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Guidelines for the control of pertussis in Australia

November 1997

The control of pertussis in Australia

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Contents

List of figures

Preface

In April 1996 the National Health and Medical Research Council (NHMRC), through its Communicable Diseases Standing Committee, convened the Pertussis Working Party (PWP) to advise on strategies to reduce the unacceptably high incidence of pertussis in Australia.

A public consultation was held in early 1996 and attracted 33 submissions. The PWP considered them in the context of the terms of reference.

With the conclusion of the 1994-96 NHMRC triennium, the PWP continued under the auspices of the National Centre for Disease Control (NCDC), within the Public Health Division of the Commonwealth Department of Health and Family Services.

It was clear to the PWP that strategies to reduce pertussis needed to concentrate on:

- achieving very high (95 per cent or more) full vaccination coverage;
- introducing vaccines with fewer side effects which would be more acceptable to the public;
- improving outbreak control to reduce transmission of the disease; and
- increasing public awareness and provider commitment to immunisation.

National action in each of the above areas is the only way that the incidence of pertussis in Australia can be effectively reduced.

Since the inception of the PWP, State and Federal Governments have introduced many strategies to improve immunisation rates in Australia. In February 1997, the Minister for Health, Dr Michael Wooldridge, launched “Immunise Australia: The Seven Point Plan”, a major initiative aimed at raising the level of immunisation in Australia. This action changed the environment in which the PWP was working and subsequently saw a revision of the group's objectives and priorities.

The Seven Point Plan included initiatives to help address the first and last points. The PWP's immediate and primary roles therefore became:

- to provide advice to the NHMRC on the use of diphtheria-tetanus-acellular pertussis vaccine (DTPa); and
- to develop national guidelines for pertussis outbreak control.

The PWP's advice on the use of DTPa was presented to the NHMRC in June 1997 as a separate document. This allowed a more timely progression of the process for approving DTPa for use in the primary immunisation schedule. Appendix C (p39) contains the NHMRC recommendations on DTPa.

The control of pertussis in Australia focuses on the remaining task of improving outbreak control to reduce transmission of the disease. It also provides an overview of pertussis in Australia and identifies gaps in our knowledge which require further research.

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This report is based on similar documents produced in Canada and the United States of America (CCDR, 1994: Centres for Disease Control and Prevention, 1996). Members of the PWP wish to thank all those who contributed to this report, particularly Associate Professor Geoff Hogg, Microbiological Diagnostic Unit, Melbourne University and Associate Professor Margaret Burgess, Dr Tim Heath and Dr Peter McIntyre, National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases.

Terms of reference

- To advise on methods for improving the uptake of pertussis vaccination;
- To develop guidelines on the control of outbreaks of pertussis; and
- To advise on the most appropriate use of acellular pertussis vaccine in the NHMRC Childhood Immunisation Schedule.

Summary of recommendations

Control of Pertussis

The Pertussis Working Party (PWP) emphasises that complete vaccination of all children remains the most important preventive measure in maintaining control of pertussis. Once an outbreak has occurred prevention of community transmission, although highly desirable, is unlikely to be feasible. The PWP believes the main objective should be to provide protection for those at highest risk of severe disease and its complications through:

- confirmation of the case;
- identification of high risk contacts, especially infants; and
- intervention to prevent transmission in close settings (such as among family members and in day-care settings).

Specifically, the PWP recommends that:

1. If a medical practitioner suspects a patient has pertussis, he/she should:
    - wherever possible, arrange appropriate laboratory tests to confirm the diagnosis (Section 2.2 p13).
    - where appropriate, recommend antibiotic treatment for the case and all household contacts. In households where there are susceptible individuals, especially infants, antibiotic treatment of household contacts should not be delayed pending confirmation of the diagnosis but must be given within the specified time period (Recommendations 3 and 4);
    - immediately advise the public health authority by telephone if the patient attends or works in high risk settings where there are susceptible individuals, especially infants (ie family day-care, child-care). If the patient does not attend or work in a high risk setting, notify the public health authority in accordance with the requirements of the relevant State or Territory. Notification should **not** be delayed because of incomplete information or lack of confirmation.
2. On receipt of a notification of pertussis, public health authorities in consultation with the medical practitioner should:
    - ascertain the pertussis immunisation status of the case (if child under the age of 10 years) (Section 3.3.1 p18);
    - provide advice for all contacts and caregivers in high risk settings such as family day-care and child-care regarding appropriate antibiotic prophylaxis (Recommendations 3 and 4);

- advise on exclusion requirements for cases of pertussis and at risk contacts (Recommendations 5 and 6);
- identify additional cases among family members and contacts in high risk settings (Section 3.4.3 p22);
- enhance pertussis surveillance when an outbreak is suspected (Section 3.7 p27);
- consider an accelerated pertussis vaccination program in communities with evidence of ongoing pertussis transmission (Section 3.6 p26).

3. Patients suspected of having pertussis should be treated with erythromycin (40 to 50mg/kg/day in four divided doses orally, maximum 1g/day, for 10 days). Antimicrobial therapy should not be commenced beyond three weeks after onset of cough (Section 3.4.1 p22).

4. Erythromycin (40 to 50mg/kg/day in four divided doses orally, maximum 1g/day for 10 days) should be recommended for all household contacts and for other contacts in high risk settings where there are susceptible individuals, especially infants. Erythromycin should be given as soon as possible, and no later than 14 days, after the recipient's first contact with a primary case during the infectious period (in high risk household exposure settings, prophylaxis may be considered for up to 21 days from a recipient's first contact with a primary case). Where infants are at risk within a household or other high risk setting, antibiotic treatment of contacts should **not** be delayed pending confirmation of the diagnosis. Note, the infectious period for untreated cases is up to 21 days from onset of cough while for cases receiving antibiotic treatment, the infectious period is five days (Section 3.5.2 p24).

5. Cases of pertussis should be excluded from school, preschool, day-care or other settings where there are susceptible individuals, especially young children and infants, for 21 days from the onset of illness or until they have received at least five days of a 10 day course of erythromycin (Section 3.4.2 p22).

6. Unimmunised household contacts less than seven years of age should be excluded from school, preschool, day-care or other settings where there are susceptible individuals, especially young children and infants, for 14 days after their last exposure to infection or until they have received at least five days of a 10 day course of erythromycin. Close child-care contacts should also be excluded for 14 days from their last exposure to infection or until they have received at least five days of a 10 day course of erythromycin (Section 3.5.3 p26).

7. Standardised criteria should be developed for laboratory identification of pertussis (Section 2.2 p13).

8. The establishment of a pertussis laboratory network should be supported (Section 2.2 p13).

9. States and Territories should collect the information specified in the Pertussis Data Collection Form (p20).

   Where resource limitations prevent investigation of all notifications, those associated with high risk settings where there are susceptible individuals, especially infants (ie family day-care, child-care) should be the highest priority (Section 3.3.1 p18).

   Where resources limit the range of data collected, the PWP urges States and Territories to collect the clinical data specified in the form as this is particularly important in the surveillance of pertussis. If the first interview is conducted within 14 days of cough onset and cough is still present, a follow-up interview must be undertaken to identify persons with a cough duration of 14 days or more (Section 3.3.1 p18).

Research

The PWP acknowledges that pertussis is a world wide problem and encourages collaborative national and international research and information exchange. Specifically, the PWP believes research in the following areas is needed to improve our knowledge and understanding of pertussis:

- dynamics of pertussis transmission, including mother to infant transmission;
- involvement of adolescents and adults in sustaining endemicity;
- improved case investigation;
- serotyping to determine serotype prevalence in the community;
- monitoring effectiveness of pertussis vaccines in the field, including comparison with new vaccines as they become available and post licencing surveillance;
- determining the duration of protection for pertussis vaccines, in particular new vaccines and acellular vaccines;
- local evaluation of new combination vaccines (eg those containing *Haemophilus influenzae* type b (Hib), hepatitis B virus (HBV), diphtheria and tetanus antigens) in terms of immunogenicity, safety and cost-effectiveness;
- a trial of adult formulated pertussis vaccines if initial studies support the view that adults are an important reservoir of *Bordetella pertussis* infection;
- development of more appropriate monitoring systems to encompass minor and severe adverse events, incorporating post-marketing surveillance;
- development of more sensitive, rapid, non-invasive tests for field use;
- development of serological/biological markers of pertussis immunity and susceptibility;
- investigation and development of molecular profiling methods (eg Pulse Field Gel Electrophoresis);

- investigation of alternative antibiotic therapy, particularly other macrolides and once daily or single dose therapy;
- greater input into education through promotional campaigns;
- improved monitoring and evaluation of parent perceptions, risk/benefits of immunisation and educational or promotional activities.

Part A

Control of Pertussis

1 The disease

Pertussis (whooping cough) is a highly contagious, acute, bacterial respiratory disease caused by *Bordetella pertussis*. The organism was first isolated by Jules Bordet in Brussels in 1906 and simple vaccines containing a suspension of whole killed organisms were available soon after.

Pertussis can cause death or serious illness, particularly among infants and young children. In unimmunised populations, epidemics occur every three to four years. Outbreaks also occur every 3 to 4 years in immunised populations, but these outbreaks are much smaller and have a lower morbidity and mortality (The Australian Immunisation Handbook 6th edition, 1997).

1.1 Epidemiology

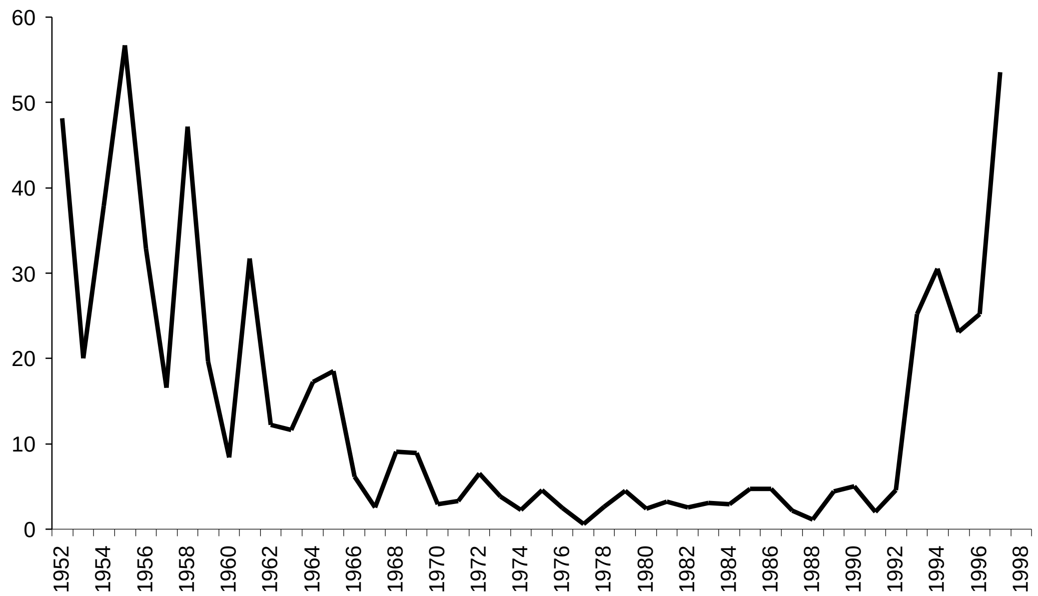
The World Health Organization (WHO) estimates there were 40 million cases of pertussis in 1994 and 360,000 deaths. In industrialised countries, four children out of every 10,000 infected die from pertussis and its complications (World Health Organisation and United Children's Fund, 1996). According to the WHO, only 1 to 2 per cent of cases are reported. Under-reporting is attributed to problems in differentiating pertussis clinically from other respiratory infections and to difficulties confirming the disease through laboratory techniques.

Changes in vaccination coverage have had a dramatic impact on the incidence of pertussis in a number of countries. In England and Wales, improved vaccination coverage (30 per cent in 1978 to 93 per cent in 1996) led to a dramatic decrease in pertussis notifications from (65,810 cases in 1982 to 3,963 cases during the epidemic year of 1994) (White J et al, 1996). In Sweden, withdrawal of the recommendation for pertussis vaccination in 1979 (because of problems with the efficacy of their vaccine) saw the incidence of pertussis in infants rise to pre-vaccination levels within four years. Similarly, a temporary (February - April 1975) suspension of pertussis vaccination in Japan and a subsequent decline in vaccination rates led to a re-emergence of pertussis epidemics throughout the whole country from 1976 to 1981. The number of cases and the number of deaths from pertussis in Japan have now both returned to the pre-1975 levels following the introduction of acellular pertussis vaccine in 1981 and recommencement of mass immunisation at 3 months of age in 1988 (Infectious Agents Surveillance Report, 1997).

In Australia the first pertussis vaccine was manufactured in the 1920s by the Commonwealth Serum laboratories (now CSL Pty Ltd). These early pertussis vaccines reduced the incidence and severity of disease but were not as efficacious as current vaccines. A more potent CSL vaccine was released in 1953. In 1954, the NHMRC recommended immunisation of infants using the new triple antigen vaccine (diphtheria, tetanus and pertussis; DTP).

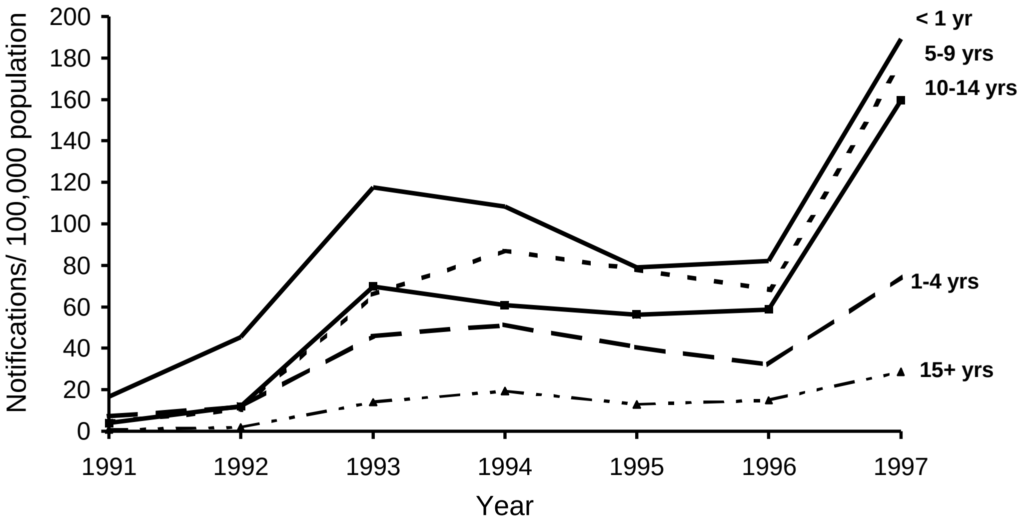
After a prolonged period of apparent low activity, Australia is now experiencing a substantial increase in notifications of pertussis; over 4,000 notified cases occurring each year since 1993 (Figure 1 p8). There is a clear seasonal pattern with 64 per cent of notifications occurring over the spring and summer months. Notification rates have been 10 times higher than those of the United States of America (USA) and three times those of England and Wales (Andrews et al, 1997). Notification rates have been highest in infants (< 1 year of age) and school aged children (five-14 years of age) (Figure 2 p9). A number of factors may be contributing to the increase in notifications including: poor vaccination coverage; waning immunity; the introduction of laboratory reporting in some States and Territories; increased awareness of pertussis and the requirement to notify cases; and/or increased testing, particularly serological testing.

Figure 1 Pertussis notification rate in Australia 1952-97



Note, Figure 1 consists of data from a variety of sources, including the Communicable Diseases Network-Australia New Zealand-National Notifiable Diseases Surveillance System (NNDSS) Notification rates are obtained by using the population of the States and Territories who provided data: 1952-1981, South Australia and Victoria; 1982-1990, includes all States and Territories except Queensland; 1991-1996, Australia (NNDSS). Important changes to pertussis surveillance over this period include the introduction of laboratory reporting in NSW in 1991 and an increase in serologically identified cases since 1993 in other States and Territories.

Figure 2 Pertussis age specific notification rate 1991-97

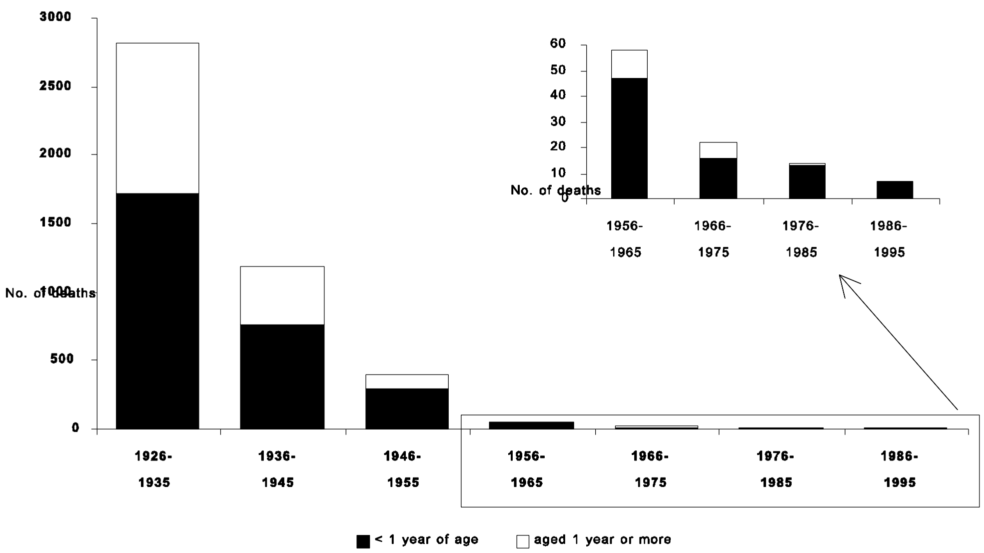


Source: Andrews et al, 1997 and later data from NNDSS

From October 1996 to September 1997, seven children between two weeks and four months of age died from pertussis (Comm Dis Intell, 1997; personal communication, J. McAnulty, NSW Health Department). In the preceding 20 years, from 1976 to 1995, 21 children died from pertussis. All but one of these were less than one year of age (Figure 3 below).

While morbidity and mortality from pertussis have declined dramatically since the pre-vaccine era, we are still seeing an unacceptable level of morbidity and mortality for a vaccine preventable disease.

Figure 3 Deaths from pertussis in Australia 1926-95



Source: ABS yearly mortality tabulations

1.2 The organism

Bordetella pertussis is a fastidious Gram negative bacterium which colonises the respiratory epithelium. Adherence to epithelial cells of the respiratory tract involves bacterial surface antigens, in particular filamentous haemagglutinin (FHA). The bacterium then produces a series of active toxins, including the pertussis toxin and other neurologically active toxins, which together produce the clinical symptoms described below. The bacterium does not invade tissues and therefore does not cause damage in the same way as other respiratory organisms which may cause a classical pneumonia. *B. parapertussis* can cause similar but often milder symptoms.

B. pertussis serotype is determined by the fimbrial antigens (agglutinogens 1, 2 and 3) expressed on the surface of the organism, giving rise to three serotypes: type 1, 2, 3; type 1, 2; and type 1, 3. Serotypes 1, 2 and 1, 3 are predominant in clinical isolates in Australia.

The serotype prevalence may be affected by the immunisation rates within the community. Serotype 1, 2 appears to predominate in unvaccinated communities. Its use in early vaccines slowly led to the emergence of type 1, 3 as the predominant serotype in many countries (Preston and Carter, 1992). In Australia, studies at the Royal Alexandra Hospital for Children (New South Wales) between 1981 and 1990 indicated a shift from the predominant serotype 1, 2 to that of 1, 3 from 1987 onwards (Burgess and Forrest, 1996).

1.3 Transmission

B. pertussis is highly infectious. It may be spread from person to person by close contact, usually by respiratory aerosols, infecting 70 to 100 per cent of household contacts.

Adults and adolescents, either unimmunised or with waning immunity, are thought to be important disseminators and reservoirs of infection (Mertsola et al, 1983; Mink et al, 1994). Pertussis may not be suspected in adults or adolescents until they have transmitted the disease to infant offspring or siblings who are more likely to develop a classic whooping cough. Humans are the only known natural reservoir of *B. pertussis*

1.4 Clinical symptoms

The incubation period for pertussis is six to 20 days, but usually less than 14 days. Infants and unimmunised children are at risk of severe disease whereas older children and adults tend to have mild or atypical disease.

The clinical phases of the disease are:

- the prodromal phase;

- the catarrhal phase which lasts about one to two weeks and is characterised by non-specific symptoms that mimic a cold or other viral upper respiratory tract infection, ie rhinorrhoea, sneezing, mild cough increasing in intensity, conjunctivitis and malaise with little or no fever. During this phase the disease becomes increasingly contagious;
- the paroxysmal phase which is characterised by sudden attacks of severe, repetitive coughing culminating in the characteristic inspiratory whoop often followed by vomiting. Transmission is most efficient in this stage of the disease, which can last up to four weeks; and
- the convalescent phase which is marked by a reduction in the frequency and duration of coughing spells. A complete recovery may take from several weeks to three or more months.

Complications of pertussis include:

- facial suffusion, small haemorrhages in the conjunctivae, small haemorrhages in the skin, particularly over the head and neck as a result of intrathoracic pressure or the force of the coughing. The force of the coughing can also lead to the development of a hernia or rectal prolapse;
- hypoxic encephalopathy can occur following serious bouts of repeated prolonged coughing. It is estimated that encephalopathy from pertussis disease occurs in 1.1 per cent of cases in infants less than six months of age and in 0.7 per cent of cases for all ages (Farizo et al, 1992). This can lead to altered conscious state and cerebral function and potentially permanent damage as a result of exposure to the neurological effects of pertussis toxins;
- malnutrition can occur in extreme cases when children are unable to stop coughing long enough to eat; and
- aspiration of food particles, vomit or mucous leading to secondary pneumonia.

Infants have the highest risk for severe complications and death from pertussis infection. There is little protection from passively acquired maternal antibody. Infants are therefore at risk from birth and can be infected before they receive their first dose of vaccine or before they have time to develop immunity as a result of vaccination.

In Australia, most deaths occur in children less than one year of age. Deaths usually occur as a result of aspiration, pneumonia or wasting associated with malnutrition, possibly complicated by hypoxic encephalopathy and resulting cardiac failure. Morbidity associated with pertussis in older children is also very substantial. Preschool and school aged children who develop symptomatic pertussis may miss several weeks of school due to the impact of the paroxysmal phase of the cough which can last three months or more.

2 Diagnosis

2.1 Clinical diagnosis

Clinical diagnosis based on the duration of cough and the characteristic nature of the disease is critical in identifying pertussis because there are often difficulties in obtaining laboratory confirmation of the diagnosis. In the absence of standardised criteria, the results of laboratory tests are also often difficult to interpret.

For severe cases, clinical diagnosis based on the presence of coughing paroxysms, inspiratory "whoop" or post-tussive vomiting without other apparent cause is often sufficiently distinctive to identify pertussis. Infants less than six months of age, and to a lesser extent those less than 12 months of age, are less likely to present with paroxysmal cough. For these children, severe apnoea may be the only or dominant manifestation.

Children who have received some but not all of the recommended doses of vaccine, and children who acquire infection despite having completed their vaccination schedule, appear to have less severe illness and are much more difficult to diagnose clinically (CCDR, 1994).

If a medical practitioner suspects a patient has pertussis, he/she should:

- wherever possible, arrange appropriate laboratory tests for confirmation of the diagnosis (Section 2.2 p13);
- where appropriate, recommend antibiotic treatment for the case and all household contacts. In households where there are susceptible individuals, especially infants, antibiotic treatment of household contacts should not be delayed pending confirmation of the diagnosis but must be given within the specified time period (Sections 3.4.1 p22 and 3.5.2 p24);
- if the patient attends or works in high risk settings where there are susceptible individuals, especially infants (ie family day-care, child-care), advise the public health authority immediately by telephone. Otherwise, notify the public health authority in accordance with the requirements of the relevant State or Territory. Notification should not be delayed because of incomplete information or lack of confirmation.

2.2 Laboratory diagnosis

The PWP encourages development of standardised criteria for laboratory identification of pertussis and supports the establishment of a pertussis laboratory network. Specific issues relating to laboratory diagnosis are as follows:

Serology

- Serologic testing of pertussis has not been standardised and should not be considered as a definitive diagnosis. IgM serology has not been adequately validated and is not considered useful. Where serologic testing is requested, IgA serology should be specified. However, *Bordetella pertussis*-specific IgA is less sensitive in children under two years of age, and is of little value in children less than three months of age. A patient with *Bordetella pertussis*-specific IgA in serum and a cough illness lasting 14 days or more should be reported to the public health authority for follow-up (Section 3 p17).

Culture

- At present, culture is the only standardised test for laboratory confirmation of pertussis and should be performed in a laboratory with established expertise in isolating the organism. Nasopharyngeal cultures should be collected by either aspiration or using a calcium alginate swab (cotton swabs must not be used). If required, nasopharyngeal cultures can be arranged through referral to a laboratory service. There is no role for oropharyngeal culture as results are likely to be falsely negative. Nasopharyngeal cultures are also likely to be falsely negative if taken more than 21 days after onset of cough, or if the individual is on antimicrobial therapy effective against *Bordetella pertussis* (eg erythromycin, trimethoprim-sulfamethoxazole, tetracycline). Under such conditions, a negative culture result does not preclude the diagnosis of pertussis.

PCR

- Identification of *Bordetella pertussis* in nasopharyngeal secretions by the polymerase chain reaction (PCR) technique is in the developmental stage but should be considered as a confirmed diagnosis if undertaken in a laboratory with established expertise in the area. It is likely that PCR will be a more widely acceptable diagnostic method in the near future.

DFA

- Owing to an unacceptably high rate of false-positive and false-negative results, commercially available direct fluorescent antibody (DFA) tests are of no use and should not be used for case confirmation. Asymptomatic people who are only DFA positive (ie culture negative) are not considered cases and no follow-up is necessary.

2.3 Case definitions

Criteria for identifying cases of pertussis at the State and Territory level should be uniform and consistent. The PWP notes that various States and Territories have not adopted the NHMRC case definition for pertussis but recognises that the definition is in need of review. The PWP urges all States and Territories to adopt the following case definitions for pertussis:

Probable

- A cough illness lasting 14 days or more with one of the following: paroxysms of coughing; inspiratory "whoop" or post-tussive vomiting, without other apparent cause; or
- A cough illness lasting 14 days or more in a patient with *Bordetella pertussis*-specific IgA detected in serum.

Laboratory Confirmed

- Isolation of *Bordetella pertussis* from a clinical specimen; or
- Positive polymerase chain reaction (PCR) assay for *Bordetella pertussis* undertaken in a laboratory with established expertise in the area.

Epidemiologically Confirmed

- A cough illness lasting 14 days or more in a patient who is epidemiologically linked to a laboratory confirmed case.

The definitions are based on those specified by the NHMRC but do not include detection of *B. pertussis* antigen in a nasopharyngeal specimen using immunofluorescence owing to difficulties in interpreting these results.

A person is considered to be "epidemiologically linked" if he/she had close contact with a confirmed case during the incubation period (six to 20 days) and if onset of cough for the person was between 30 days before to 30 days after onset of cough in the confirmed case.

3 Response

The PWP emphasises that complete vaccination of all children remains the most important preventive measure in maximising control of pertussis.

3.1 Objectives

Once an outbreak of pertussis has occurred prevention of community transmission, although highly desirable, is unlikely to be feasible. The PWP believes the main objective should be to provide protection for those at highest risk of severe disease and its complications through:

- confirmation of the case;
- identification of high risk contacts, especially infants; and
- intervention to prevent transmission in close settings (such as among family members and in day-care settings).

This requires a close partnership between medical practitioners and public health authorities, including frequent and early two-way communication.

3.2 Surveillance and reporting

Ongoing surveillance has a critical role in the management of pertussis through:

- monitoring the effectiveness of vaccine programs by detecting outbreaks in the community and establishing whether the problem is due to a failure to vaccinate or vaccine failure.
- monitoring the incidence of the disease; and
- detecting cases at the earliest opportunity to enable optimal public health interventions.

Pertussis is a notifiable disease under the public health legislation of each State and Territory and should be reported to the public health authority in accordance with the requirements of each State and Territory. **If a patient suspected of having pertussis attends or works in high risk settings where there are susceptible individuals, especially infants (ie family day-care, child-care), the public health authority should be advised immediately by telephone because early notification is essential for effective public health intervention.** Reporting should **not** be delayed because of incomplete information or lack of confirmation.

3.3 Public health action

Upon receiving a notification of pertussis, public health authorities in consultation with the medical practitioner should

- ascertain the pertussis immunisation status of the case (if the case is a child under 10 years of age) (Section 3.3.1 p18);
- provide advice for all contacts and caregivers in high risk settings such as family day-care and child-care regarding appropriate antibiotic prophylaxis (Section 3.5 p23);
- advise on exclusion requirements for cases of pertussis and at risk contacts (Sections 3.4.2 p22 and 3.5.3 p26);
- identify additional cases among family members and contacts in high risk settings (Section 3.4.3 p22);
- enhance pertussis surveillance when an outbreak is suspected (Section 3.7 p27);
- consider an accelerated pertussis vaccination program in communities with evidence of ongoing pertussis transmission (Section 3.6 p26).

3.3.1 Information to collect

Each State and Territory currently forwards de-identified notification data to the National Notifiable Diseases Surveillance System (NNDSS) on a fortnightly basis. The data include age in years, date of onset and date of notification to the relevant public health authority. Summary data are reported in *Communicable Diseases Intelligence* (CDI). Gaps in national surveillance include the need for information on the vaccination status of cases, the method of diagnosis, and the date of birth (or age in months if less than two years of age) (Andrews et al, 1997).

The PWP recommends States and Territories collect the information specified in the Pertussis Data Collection Form (p20). The information in the form is considered epidemiologically important (Centres for Disease Control and Prevention, 1996), however the PWP acknowledges that resource limitations within States and Territories may prevent investigation of all cases or limit the range of data collected. In these circumstances the PWP recommends:

- where resource limitations prevent investigation of all notifications, those associated high risk settings where there are susceptible individuals, especially infants (ie family day-care, child-care) should be the highest priority.
- where resources limit the range of data collected, the PWP urges States and Territories to collect the clinical data specified in the form. This is particularly important in the surveillance of pertussis because of the limitations of laboratory testing. If the first interview is conducted within 14 days of cough onset and cough is still present, a follow-up interview must be undertaken to identify persons with a cough duration of 14 days or more.

The data collection form is provided as a guide. While States and Territories are encouraged to adopt the form, some may decide not to collect all the information (for example, the information relating to treatment may be omitted). Where information is collected, this should be done in the prescribed format or be compatible with the prescribed format.

The PWP suggests that the patient's Medicare number be included in the data collected at the State or Territory level to enable validation of the patient's reported vaccination status against the Australian Childhood Immunisation Register (ACIR). It would not, however, be necessary to include the Medicare number in the minimum data set for national reporting.

The data collection form does not include serotype as this information will be collected through the Pertussis Laboratory Network which has undertaken to store pertussis isolates for the foreseeable future and to ensure the isolates are available for typing studies as appropriate. Agreed standardised methods for the typing of pertussis will be developed through the pertussis laboratory network.

Pertussis Data Collection Form

State/Territory use

Reporting GP/Clinic/Laboratory/Hospital
Address
Phone

Patient Surname
First Name
Medicare No.

Address (No. & Street)
Town/Suburb
Phone

Patient details

Post code
State/Territory
Notification date (day, month, year)

State/Territory Identification No.

Date of birth (day, month, year)

If D.O.B unknown specify
Age (Unk = 999)
Unit: Y=Years, M=Months (if < 2 yrs), U=Unknown

Sex: M=Male, F=Female, U=Unknown

ATSI origin: A=Aboriginal or Torres Strait Islander, N=Not Aboriginal or Torres Strait Islander, U=Unknown

Clinical data

Any cough?
Coughing paroxysms?
Inspiratory "whoop"?
Post-tussive vomiting?
Y=Yes, N=No, U=Unknown

Date of cough onset (day, month, year)

Final interview date (day, month, year)

Cough at final interview? Y=Yes, N=No, U=Unknown

Days of cough at final interview (Unk=999)

Complications

Hospitalised: Y=Yes, N=No, U=Unknown

Days hospitalised (Unk = 999)

Pneumonia documented by chest x-ray
Seizures due to pertussis
Acute encepatholopathy due to pertussis
Y=Yes, N=No, X=X-ray not done, U=Unknown

Died: Y=Yes, N=No, U=Unknown

Laboratory

Was laboratory testing for pertussis done? Y=Yes, N=No, U=Unknown

	Date specimen taken (day, month, year)	Result
Culture		
PCR		
IgA serology		

Result: P=Positive, N=Negative, I =Intermediate, E=Pending, X=Not done, U=Unknown, S=Parapertussis

Note: IgG and IgM serology should not be accepted.

Treatment

Were antibiotics given? Y=Yes, N=No, U=Unknown

1st antibiotic received: E=Erythromycin, C=Cotrimoxazole, O=Other, U=Unknown

Date 1st antibiotic started

Days actually taken (Unk=99)

2nd antibiotic received (see choices for 1st antiobiotic)

Date 2nd antibiotic started

Days actually taken (Unk=99)

Epidemiological

Date case investigation started

Outbreak related?
Epi-linked? (see Notes at rear)
Y=Yes, N=No, U=Unknown

Outbreak name

Where did this case acquire pertussis? (1-10) (Unk=99)

Was there further documented spread within the home from this case? Y=Yes, N=No, U=Unknown

To where was there further documented spread outside the home from this case? (2-12) (Unk=99)

1=Home
2=Family day-care
3=Other child-care
4=Pre-school
5=Primary school
6=Secondary Sch./Uni. /Work
7=Health care facility
8=Closed setting
9=Remote community
10=Other
11=Spread to > 1 setting
12=No further documented spread
99=Unknown

Number of contacts in any setting recommended antibiotics (Unk=999)

Pertussis vaccination

Complete this section if child < 10 yrs

Ever had any vaccines against pertussis? Y=Yes, N=No, U=Unknown

No. of doses of pertussis-containing vaccines prior to illness onset

	Date given (day, month, year)	Vaccine type	Information source
1st			
2nd			
3rd			
4th			
5th			

Type Codes: W=Wholecell, A =Acellular, U =Unknown

Source Codes: 1=Parent recall, 2=Parent record, 3=Provider record, 4=ACIR record, 5=State/Local govt. register, 6=Other, 9=Unknown

Pertussis Data Collection Form

Comments

Notes

Patient details	
Age	* Age of patient at onset of cough in years or, if the patient is aged < 2 yrs, in months.
ATSI origin	* Ask "Are you (is the person) of Aboriginal or Torres Strait Islander origin?"
Clinical data	
Coughing paroxysms	* Sudden attacks of severe repetitive coughing where one cough follows the next without a break for breath.
Inspiratory "whoop"	* High pitched noise heard on breathing in after a coughing spasm.
Post-tussive vomiting	* Vomiting that follows coughing spasms.
Final interview date	* Date of the last interview conducted with the patient or provider to obtain case information.
Cough at final interview	* Was the patient still coughing at the time of the final interview?
Days of cough	* The total number of days the patient has coughed by the time of the final interview. If cough < 14 days when the case is reported, a follow up interview must be undertaken to identify persons with a cough ≥ 14 days.
Complications	
Chest x-ray	* Documented pneumonia from chest x-ray = Yes; chest x-ray done but no pneumonia = No.
Seizures	* Generalised or focal seizures due to pertussis.
Acute encephalopathy	* Acute illness of the brain manifesting as decreased level of consciousness (excluding postictal state) and reduced level of nervous system functioning. Seizures may or may not occur. Such patients are always hospitalised and have undergone extensive evaluation. (This should be verified by a medical practitioner).
Died	* If patient died from pertussis, verification with the medical practitioner is recommended.
Epidemiological	
Outbreak related	* The case is part of a documented outbreak where there has been at least one PCR or culture confirmed case and an increase in the number of pertussis cases above that normally expected to occur.
Epi-linked	* The case has had close contact with a PCR or culture confirmed case during the incubation period (6-20 days), with cough onset in the case between 30 days before to 30 days after cough onset in the "laboratory confirmed" case.
No. of contacts recommended antibiotics	* Indicate the number of contacts of this case for whom antibiotics were recommended. If this case is part of an outbreak, only count the additional contacts associated with the case not those that have already been counted for other cases.
Closed setting	* Includes boarding schools, school camps and military barracks where individuals sleep in the same room, dormitory or tent.

3.4 Management of cases

3.4.1 Treatment of cases

Although antibiotics may have little effect on the clinical course once symptoms are established, their use can accelerate clearance of the organism and limit spread of the disease. Authorities in the USA recommend 14 days of erythromycin at up to 2g/day for adults for treatment and prophylaxis (American Academy of Pediatrics, 1991) while Canadian authorities recommend up to 1g/day for 10 days (CCDR, 1994). The PWP believes compliance would significantly improve if a shorter course with a lower amount of erythromycin is recommended.

A recent report demonstrated that a seven day course of erythromycin estolate is as effective as a 14 day course (Halperin et al, 1997), however, this has not yet been shown for other erythromycin preparations. The product information for erythromycin ethyl succinate, erythromycin stearate and erythromycin estolate each recommend doses of between 30 and 50 mg/kg/day for at least 10 days. The PWP therefore supports a 10 day course of erythromycin until the effectiveness of a shorter course, eg seven days, is demonstrated.

The PWP recommends that **patients suspected of having pertussis should be treated with erythromycin (40 to 50mg/kg/day in four divided doses orally, maximum 1g/day, for 10 days)** but it must be noted that beginning antimicrobial therapy beyond three weeks after onset of cough is of no benefit because the organism is spontaneously cleared from the nasopharynx by that time. Wherever possible, nasopharyngeal cultures should be arranged prior to commencement of antimicrobial treatment and within 21 days of cough onset (Section 2.2 p13).

Trimethoprim-sulfamethoxazole may be used if erythromycin is not tolerated, although data demonstrating its effectiveness are limited. Roxithromycin may be an acceptable alternative to erythromycin, but to date it has not been approved for that purpose and there are no published data regarding its efficacy against pertussis (Section 4.5 p30).

3.4.2 Exclusion of cases

Cases of pertussis should be excluded from school, preschool, day-care or other settings where there are susceptible individuals, especially young children and infants, for 21 days from the onset of illness or until they have received at least five days of a 10 day course of erythromycin.

3.4.3 Finding additional cases

The objective for finding additional cases is to protect infants from exposure to pertussis disease from unrecognised or unreported cases. At the first level, identification of cases is the responsibility of individual medical practitioners who may be unaware of local circumstances.

In that situation they would need to use conventional clinical criteria for initial diagnosis (Section 2 p11). If an individual practitioner suspects that pertussis is circulating in their local community, the public health authority should be contacted to enable appropriate action regarding diagnosis and detection.

It is generally the public health authority's role to search for additional cases among contacts. When investigating notifications the public health authority should search for additional cases among contacts in the family day-care and child-care settings (Section 3.5.1 p23).

Additional cases should be excluded from schools and other settings in accordance with Section 3.4.2 p22 and offered treatment in accordance with Section 3.4.1. p22. All additional cases should be reported by the public health authority to the national database.

3.5 Management of contacts

Children less than one year of age are at the greatest risk from pertussis and its complications. Management of contacts is based on the risk of severe disease in the individual who may acquire the infection and the degree of risk resulting from the contact setting. If a person with pertussis attends or works in a high risk setting where there are susceptible individuals, especially infants (ie family day-care, child-care), the public health authority should provide advice to contacts and caregivers regarding appropriate antibiotic prophylaxis and exclusion requirements.

3.5.1 Definition of contacts

Although the definition of significant contact may vary according to the situation, direct contact with respiratory secretions from the case (eg an explosive cough or sneeze, sharing food, sharing eating utensils during a meal, kissing, mouth-to-mouth resuscitation or full medical/dental examination of the nose, throat or mouth) are generally considered to be significant (Centres for Disease Control and Prevention, 1996). Identifying significant contact must be on an individual basis and take into consideration the degree of risk to the individual and the specifics of the exposure. For example, a significant contact may include an infant being in the same room for an hour with a case or a newborn being directly coughed upon by a case (CCDR, 1994).

Contact within a family day-care setting is considered equivalent to household contact. In day-care centres and preschool, the degree of contact should be assessed according to the individual circumstances and discussed, if necessary, with an experienced public health professional. Where there are morning and afternoon sessions, only the affected group need be regarded as at increased risk; the other group should be given an advisory letter.

While listing specific settings and durations of exposure can be problematic, the following priority for action, in decreasing order, is provided as a guide:

Setting		Persons considered contacts (Section 3.5.2 and 3.5.3)
1. Family		All immediate family and household members in contact with the case since onset of the disease, usually taken as the date of cough onset. Very close friends with whom there was generally at least one hour of close contact a day should be included.
2. Family day-care		All residents of the household providing care and all attendees in contact with the case since onset of the disease.
3. Day-care and Preschool	one case	All children under one year of age and children not up-to-date with the recommended vaccinations against pertussis who have been in contact with the case since onset of the disease.
	> one case	All attendees and staff in contact with the cases since onset of the disease.
4. Closed settings (eg boarding schools, school camps and military barracks)		All individuals who slept in the same room, dormitory or tent with the case.

Contacts in the above settings should be identified and interviewed to detect any additional cases. Whenever possible, an attempt should be made to identify the source of infection. Symptomatic contacts should have a thorough medical examination, including nasopharyngeal culture. Pertussis cultures are of no use in asymptomatic contacts for outbreak control or for assessing the need for antibiotics.

The PWP considered other settings including primary and secondary schools, universities and work places, however antibiotic prophylaxis in these circumstances was generally not considered valuable as prevention of transmission in these settings was unlikely and widespread use of antibiotics was undesirable. It was not considered feasible to routinely offer antibiotic prophylaxis to health care staff caring for infected children.

3.5.2 Antibiotic prophylaxis of contacts

The purpose of antibiotic prophylaxis is to prevent disease in those exposed to a case and to decrease transmission to those at highest risk of severe disease.

Cases and outbreaks of pertussis continue to occur because of a number of factors: incomplete immunisation coverage; the need for multiple doses of vaccine to achieve protection; the less than 100 per cent efficacy of the vaccine; and continued circulation of the organism. While vaccination against pertussis is effective in reducing the incidence of the disease, vaccination prevents NEITHER colonisation NOR transmission of *B. pertussis*. This means that those who have been vaccinated can still be infected and transmit *B. pertussis*. Erythromycin therapy for cases and prophylactic treatment of contacts may therefore be beneficial. Although there have been no controlled, blinded studies of the efficacy of erythromycin in preventing transmission of pertussis to contacts, a number of retrospective studies suggest that erythromycin given to contacts within two weeks of onset of cough in the index case (the case to whom the contact was exposed) halts transmission and prevents disease in contacts.

The medical practitioner treating a case of pertussis should notify and consult with public health authorities and ensure that all household contacts, regardless of age and immunisation status, are offered appropriate prophylaxis.

It is the public health authority's role to provide advice for all contacts and caregivers in high risk settings such as a family day-care and child-care regarding appropriate prophylaxis. In other settings, prophylaxis should be undertaken after an assessment of risk (Section 3.5.1 p23). Contacts under one year of age and children not up-to-date with the recommended vaccinations against pertussis should routinely receive prophylaxis, as should infants less than one year of age who have significant contact in other community settings. Prophylaxis is not recommended routinely for health care staff caring for infected children. When required, prophylaxis is most effectively accomplished by providing medication or prescriptions directly rather than advising families to obtain the medication from their own medical practitioner.

Erythromycin (40 to 50mg/kg/day in four divided doses orally, maximum 1g/day for 10 days) should be recommended for all household contacts and other contacts in high risk settings where there are susceptible individuals, especially infants. Erythromycin should be given as soon as possible, and no later than 14 days, after the recipient's first contact with a primary case during the infectious period (in high risk household exposure settings prophylaxis may be considered for up to 21 days from a recipients first contact with a primary case) (American Academy of Pediatrics, 1991). Where infants are at risk within a household or other high risk setting antibiotic treatment of contacts should NOT be delayed pending confirmation of the diagnosis. Note, the infectious period for untreated cases is up to 21 days from onset of cough while for cases receiving antibiotic treatment the infectious period is five days.

Maternal antibodies do not protect newborns against pertussis. Management of pregnant contacts must be on an individual basis and should be discussed with local experts. Erythromycin is poorly tolerated during pregnancy because of its gastrointestinal side effects, however, infants of mothers who become symptomatic with pertussis up to three weeks before labour have an extremely high risk of disease. Household contacts who are pregnant should therefore be offered prophylaxis. If treatment is not tolerated or not complete by the time of delivery, both mother and baby should be given prophylaxis after delivery. In such cases, newborn babies should be given erythromycin syrup 40mg/kg/day in four divided doses for 10 days from birth.

Erythromycin must be considered for each new episode of close exposure unless the contact was receiving erythromycin at the time of exposure.

For situations in which erythromycin is contraindicated or cannot be tolerated, trimethoprim-sulfamethoxazole (Cotrimoxazole) has been recommended, although there are no data regarding its efficacy. While roxithromycin appears to be an acceptable alternative to erythromycin, it has not been approved for that purpose and there are currently no published data regarding its efficacy (Section 4.5 p30).

3.5.3 Exclusion of contacts

Unimmunised household contacts less than seven years of age should be excluded from school, preschool, day-care or other settings where there are susceptible individuals, especially young children and infants, for 14 days after their last exposure to infection or until they have received at least five days of the 10 day course of erythromycin. Close child-care contacts should also be excluded for 14 days from their last exposure to infection or until they have received at least five days of the 10 day course of erythromycin. A child under seven years of age who has not received at least three doses of a vaccine against pertussis should be considered unimmunised.

3.6 Role of vaccination

Complete vaccination of all children is the most important preventive measure for control of pertussis.

In communities with evidence of ongoing pertussis transmission, routine vaccination with diphtheria-tetanus-pertussis vaccine (DTP) can begin for children as young as six weeks of age and subsequent doses given every four weeks. In such cases, oral poliovirus vaccine and *Haemophilus influenzae* type b (Hib) vaccine may also be given with each dose of DTP. An accelerated schedule should only be considered after consultation with an experienced public health professional.

Vaccination of contacts will not prevent infection in those who have already been exposed to the disease and is not an alternative to antibiotic prophylaxis. Nevertheless the medical practitioner treating a case should consult with public health authorities and ensure that all household contacts under eight years of age have their vaccination updated if required. Vaccination is not usually indicated for children eight years of age or older.

Passive immunisation with currently licensed immunoglobulin has no place in the management of pertussis.

3.6.1 Vaccine effectiveness monitoring

It is important to monitor the effectiveness of pertussis vaccines so that we can determine whether adequate protection is being provided against the disease. With the recent introduction of DTPa, and the marketing of combination vaccines in Australia likely to occur in the near future, vaccine effectiveness monitoring plays an essential role in ensuring that protection against pertussis is maintained.

One method of measuring vaccine effectiveness based on information gathered in disease surveillance has been described by Farrington (1993). The method uses the proportion of the population vaccinated (PPV) and the proportion of cases vaccinated (PCV) to estimate vaccine effectiveness (VE):

$$VE = 1 - \frac{PCV}{(1 - PCV)} x \frac{(1 - PPV)}{PPV}$$

Australia's capacity to determine pertussis vaccine effectiveness using this method has, in the past, been hampered by incomplete data on the vaccination status of the population and no information of the vaccination status of the cases.

Data collected on the ACIR will enable estimates of vaccine coverage (PPV) for each age group and for geographical areas as small as postcodes. The ACIR will routinely produce reports on aggregates such as Local Government Areas (LGA), Statistical District (SD), State/Territory and country. Stratification by region should help to identify locations in need of special attention, such as intense education or more targeted immunisation campaigns. Stratification by age should enable a more accurate estimate of vaccine effectiveness in various age groups over time. ACIR data will include distinction between acellular (DTPa) and whole cell (DTPw) vaccines. This should help to discriminate any differences in effectiveness between the two vaccines.

If the PWP recommendations are adopted by States and Territories, an estimation of the PCV will be available through the NNDSS. Decisions need to be made on the best way to use the formula once the spectrum of available pertussis vaccines increases. At the moment the vaccine schedule is relatively simple and so PCV estimation will be straightforward. A more complicated situation could exist within the next twelve months as PPV and PCV may constitute mixtures of DTPa and DTPw, making it difficult to discern between effectiveness of the two vaccines. It is likely that this problem will be compounded as combination vaccines and/or other acellular vaccines become available.

3.7 Enhanced surveillance

When an increase in the incidence of pertussis is suspected in a particular region, surveillance for cases should be enhanced and appropriate epidemiological and microbiological information collected. Active surveillance should be initiated with frequent contact with microbiological laboratories, hospital emergency departments, hospital admission offices, medical practitioners' surgeries and schools. This will heighten awareness of pertussis as a potential cause of cough illness in the community and promote the use of appropriate laboratory confirmation. As the disease may be atypical in older children and adults, earlier and more frequent use of diagnostic nasopharyngeal cultures should be considered in people presenting with respiratory symptoms during suspected outbreaks. If required, nasopharyngeal cultures can be arranged through referral to a laboratory service.

4 Research priorities

Research on pertussis is essential for improving our understanding and control of this disease both in Australian communities and on a global scale. Improved vaccines, together with behavioural research, can contribute substantially to improving vaccination coverage. Introducing uniform case definitions, reporting methods and enhanced surveillance will help to provide useful information on the epidemiology and nature of pertussis infections. New diagnostic tests are urgently needed to complement reporting and surveillance activities and to assist medical practitioners in the accurate and timely diagnosis of pertussis infections.

The following summary identifies priority research areas that are required in order to achieve maximum control of pertussis infection.

4.1 Epidemiology

Improving the sensitivity of case detection and the quality of surveillance data will greatly increase our understanding of pertussis disease in Australia. Further insights may be achieved by studying the dynamics of pertussis transmission, especially in households, child-care, schools, and health care settings. We need to examine how adolescents and adults are involved in sustaining endemicity, and initiating outbreaks of pertussis. In particular, the importance of mother to infant transmission deserves further investigation.

4.2 Vaccines

Now that acellular pertussis vaccines have been incorporated into the NHMRC primary immunisation schedule, their effectiveness should be monitored in the field, and if possible compared with the existing whole cell vaccine. This will be important in considering the usefulness of future combination vaccines based on the current whole cell vaccine. The duration of protection afforded by acellular vaccines is uncertain, and this should be tested. Newer combination vaccines which include whole cell or acellular pertussis as well as Hib, hepatitis B virus (HBV), diphtheria and tetanus antigens should be evaluated locally, in terms of immunogenicity, safety and cost-effectiveness. The use of whole cell pertussis combination vaccines in an accelerated primary vaccination regimen, which might reduce local adverse effects and improve immunisation coverage, may also be worth examining. Adult formulation pertussis vaccines should be trialed. Provided the vaccines are safe and immunogenic, routine adult immunisation should be considered, if surveillance and research data support that adults are an important source of pertussis infection in Australia.

4.3 Adverse events following vaccination

The introduction of acellular pertussis vaccines will probably reduce the incidence of local and minor generalised adverse events following immunisation, and it is widely hoped that vaccination coverage will increase as a result. It is important that this policy is evaluated. Pertussis vaccination coverage, whole cell and acellular, must be monitored carefully with the help of the ACIR. The present system for monitoring serious adverse events (such as encephalopathy) is insensitive, its quality is uncertain, and it is unsuitable for monitoring minor adverse events. In addition to improving this passive surveillance system, innovative approaches are needed for post-marketing surveillance of less serious adverse reactions. Without these types of initiatives, we will be unable to measure the impact from the introduction of acellular vaccines.

4.4 Diagnosis

More sensitive, rapid, preferably non-invasive tests for diagnosing pertussis in the field are needed. This would assist timely surveillance, treatment, and prophylaxis of contacts. There is an urgent need for improved serological/biological markers of pertussis immunity and susceptibility. Serosurveys are an important means of measuring age specific population susceptibility and predicting disease outbreaks, but at present there are no reliable tests for pertussis susceptibility. As pertussis control improves it will be necessary to more thoroughly investigate the link between cases and to detect imported infection. While molecular profiling methods such as Pulsed Field Gel Electrophoresis (PFGE) may be very useful in this respect, further development and standardisation of these technologies in the context of pertussis testing is required. Serotyping of pertussis isolates is less discriminating than PFGE, but will help to discern whether introducing acellular vaccines influences the prevalence of pertussis serotypes.

4.5 Treatment and prophylaxis

The currently recommended therapy (treatment and prophylaxis) for pertussis infection is inconvenient and prolonged, and it is likely that compliance is often poor. It would be very helpful to have once daily therapy, or even single dose therapy. Other macrolides, such as roxithromycin and azithromycin, may have advantages in terms of convenience and compliance; these deserve further consideration and study. Cotrimoxazole, the currently recommended alternative therapy, has not been adequately evaluated.

4.6 Behavioural research

Education and promotional campaigns may play an important role in pertussis control. Research is needed to clarify whether parent and provider perceptions of vaccine preventable diseases and immunisation are important determinants of immunisation coverage in Australia, or whether parent socio-demographic characteristics are more influential. If perceptions regarding the risks and benefits of immunisation are found to be important predictors of immunisation, monitoring them may provide more timely insights into the success of promotional efforts.

4.7 Regional collaboration

For optimal control of pertussis in Australia we need to communicate with other countries in our region, learn from their experience, and where necessary undertake collaborative research. It would be helpful to have a clear understanding of surveillance resources and methodologies in Asia-Pacific nations, as well as improve the more traditional links with the USA and the United Kingdom. Pertussis elimination will not be possible without a cooperative approach.

Part B

Background information

Appendix A Vaccines

Historical perspective

Immunisation remains the most effective means of controlling the incidence of pertussis in our community.

In Australia the first pertussis vaccine was manufactured by the Commonwealth Serum Laboratories (CSL) in the 1920s and a more effective vaccine was released in 1953. In 1954, the NHMRC recommended immunisation of infants using the new triple antigen vaccine (NHMRC, 1954.). This vaccine (and subsequent improved formulations of the vaccine) has formed the foundation of pertussis control in Australia since that time.

The schedule for pertussis immunisation has been adjusted several times. In 1978 the 4th dose of DTP was dropped from the schedule in line with global concerns about the safety of pertussis vaccines. An increased incidence of pertussis followed both in Australia and the United Kingdom. This increase was not seen in the USA where both 4th and 5th doses of DTP were retained. Australia reintroduced the 18 month booster in 1986.

A 5th dose of pertussis vaccine was introduced in Australia in 1994, on the basis of evidence of increased pertussis incidence (particularly in school aged children) and in consideration of current practice in the USA, Canada and some parts of Europe and the western Pacific. The 5th dose was intended to boost antibody levels, and reduce the transmission of pertussis from school age children to younger siblings, the group at highest risk of severe consequences from pertussis.

There are two types of pertussis vaccine in Australia, whole cell vaccine (DTPw) and acellular vaccine (DTPa). Both types are used overseas. DTPw (manufactured by CSL) is currently recommended in the NHMRC primary immunisation schedule.(See Appendix C) DTPa has been approved for use in the primary schedule.

Whole cell vaccine is effective in preventing pertussis. It does, however, cause frequent mild to moderate systemic and local effects and is responsible for most reactions to trivalent (DTP) vaccines.

DTPa vaccines cause fewer fevers and local reactions than DTPw, and although hypotonic-hyporesponsive episodes do occur, they do so less frequently than with the whole cell vaccines (Bernstein et al, 1995; Wintermeyer et al, 1994; Pichichero, 1994; The Australian Immunisation Handbook 6th ed, 1997).

Whole cell vaccine

The whole cell pertussis vaccine is a heat killed preparation of *B. pertussis* bacteria containing an aluminium phosphate adjuvant. At present a whole-cell pertussis vaccine is licenced for the primary course of immunisation (two, four, six months of age) and for the booster doses at 18 months of age and prior to school entry at four to five years of age. The vaccine is available primarily as a trivalent preparation containing diphtheria, tetanus and pertussis vaccine (ie DTPw).

Acellular pertussis vaccine

Acellular pertussis vaccines (Pa) are composed of purified components of the bacteria. Different Pa vaccines may contain different purified components. All contain pertussis toxoid, and in most cases this is combined with filamentous haemagglutinin (FHA) and often additional *B. pertussis* components, eg fimbrial antigens and pertactin. Recent trials have shown that five component Pa vaccines have higher efficacy than two or three component vaccines.

The first Pa vaccines were developed in Japan. In 1981 Japan licenced Pa vaccine for use in children aged two years or more, and in 1989 for infants from three months of age. DTPa has been licenced for booster doses in the USA since 1992 (MMWR, 1992). More recently it was approved in the USA for all doses (MMWR, 1997).

The first DTPa vaccine to be released in Australia was *Infanrix*, a SmithKline Beecham product, in 1996. The vaccine contains three pertussis components; pertussis toxoid, Filamentous Haemagglutinin (FHA) and pertactin (formerly designated 69kDa outer membrane protein). A five component vaccine, *Tripacel*, marketed by CSL, is also available. In addition to the previously mentioned three components, Tripacel contains Pertussisfimbriae 2 + 3.

In November 1996 the NHMRC endorsed the use of DTPa for booster injections at 18 months of age and prior to school entry at four to five years of age. This use was extended in June 1997 when the NHMRC accepted the PWP's recommendation that DTPa be included in the immunisation schedule for primary doses as well as for boosters. The recommendations endorsed by NHMRC are given in Appendix C.

Appendix B Immunisation coverage

Assuming the vaccine used is 100 per cent effective and that it is given at the optimum time, it has been estimated that between 92 and 95 per cent of the population need to be immunised to block transmission of pertussis (Anderson and May, 1990). Immunisation coverage in Australia has historically been lower than this.

Consistent and comparable data on immunisation coverage across all States and Territories has been difficult to obtain because of the varying methodologies used in assessing coverage. To date, there has not been a nationally agreed definition of full immunisation coverage. The Australian Bureau of Statistics (ABS) conducted immunisation coverage surveys in 1989-90 and 1995. In the 1989-90 survey, fully immunised children were defined as those who received the recommended number of vaccinations appropriate to their age. Overall 71 per cent of children from birth to six years of age were considered fully immunised against pertussis with coverage rates varying from 69 per cent in Victoria to 77 per cent in Tasmania. Following the 1995 survey the ABS reported that an estimated 58 per cent of children aged two years were fully immunised against pertussis. Data from the two surveys cannot be directly compared due to changes in methodology. However, data from both surveys shows close to 90 per cent of one year old children had completed the primary course of vaccinations against pertussis (88 per cent in 1989-90 and 86 per cent in 1995). Other surveys conducted at State level, using the WHO cluster sampling method, have also shown immunisation coverage is probably satisfactory for the first three doses of DTP, but that coverage falls significantly for the fourth and fifth doses (Carnie et al, 1995).

In 1996 the Australian Childhood Immunisation Register (ACIR) was established, providing Government with a mechanism to determine the rate of childhood immunisation coverage more accurately. To assist the ACIR in accurate data collection it will be necessary to develop a consistent, nationally agreed definition of full coverage. The Department of Health and Family Services is currently working on this.

Appendix C Recommendations on the use of DTPa endorsed by NHMRC in June 1997

The National Health and Medical Research Council (NHMRC):

1. Recommends DTPa as the preferred vaccine for use in the primary schedule (ie at two, four and six months of age), in addition to its use as a booster.

2. Supports the use of whole cell pertussis vaccine (DTPw) as an alternative to DTPa in the primary schedule.

3. Recommends that normally where a primary course is started with either DTPw or DTPa, the same type of vaccine should be administered for the remainder of the primary course (ie at four and six months of age).

4. Recommends that where adverse effects occur with DTPw, changing to DTPa for the remaining one to two doses for the primary course is appropriate.*

    * *Severe reactions contraindicate the use of either DTPa or DTPw.*

    Recommendation 4 refers only to minor adverse reactions.

    Severe reactions include:

    - encephalopathy within seven days, defined as severe acute neurological illness with prolonged seizures and/or unconsciousness and/or focal signs (but not a simple febrile convulsion); and

    - immediate severe allergic or anaphylactic reactions to vaccination with DTP.

    (The Australian Immunisation Handbook, 6th ed. 1997)

5. Recommends the use of monovalent pertussis vaccine for catch-up vaccination.**

    ** *This recommendation applies to children up to eight years of age.*

    The primary schedule and appropriate catch-up schedule are given in The Australian Immunisation Handbook 6th ed. 1997.

    Appropriate vaccines should be used to ensure each child has the appropriate number of vaccinations against each antigen for age, according to the schedule.

Appendix D List of submissions received from consultation

Aboriginal and Torres Strait Islander Commission, Lois O'Donoghue

AGHS, A/Director, Policy and Marketing, Dr Michael Pincus

AIHW, A/Director, JW Donovan

Australian College of Paediatrics, Chair, Immunisation Standing Committee, A/Prof John Ziegler

Central Queensland Rural Division of General Practice, Medical Director, Dr JW Lock

Central Western Public Health Unit, Bathurst, Dr Peter Christopher

Child and Youth Health, SA, Director of Nursing/Director Planning and Development, Nan Davies

Department of Community Services and Health (Tas), Director, Environmental and Public Health, Dr Mark Jacobs

Department of Education (Qld), Director-General, F J Peach

Department of Education and Children's Services, Office of the Chief Executive

Department of Education, Employment and Training (ACT), A/FAS, Schools and Curriculum Division, Chris Evans

Department of Health and Community Services(Vic), Manager, Health Promotion, Dr WG Hart

Directorate of School Education (Vic), Group Manager, School and Community Support Branch, Bob Maguire

Haemophilia Foundation, Executive Director, Jennifer Ross

Health Department of Western Australia, Director, Disease Control, Dr Jag Gill

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Glossary/Abbreviations

ABS	Australian Bureau of Statistics
ACIR	Australian Childhood Immunisation Register
Apnoea	prolonged breathlessness which may occur after a coughing spasm or spontaneously in infants
Asymptomatic	exhibiting or producing no symptoms
Bordetella pertussis	the causative agent of pertussis (whooping cough) infections
Bordetella parapertussis	the causative agent of parapertussis. Not a cause of pertussis (whooping cough)
CDI	*Communicable Diseases Intelligence*
CSL	CSL Pty Ltd (formerly Commonwealth Serum Laboratories)
Day-care	Child-care provided in a day-care centre, not a private home
DFA	direct fluorescent antibody
DTP	diphtheria-tetanus-pertussis vaccine
DTPa	diphtheria-tetanus-acellular pertussis vaccine
DTPw	diphtheria-tetanus-whole cell pertussis vaccine
Family day-care	Child-care provided in another person's private home
FHA	filamentous haemagglutinin
HBV	hepatitis B virus
Hib	*Haemophilus influenzae* type b
Ig	Immunoglobulin eg IgA, IgM
Immunisation	the process of inducing or providing immunity by the administration of an immunological product
Infant	a child less than one year of age
LGA	Local Government Area
NCDC	National Centre for Disease Control
NHMRC	National Health and Medical Research Council
NNDSS	National Notifiable Diseases Surveillance System
Notified cases	cases officially notified to public health authorities

Pa	acellular pertussis vaccine
Paroxysmal cough	sudden attacks of severe repetitious coughing where one cough follows the next without a break for breath
PCR	polymerase chain reaction
PCV	proportion of cases vaccinated
Pertussis	highly infectious respiratory disease caused by the bacteria *Bordetella pertussis*
PFGE	Pulsed Field Gel Electrophoresis
Post-tussive	occurring after a cough
Prophylaxis (antibiotic)	administration of antibiotics to prevent the development or spread of a bacterial disease
PPV	proportion of the population vaccinated
PWP	Pertussis Working Party
SD	Statistical District
Symptomatic	showing symptoms of a given disease
USA	United States of America
Vaccination	the administration of a vaccine or toxoid, whether or not the injection is successful or not in making the recipient immune
VE	vaccine effectiveness
WHO	World Health Organization
Whooping cough	see Pertussis

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