

# Pertussis vaccine for Australians: information for GPs and immunisation providers

### Pertussis disease burden in Australia<sup>1</sup>

Pertussis is the least well controlled of all the vaccine preventable diseases (VPDs) targeted by the National Immunisation Program (NIP), with periodic epidemics (1993–94, 1997–98, 2001–02, 2004–05) occurring at intervals of three to four years against a background of endemic circulation. This is despite increasing vaccination coverage and reductions of disease in immunised children. Control of pertussis is problematic because immunity to pertussis, whether from vaccination or infection, wanes over time (approximately 6–10 years), resulting in renewed susceptibility to infection in older age groups. There were 75,458 notifications of pertussis nationally between 1995 and 2005, ranging from 4194 notifications in 1995 to 11,202 in 2005.

### Age distribution

Pertussis is now a problem in two broad age groups in Australia – those older than 20 years (accounting for more than 80% of pertussis notifications in 2005) and those under the age of 6 months. Adolescents and adults are an important reservoir of pertussis infection, capable of transmitting the disease.<sup>2,3</sup> Infants who are too young to have received two or more doses of DTPa are of particular concern as they are more likely to have severe disease, resulting in hospitalisation or death.<sup>4</sup> Between June 2002 and June 2005, infants accounted for 50% (655 of 1319) of pertussis-related hospitalisations. The overall mortality from pertussis is 0.03% but the mortality in hospitalised babies under 6 months of age is substantially higher (3.5%).

### Pertussis vaccine efficacy

In contrast to vaccines like measles-mumps-rubella vaccine, pertussis vaccines primarily prevent symptomatic disease rather than infection. A series of vaccine trials in the 1980s established that acellular pertussis vaccines with three or more antigens had similar efficacy (80–84%)<sup>5</sup> to good quality whole-cell vaccines (DTPw) yet were significantly less reactogenic, causing fewer local reactions, fevers and other systemic reactions.<sup>6</sup> The immunogenicity and reactogenicity of adolescent/adult dTpa formulations are comparable to dT vaccines.<sup>7</sup> Clinical trials have demonstrated the ability of dTpa in adults to produce antibody levels higher than those achieved in infants following a three dose primary series with DTPa, and vaccine efficacy in adults has been estimated to be 92%.<sup>8</sup>

### Rationale for the changes to the pertussis vaccine schedule

Acellular pertussis vaccines were funded for use in both primary and booster vaccination schedules in Australia in February 1999, replacing the Australian-made whole-cell vaccine in the NIP. In September 2003, the booster previously scheduled at 18 months of age was no longer recommended and an adolescent/adult-formulated (dTpa) booster replaced ADT at 15–17 years of age.<sup>9</sup> The 18-month-old DTPa booster was removed from the NIP due to evidence that three doses of acellular pertussis vaccine in the first year of life provide good (>80%) protection until the age of 6 years.<sup>10</sup> The change should reduce the frequency of local reactions following the 4-year-old booster dose (see 'Local reactions' below).

### Pertussis vaccine safety<sup>9</sup>

#### Serious adverse events

Although serious systemic adverse events such as hypotonic-hyporesponsive episodes can still occur, they are much less common than with DTPw. Pertussis vaccine does not cause infantile spasms, epilepsy or sudden infant death syndrome (SIDS). Vaccine-induced fever may occasionally lead to a febrile convulsion, though much less commonly with DTPa than with DTPw.<sup>6</sup>

## Local reactions

The incidence of local reactions (redness, swelling and pain) increases with each dose of DTPa, particularly the fourth and fifth doses. Localised swelling greater than 5cm occurs in around 10–20% of children following a fourth or fifth dose of DTPa and entire limb swelling occurs in 1–2% of these vaccinees,<sup>11-13</sup> but pain is usually not a prominent symptom. It is anticipated that postponing the fourth dose of DTPa until 4 years of age will reduce the proportion of children experiencing extensive local reactions, without reducing protection against pertussis infection.<sup>13</sup>

## Use in adults

Acellular vaccines are also immunogenic, safe and well tolerated in adults.<sup>7</sup> The adult/adolescent formulation (dTpa) contains lower concentrations of diphtheria and pertussis antigens. Previous pertussis infection is not a contraindication to vaccination. As adequate human data on the use of adult/adolescent formulation dTpa during pregnancy are not available, dTpa should only be given in pregnancy when the possible advantages outweigh the possible risks to the foetus.

## Contraindications

Encephalopathy without another evident cause within 7 days of vaccination. This does not include febrile convulsions. In the whole cell vaccine era, it was considered that if encephalopathy was vaccine-related, the pertussis component was the most likely cause and DT vaccine was indicated. There is no evidence of vaccine-related encephalopathy occurring after DTPa<sup>14</sup> and DT vaccine is no longer available. Situations should be considered on a case by case basis, preferably in consultation with a clinic specialising in the assessment and management of putative adverse events following vaccination.

Immediate severe allergic reaction: defined as generalised urticaria, bronchospasm, hypotension, collapse or anaphylactic reaction occurring within 20 minutes of receiving either DTPa or other pertussis-containing vaccines. Such situations are rare and should be considered on a case by case basis, preferably in consultation with a specialist paediatric immunologist or a clinic specialising in the assessment and management of putative adverse events following vaccination.

## Available pertussis formulations

*Children under 8 years:* the paediatric formulation DTPa is available as a single injection (Infanrix™ or Tri-pacel™) or in combination with other antigens: Infanrix HepB™, Infanrix-IPV™, Quadracel™ (DTPa-IPV), Infanrix Penta™ (DTPa-HepB-IPV) and Infanrix Hexa™ (DTPa-HepB-IPV-Hib). The DTPa component is equivalent in all paediatric formulations and has an upper age limit for use of 8 years.

*Persons 8 years and over:* there are three adult/adolescent formulations available in Australia: Boostrix™ (dTpa), Boostrix-IPV™ (dTpa-IPV) and Adacel™ (dTpa).

## Pertussis vaccine: current recommendations<sup>9</sup>

These recommendations are funded under the National Immunisation Program:

*Primary course of DTPa,* for all infants from 2 months of age, unless there is an absolute contraindication. The same brand of vaccine should be used for each of the three doses at 2, 4 and 6 months, but if the brand is not known, any available vaccine can be used. In view of the high morbidity and mortality associated with pertussis under the age of 6 months, receipt of the first dose of vaccine as soon as possible after 2 months of age should be strongly emphasised.

- *Booster of DTPa being given prior to school entry at 4 years of age.* As the 18-month-old DTPa booster dose is now omitted, providers need to stress the importance to parents of this fourth dose.
- *A low dose dTpa vaccine* as a single dose at 15 to 17 years of age, replacing ADT vaccine.

A booster dose of dTpa is recommended for the following groups, but is not funded:

- Before planning pregnancy, or for both parents as soon as possible after delivery of an infant (preferably prior to hospital discharge), unless contraindicated;
- For adults working with young children. Immunisation is especially recommended for child-care workers and health-care workers in contact with young infants, such as maternity and nursery staff. Several case reports have documented nosocomial infection in young infants acquired from health-care workers;<sup>15,16</sup>
- Any adult expressing an interest in receiving a booster dose of dTpa should be encouraged to do so. With this same provision, dTpa may be used instead of ADT vaccine at 50 years of age.

At this stage, additional booster doses of dTpa are not recommended because of the lack of data on the duration of immunity from a booster dose of dTpa.



## References

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