Surveillance of adverse events following immunisation for children aged less than 7 years, 1 January to 30 June 2004

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Surveillance of adverse events following immunisation (AEFI) is an integral component of the management of immunisation programs. In Australia, national AEFI surveillance data have been collated in the Adverse Drug Reactions Advisory Committee (ADRAC) database since 2000. AEFIs are notified to ADRAC by state and territory health departments, health care professionals, vaccine companies and the public. Two reports summarising national AEFI data have been published in *Commun Dis Intell* for vaccines received between January 2000 and September 2002,[1] and between October 2002 and December 2003.[2]

This report summarises national AEFI surveillance data for children aged less than seven years who received vaccines between 1 January and 30 June 2004 and were reported to ADRAC by 30 September 2004. The average annual population-based AEFI reporting rates were calculated using mid-2003 population estimates. Reporting rates per 100,000

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doses of vaccine were calculated for seven vaccines that are funded by the National Immunisation Program using denominator data from the Australian Childhood Immunisation Register (ACIR) for the period 1 January to 30 June 2004. Reporting rates could not be estimated for some vaccines due to inadequate denominator data. These include the pneumococcal, varicella, influenza and monovalent hepatitis B vaccines.

The data reported here are provisional only. It is important to note that AEFIs are defined as medically important events that are temporally associated with immunisation but are not necessarily causally associated with immunisation. Readers are referred to previous reports for a description of the national AEFI surveillance system,[1] methods used to analyse the data[1,2] 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 will be greater than the number of AEFI records analysed.

There were a total of 219 records of adverse events following immunisation (AEFI) (24.5 per 100,000 population) for children aged less than seven years where suspected vaccines were administered in the first six months of 2004 to children aged less than seven years. This was a 54 per cent reduction on the 474 records (53.0 per 100,000 population) for the corresponding six month period in 2003. Sixty-six percent (n=144) of records were for children aged 2 to <7, with 11 per cent (n=23) for children aged 1 to <2 years and 24 per cent (n=52) for children aged <1 year. The relative contribution of children aged 1 to <2 years is lower (down from 33%) compared with the first six months of 2003, while that of children aged 2 to <7 years is higher (up from 50%). The male to female ratio was 1.3:1.0, and similar to that seen previously.

Of the 219 records analysed, 19 (8.7%) were defined as having 'serious' outcomes (recovery with sequelae, hospitalisation or death), and was similar to previously reported (9%).[2] Two deaths were reported: neither was thought to be causally related to vaccination. Other serious or potentially life-threatening AEFIs reported were hypotonic-hyporesponsive episode (n=4) and seizure (n=1). The most commonly reported reaction categories were injection site reaction (n=117; 53%) and fever (n=46; 21%).

One or more of the seven vaccines shown in the Table were recorded as being suspected of involvement in the reported adverse event for 205 of the 219 records analysed. The 14 records that listed other

Table. Reporting rates of adverse events following immunisation (AEFI) per 100,000 vaccine doses,* children aged less than seven years, ADRAC database, January to June 2004

Suspected vaccine or AEFI category†	AEFI records‡ (n)	Vaccine doses* (n)	Reporting rate per 100,000 doses§	Difference‖
Diphtheria-tetanus-pertussis	122	255,758	47.7	-16.6
Diphtheria-tetanus-pertussis-hepatitis B	32	226,240	14.1	-4.8
Haemophilus influenzae type b	44	227,364	19.4	-2.4
Haemophilus influenzae type b-hepatitis B	8	127,501	6.3	-5.0
Poliovirus (oral or inactivated)	50	478,488	10.4	-4.4
Measles-mumps-rubella	78	239,256	32.6	+1.4
Meningococcal C conjugate	51	179,379	28.4	-10.3
Total†	205	1,749,075	11.7	-8.1
'Certain' or 'probable' causality rating†	73	1,749,075	4.2	-5.8
'Serious' outcome†	17	1,749,075	1.0	-0.2

* Number of vaccine doses recorded on the Australian Childhood Immunisation Register (ACIR) and administered between 1 January and 30 June 2004.

† Records where at least one of the 7 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 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 2004. More than one vaccine may be coded as 'suspected' if several were administered at the same time.

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

‖ Difference in reporting rate per 100,000 doses for vaccines administered during January–June 2004 compared with October 2002–December 2003.[2]

suspected vaccines, for which adequate denominator data are not available, included pneumococcal (n=8), monovalent hepatitis B (n=8), varicella (n=7) and influenza (n=1) vaccines.

The AEFI reporting rates per 100,000 vaccine doses, both overall and for specific vaccines, were generally similar to those for January 2000–September 2002[1] and significantly lower than observed for the October 2002–December 2003 period[2] (Table). The largest reductions in reporting rates were for diphtheria-tetanus-pertussis (acellular) (DTPa) vaccine and meningococcal C conjugate vaccine (MenCCV) (Table, Figures 1 and 2). The reporting rate for AEFIs with outcomes defined as 'serious' for the seven vaccines declined slightly from 1.2 to 1.0 per 100,000 doses (Table).

The observed reduction in the number of AEFI reports received for children aged less than seven years during the first half of 2004, and the change in the age distribution, corresponds in time with removal of the fourth dose of DTPa vaccine (previously due at 18 months of age) from the Australian Standard Vaccination Schedule in September 2003 (Figure 1, Table), and with the completion of the MenCCV catch-up campaign for children born before 2002 (Figure 2). The lower AEFI reporting rates per 100,000 doses of MenCCV may also be due to more accurate denominator data recorded on the ACIR and/or to increased familiarity among providers about the more common, less serious side-effects of the vaccine resulting in reduced reporting to ADRAC.

Conclusion

There was a marked decline in the overall AEFI reporting rates for children aged less than seven years during January–June 2004 compared with the previous year. Reporting rates of AEFIs with outcomes defined as 'serious' were stable. Annual reports summarising all AEFI data collated in the ADRAC database are planned for the future with supplementary reports summarising AEFI data for children aged less than seven years for vaccines received in first six months of each year.

Figure 1. Reports of injection site reaction following diphtheria-tetanus-pertussis (acellular) vaccine, ADRAC database, January 2000 to June 2004, by age group and quarter of vaccination

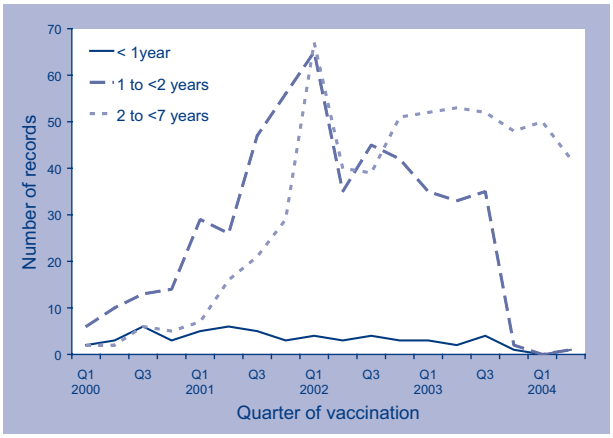
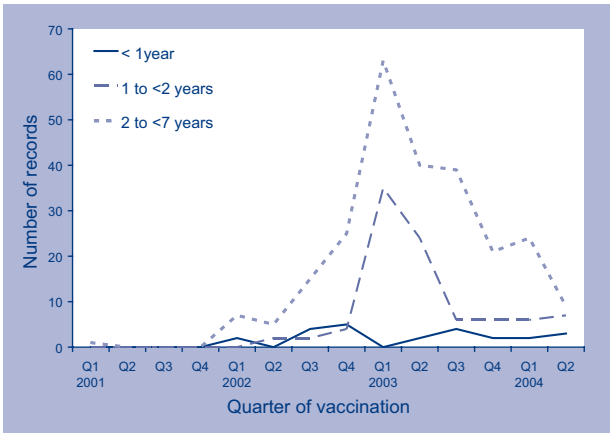


Figure 2. Reports of adverse events reports following meningococcal C conjugate vaccination, ADRAC database, January 2001 to June 2004, by age group and quarter of vaccination



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References

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