

Vaccines: the new Australian best-practice schedule

Although some vaccines new to the childhood schedule are not free, they are strongly recommended

IN SEPTEMBER 2003, the National Health and Medical Research Council (NHMRC) approved the new Australian Standard Vaccination Schedule recommended by the Australian Technical Advisory Group on Immunisation (ATAGI) (Box). The schedule includes inactivated poliomyelitis vaccine (IPV), varicella vaccine and seven-valent pneumococcal conjugate vaccine (7vPCV) for infants and young children. Earlier, in late 2002, routine meningococcal C conjugate vaccine was approved and funded for children aged 12 months, together with a cross-sectional catch-up program for young people to the age of 19 years (media release, Senator Kay Patterson, 24 November 2002). For the first time since 1994 — when all vaccines recommended on the schedule were funded for children vaccinated by both private and public providers under the National Immunisation Strategy¹ — the childhood schedule recommended by NHMRC contains vaccines (IPV, varicella and 7vPCV) not available free of charge to parents.

As well as adding these four vaccines to the childhood program, the NHMRC also approved changes to the pertussis vaccination schedule. Since the diphtheria–tetanus–acellular pertussis (DTPa) vaccine at 4–5 years in 1995, the peak age of pertussis has progressively risen to 13–18 years.² Based on recent evidence that three doses of DTPa in the first year of life provide good protection until the age of 6 years,³ it was decided to adjust the schedule so that the fifth dose is now given to adolescents at 15–17 years, using an adult-formulated vaccine (dTpa). This was done by removing the 18-month dose, thus making the 4-year dose the fourth dose. This is not expected to lower preschoolers' protection from pertussis,⁴ but should help reduce the

number of large local reactions seen when the dose was given at 18 months.⁵

Inactivated poliomyelitis vaccine was recommended because it does not cause the extremely rare (1 in 2.4 million doses) live-vaccine-associated paralytic polio. The United States has already changed to inactivated vaccine,⁶ and other countries are considering doing so. The change to this vaccine in Australia may take time, as it is many times more costly than the oral vaccine and has had limited availability. Although various combinations of IPV with diphtheria, tetanus, acellular pertussis, *Haemophilus influenzae* type b and hepatitis B vaccines are licensed in Australia,⁷ they are not yet available, as the companies producing them are uncertain of the potential market. In the interim, the Australian Government's National Immunisation Program will continue to provide free oral live-attenuated poliomyelitis vaccine.

In making recommendations about the inclusion of each new vaccine in the childhood vaccination schedule, ATAGI took into account a wide range of factors. These included:

- vaccine safety and efficacy;
- the preventable burden of the disease targeted by the vaccine;
- the ease with which the vaccine could be integrated into the existing schedule;
- any likely effects on herd immunity, reduction in antibiotic resistance or impact on disease epidemiology; and
- cost-effectiveness and equity issues.

Some of the information used by ATAGI as the basis for its recommendations is contained in the *The Australian immunisation handbook* (8th edition), while the levels of evidence for the new recommendations are available on the

Australian standard vaccination schedule⁷

Vaccination	Birth	2 months	4 months	6 months	12 months	18 months	4 years	10-13 years	15-17 years	≥50 years	≥65 years
Hepatitis B	Hepatitis B	Hepatitis B	Hepatitis B	Hepatitis B*	Hepatitis B*			Hepatitis B†			
Diphtheria-tetanus-pertussis		DTPa	DTPa	DTPa			DTPa		dTpa	dT	
<i>Haemophilus influenzae</i> type b		Hib	Hib	Hib‡	Hib						
Poliomyelitis§		IPV	IPV	IPV			IPV				
Measles-mumps-rubella					MMR		MMR				
Varicella zoster						VZV		VZV¶			
Pneumococcus		7vPCV	7vPCV	7vPCV		23vPPV**				23vPPV	23vPPV
Meningococcus					MenCCV						
Influenza										Influenza	(annual)

Recommendation and funding

- Currently funded under the National Immunisation Program.
- Recommended for all infants but funded only for Aboriginal and Torres Strait Islander children and children with certain medical risk factors.
- Recommended and funded only for Aboriginal and Torres Strait Islander people.
- Recommended but not funded.

Vaccine key

- DTPa = Diphtheria-tetanus-acellular pertussis
- dTpa = Diphtheria-tetanus-acellular pertussis (adult formulation)
- dT = Diphtheria-tetanus (adult formulation)
- Hib = *Haemophilus influenzae* type b
- IPV = Inactivated poliomyelitis vaccine
- MenCCV = Meningococcal C conjugate vaccine
- MMR = Measles-mumps-rubella
- VZV = Varicella zoster
- 7vPCV = 7-valent pneumococcal conjugate vaccine
- 23vPPV = 23-valent pneumococcal polysaccharide vaccine

* Fourth dose at 6 or 12 months depending on the vaccine formulation used.⁷
 † Adolescents not vaccinated in childhood are recommended to have a primary schedule for hepatitis B.⁷
 ‡ 6-month dose required for all Hib vaccine formulations except those containing PRP-OMP (purified capsular polysaccharide conjugated to outer membrane protein of *Neisseria meningitidis* type C).⁷
 § IPV preferred, but live oral poliomyelitis vaccine acceptable.
 ¶ Vaccination only for children with no history of clinical varicella or vaccination.
 ** Recommended and funded only for Aboriginal and Torres Strait Islander children residing in Western Australia, South Australia, Northern Territory and Queensland.

Internet and on CD-ROM.⁷ NHMRC resolved that the benefits of these vaccines were sufficient for them to be included in the schedule, irrespective of the provision of public funding.

These new vaccines are more costly than any previous additions to the vaccination schedule. In the private market, three doses of conjugated pneumococcal vaccine cost far more than \$300, one dose of varicella vaccine more than \$40 and combinations with IPV more than an extra \$18 for the IPV component. At the government level, the total annual cost of adding IPV, varicella vaccine and 7vPCV to the schedule would be about \$100 million, and would almost double the current cost of all other childhood vaccines. This is a large expenditure. The cost-effectiveness of these three vaccines in Australia is therefore important.⁸⁻¹⁰

Changing to IPV (at \$14 per dose) is estimated to prevent one case of vaccine-associated paralytic polio every 2-3 years, a cost of \$17 million per case averted.⁸ This must be considered in the context of the maintenance of public confidence in immunisation programs.

For varicella vaccine (at \$53 per dose), universal vaccination of infants could prevent 450 hospitalisations each year, at a cost of \$21 000 per hospitalisation averted, and one death per year, at a cost of \$10 million per death averted, over a 30-year period.⁹ This does not include the out-of-

pocket costs to families of a child having varicella, which make vaccination cost-effective in the United States.¹¹

Universal use of 7vPCV (at \$90 per dose) could prevent two to three deaths, 13 cases of meningitis, 110 cases of invasive pneumococcal disease, 800 cases of pneumonia and 14 600 cases of otitis media which would otherwise occur annually in each birth cohort of about 240 000 non-Indigenous Australian children by their fifth birthday.¹⁰ The cost per death averted and the cost per life-year saved by 7vPCV is estimated to be \$5 million and \$230 000, respectively.¹⁰ This does not take into account the impact of universal 7vPCV on adult pneumococcal disease or pneumococcal antibiotic resistance, as documented in the United States.¹²

However, these economic data were only part of the many reasons that ATAGI and NHMRC recommended that all children receive these vaccines (see above). Parents should be strongly encouraged by their physicians to have their children vaccinated. Conjugated pneumococcal vaccine is funded for a small group of children with medical conditions placing them at high risk of disease, as well as for Aboriginal and Torres Strait Islander children.⁷ For some parents the NHMRC recommendation will be sufficient; for others further discussion of the vaccine costs and benefits will be needed. Detailed fact sheets to assist providers and parents are available on the website of the National Centre for

Immunisation Research and Surveillance of Vaccine Preventable Diseases <www.ncirs.usyd.edu.au>.

Until all recommended vaccines are available free at the point of service, there is a dilemma for the community and for policy makers. The objectives of high childhood vaccine coverage and of equity for children could be at stake. This will be a continuing issue over the next 5–10 years as more new vaccines become available. These include rotavirus vaccine, live attenuated intranasal influenza vaccine, and other live vaccines targeting viral respiratory pathogens. Until now, vaccines have had a very high cost–benefit ratio, often being cost-saving,¹³ in contrast to many other prophylactic and most curative treatments. We can no longer expect vaccines to be cost-saving, with the increasing cost of the large clinical trials now needed to measure impact on rare diseases and to exclude rare adverse effects. Nevertheless, despite the fall in cost–benefit ratio in absolute terms, the economic benefits of vaccines relative to pharmaceuticals will persist.¹³ We now need greater public awareness of the current and potential benefits of disease prevention from vaccines, leading to greater public advocacy. Maximal benefit from vaccines can only be obtained by ensuring their availability and use across all age-eligible members of the population.

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