000/100,000.

Polio has been effectively controlled in NSW. No cases of polio have been reported since 1982.

POLIOMYELITIS VACCINE (SABIN)

Cases of vaccine-associated poliomyelitis have been reported in people who received oral polio vaccine and in those who had been close contacts with recipients. In the 12-year period, 1969-1980, about 290 million doses of oral polio vaccine were distributed in the US and 92 cases of vaccine-associated paralysis were reported (0.03/100,000 doses)[11]. 25 of these cases were in healthy recipients (0.01/100,000), 55 in healthy close contacts of recipients (0.02/100,000) and 12 (0.004/100,000) in recipients or contacts with immune deficiency conditions.

A large study conducted by the World Health Organisation in 1988 concluded that oral polio vaccine continued to be one of the safest vaccines in use. The risk of vaccine-associated polio was less than one per million vaccinees[13].

CONCLUSION

Current recommendations balance the scientific evidence of benefits, costs and risks. Vaccines used in NSW are safe — both in their own right and in the light of the diseases that they prevent. The benefits of immunisation are substantial — both to the individual child and to the community.

The benefits of the existing immunisation program can be preserved only if immunisation levels are maintained or improved.

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