Supplementary report: surveillance of adverse events following immunisation among children aged less than 7 years in Australia, 1 January to 30 June 2005

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This report summarises national passive surveillance data contained in the Adverse Drug Reactions Advisory Committee (ADRAC) database at 30 September 2005 for adverse events following immunisation (AEFI) reported for children aged <7 years who received vaccines between 1 January and 30 June 2005.[1–3] The average annual population-based AEFI reporting rates were calculated using mid-2004 population estimates. Reporting rates per 100,000 doses of vaccine were calculated for eight vaccines that are funded by the National Immunisation Program (NIP) using denominator data from the Australian Childhood Immunisation Register (ACIR). The report includes data for adverse events following receipt of the seven-valent pneumococcal conjugate vaccine (7vPCV), which has been funded under the NIP from 1 January 2005 for all infants at two, four and six months of age, with a catch-up program for children born from 1 January 2003.[4] AEFI reporting rates were not estimated for some vaccines due to lack of reliable denominator data.

The data reported here are provisional only. It is important to note that an AEFI is defined as a medically important event that is temporally associated with immunisation but not necessarily causally associated with immunisation. Readers are referred to previous reports for a description of the national AEFI passive surveillance system,[1] methods used to analyse the data[1–3] and information regarding limitations and interpretation of the data.[2] Often, more than one vaccine is listed as suspected of involvement in the reported adverse event, so the number of vaccines listed will be greater than the number of AEFI records analysed.

1 January to 30 June 2005

There were a total of 254 AEFI records (28.5 per 100,000 population) for children aged <7 years for vaccines administered in the first six months of 2005. This was a 16 per cent increase on the 219 records (24.5 per 100,000 population) for the corresponding six month period in 2004. Thirty-five per cent (n=88) of records were for children aged <1 year, 17 per cent (n=44) for children aged 1 to <2 years and 48 per cent (n=122) for children aged 2 to <7 years. The male to female ratio was 1.6:1.0.

Of the 254 records analysed, 15 (5.9%) had outcomes defined as 'serious' (i.e. recovery with sequelae, hospitalisation, life-threatening event or death), and was lower than previously reported (9%).[2] Serious or potentially life-threatening AEFIs reported included anaphylactic reaction (n=2), seizure (n=5), hypotonic-hyporesponsive episode (HHE) (n=5) and thrombocytopenia (n=3). No deaths were reported. The most common reaction categories were injection site reaction (n=138; 54%), allergic reaction (n=62; 24%) and fever (n=46; 18%).

One or more of the eight vaccines shown in the Table was recorded as suspected of involvement in the reported adverse event for 248 of the 254 records analysed. The six records that listed other suspected vaccines included Bacille Calmette-Guérin (n=1), varicella (n=3) and pneumococcal polysaccharide (n=2) vaccines.

The AEFI reporting rates per 100,000 vaccine doses recorded on the ACIR, both overall and for specific vaccines, were generally similar to those for 2004[2,3] and lower than the average reporting rate

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for vaccines received in the first six months for the four years 2001 to 2004 (Table). The reporting rate for AEFIs with outcomes defined as 'serious' for the eight vaccines decreased from 1.0 to 0.6 per 100,000 doses (Table).

The largest reductions in reporting rates of specific vaccines were for meningococcal C conjugate vaccine and measles-mumps-rubella vaccine (Table). There was an increase in the reporting rate in 2005, compared with 2004, for the combined *Haemophilus influenzae* type b-hepatitis B vaccine (Table) and diphtheria-tetanus-acellular pertussis vaccine for children aged <1 year (16.3 vs 8.0 per 100,000 doses). This may relate to reporting of AEFIs following 7vPCV during 2005 as the vaccines are usually given concurrently at two, four and six months of age.

AEFI reporting rates for January to June 2005 were lower among the 2 to <7 year age group and slightly higher for the <1 and 1 to <2 year age groups compared with January to June 2004 (Table). Much of the increase in reporting for the two younger age groups appears to be related to the commencement, on 1 January 2005, of the universal 7vPCV program for infants and the catch-up program for children born on or after 1 January 2003 (Figure 1).

Table. Reporting rates of adverse events following immunisation (AEFI) per 100,000 vaccine doses,* children aged <7 years, ADRAC database, January to June 2005

	AEFI records‡ (n)	Vaccine doses* (n)	Reporting rate per 100,000 doses§		Ratio of 2005 rate and 4-year mean‖
			Jan-June 2005	Jan-June 2004	
AEFI category†					
Total	248	2,407,362	10.3	12.2	0.6
'Certain' or 'probable' causality rating	114	2,407,362	4.7	4.5	0.6
'Serious' outcome	14	2,407,362	0.6	1.0	0.4
Vaccine					
Diphtheria-tetanus-pertussis	126	263,576	47.8	48.5	0.8
Diphtheria-tetanus-pertussis-hepatitis B	37	224,070	16.5	14.1	0.7
Haemophilus influenzae type b	41	226,782	18.1	20.1	0.6
Haemophilus influenzae type b-hepatitis B	20	129,600	15.4	6.0	1.5
Poliovirus (oral or inactivated)	56	486,445	11.5	10.4	0.9
Pneumococcal conjugate	104	666,299	15.6	–	–
Measles-mumps-rubella	59	254,198	23.2	33.6	0.8
Meningococcal C conjugate	28	156,392	17.9	29.1	0.5
Age group					
<1 year	87	1,395,474	6.2	4.9	0.8
1 to <2 years	40	541,852	7.4	6.7	0.3
2 to <7 years	212	470,036	25.7	32.3	0.9

* Number of vaccine doses recorded on the Australian Childhood Immunisation Register (ACIR) and administered between 1 January and 30 June 2005.

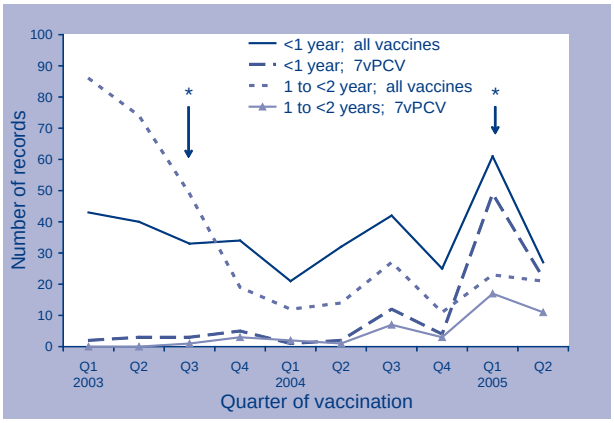
† Records where at least one of the eight vaccines shown in the table was suspected of involvement in the reported adverse event. AEFI category includes all records (i.e. total), those assigned 'certain' or 'probable' causality ratings, and those with outcomes defined as 'serious'. Causality ratings were assigned using the criteria described previously.[1,2] A 'serious' outcome is defined as recovery with sequelae, hospitalisation, life-threatening event or death.[1,2]

‡ Number of AEFI records in which the vaccine was coded as 'suspected' of involvement in the reported adverse event and the vaccination was administered between 1 January and 30 June 2005. More than one vaccine may be coded as 'suspected' if several were administered at the same time.

§ The estimated AEFI reporting rate per 100,000 vaccine doses recorded on the ACIR.

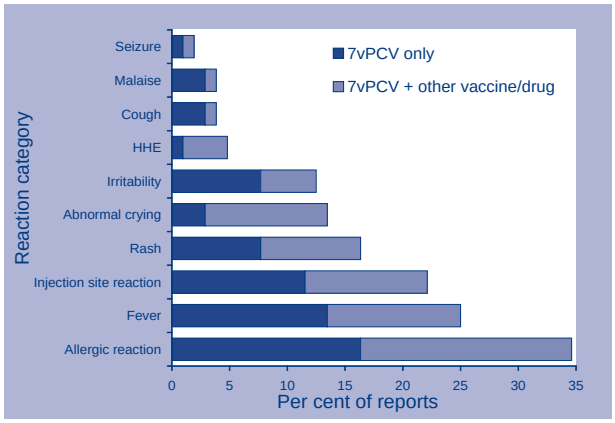
‖ Ratio of the reporting rate for January to June 2005 to the average (mean) reporting rate for January to June of the previous four years (2001–2004) (or 2003–2004 for meningococcal C conjugate vaccine).[2]

Figure 1. Reports of adverse events following immunisation, ADRAC database, 1 January 2003 to 30 June 2005, by age group and suspected vaccine



* Arrows indicate changes to national immunisation policy: (i) in September 2003, the 7-valent pneumococcal conjugate vaccine (7vPCV) was recommended for all children aged <2 years and the fourth dose of diphtheria-tetanus-acellular pertussis vaccine, due at 18 months of age, was removed from the immunisation schedule;[5] (ii) commencement of the nationally funded 7vPCV program for all children from 1 January 2005, with a catch-up program for children born from 1 January 2003.[4]

Figure 2. Frequently reported adverse events following receipt of seven-valent pneumococcal conjugate vaccine, ADRAC database, 1 January to 30 June 2005



HHE Hypotonic-hyporesponsive episode.

Pneumococcal conjugate vaccine

There were 104 reports where 7vPCV was listed as suspected of involvement in the reported AEFI and the vaccine was administered during January to June 2005. The AEFI reporting rate was 15.6 per 100,000 doses of 7vPCV recorded on the ACIR and was similar for the three age groups analysed (16.4, 13.9 and 15.6 per 100,000 doses for the <1 year, 1 to <2 years and 2 to <7 years age groups, respectively). Of the 104 records, 7vPCV was listed as the only suspected vaccine for 45 (43%) records while 10 (9.6%) records listed outcomes defined as 'serious'.

The most frequently reported adverse events following 7vPCV were allergic reaction (35%), fever (25%) and injection site reaction (22%) (Figure 2). More severe AEFIs where 7vPCV was the only suspected vaccine included HHE (n=1), seizure (n=1), severe allergic reaction (n=1) and thrombocytopenia (n=1). The United States of America passive AEFI surveillance system (Vaccine Adverse Events Reporting System) has also received reports of HHE and thrombocytopenia following 7vPCV where it was the only vaccine administered.[6] A causal relationship has not been established between 7vPCV and these AEFIs.

Conclusion

As seen previously, changes in the Australian Standard Vaccination Schedule are reflected in the AEFI surveillance data.[2,3] The increased AEFI reporting rate for children aged <1 year in the first six months of 2005, compared with the same period for 2004, corresponds in time with the introduction of the universal 7vPCV program in January 2005. Previous reports showed changes in AEFI reporting patterns following the commencement of the national meningococcal C program in January 2003 and conclusion of the catch-up component of the program during 2004, and removal from the immunisation schedule of the fourth dose of diphtheria-tetanus-acellular pertussis, due at 18 months of age, in September 2003.[2,3]

Overall, AEFI reporting rates for the first six months of 2005 have decreased among children aged <7 years for most vaccines funded under the NIP compared with average reporting rates for the previous four years. The reporting rate of serious AEFIs among Australian children remains low, with the majority of reported AEFIs being mild, transient events.

Acknowledgment

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References

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Erratum

Table 1 in the adverse events following immunisation annual report published in the last issue of *CDI*, (Lawrence GL, Boyd I, McIntyre PB, Isaacs D. Annual report: surveillance of adverse events following immunisation in Australia, 2004 *Commun Dis Intell* 2005;29:248-262), was incorrect. The rows for the Australian Capital Territory and New South Wales were omitted. The corrected table has been reprinted below.

Table 1. Adverse events following immunisation (AEFI), ADRAC database, 1 January to 31 December 2004, by jurisdiction

Jurisdiction	AEFI records		Annual reporting rate per 100,000 population*			
	n	%	Overall	'Certain' or 'probable' causality rating†	'Serious' outcome‡	Aged <7 years
Australian Capital Territory	116	12	35.9	16.0	1.54	179.6
New South Wales	318	33	4.7	2.3	0.46	18.7
Northern Territory	35	4	17.5	9.0	1.50	74.3
Queensland	170	17	4.4	2.1	0.49	25.4
South Australia	127	13	8.3	4.2	0.39	50.7
Tasmania	6	1	1.2	0.2	0.21	0.0
Victoria	123	13	2.5	1.0	0.18	13.9
Western Australia	59	6	3.0	1.1	0.40	21.5
Other§	21	2	na	na	na	na
Total	975	100	4.8	2.2	0.44	24.5

* Average annual rates per 100,000 population calculated using mid-2004 population estimates (Australian Bureau of Statistics).

† See previous report[7] for criteria used to assign causality ratings.

‡ Adverse event following immunisation records defined as 'serious' (i.e. recovery with sequelae, hospitalisation, life-threatening event or death, Table 2).

§ Records where the jurisdiction in which the AEFI occurred was not reported or was unclear, including AEFIs notified by pharmaceutical companies (n = 17).

na Not available.