Annual report: surveillance of adverse events following immunisation in Australia, 2009

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Abstract

This report summarises Australian passive surveillance data for adverse events following immunisation (AEFI) reported to the Therapeutic Goods Administration (TGA) for 2009, and describes reporting trends over the 10-year period 2000 to 2009. There were 2,396 AEFI records for vaccines administered in 2009, the highest number reported, a 46% increase over the 1,638 in 2008. The increase was almost entirely due to reports related to the introduction of pandemic H1N1 (pH1N1) 2009 influenza vaccine from September 2009 (n=1,312) largely from the members of the public. The pH1N1 AEFI reporting rate for people aged ≥18 years was 34.2 per 100,000 administered doses compared with 2.8 for seasonal influenza vaccine. The rates in ≥65 year-olds were 28.0, 1.6 and 13.3 for pH1N1, seasonal influenza and polysaccharide pneumococcal, respectively. The high reporting rate for pH1N1 vaccine is likely to be at least partly due to enhanced reporting seen for all new vaccines and greater levels of reporting from members of the public in response to the implementation of strategies to encourage reporting, as part of the pH1N1 program. For children <7 years, AEFI reporting rates in 2009 (14.1 per 100,000 administered doses) were similar to previous years. There were 193 (8%) AEFI reports classified as serious; 6 deaths temporally associated with immunisation were reported but none were judged to have a causal association. As in previous years, the most commonly reported reactions were allergic reaction, injection site reaction, fever, headache, malaise, nausea and myalgia. The most commonly reported reactions following pH1N1 influenza vaccine were allergic reaction (n=381), headache (n=289), fever (n=235), pain (n=186), nausea (n=180) and injection site reaction (n=178). The data within the limitation of passive surveillance provide a reference point for ongoing reporting of trends in AEFI by age group, severity and vaccine type and illustrate the value of the national TGA database as a surveillance tool for monitoring AEFI nationally. *Commun Dis Intell* 2010;34(3):259–276.

Keywords: AEFI, adverse events, vaccines, surveillance, immunisation, vaccine safety

Introduction

The aim of passive post-licensure surveillance of adverse events following immunisation (AEFI) is to monitor vaccine and immunisation program safety. An 'adverse event following immunisation' is generally regarded as any serious or unexpected adverse event that occurs *after* a vaccine has been given, which may be related to the vaccine itself or to its handling or administration. An AEFI can be *coincidentally* associated with the *timing* of immunisation without necessarily being caused by the vaccine or the immunisation process. Analysing trends in passive reports can identify signals that are unexpected adverse events that have not been detected in pre-licensure vaccine trials.[1,2] Passive surveillance is unable to determine the causal relationship between an event and vaccination. Hence, a signal may require the generation of a hypothesis and appropriate epidemiological studies to investigate causality.

Several important changes to vaccine funding and availability occurred in 2008 and 2009 that impact on the AEFI surveillance data presented in this report.

- The most significant change during 2009 was the introduction of pandemic H1N1 2009 influenza (pH1N1) vaccine (Panvax®), which was rolled out across Australia on 30 September 2009 for people aged ≥10 years. In December 2009, the pandemic vaccine was made available to children aged 6 months to 10 years.

- The Northern Territory commenced using a new 10-valent pneumococcal vaccine (Synflorix®) from October 2009 at 2, 4, 6 and 12 months of age instead of the 3-dose 7-valent pneumococcal schedule (Prevenar®). At the same time they also ceased using the 23-valent pneumococcal polysaccharide booster for Indigenous children at 18 months of age.

- By late 2009, all states and territories were using the single hexavalent DTPa-IPV-HepB-Hib (Infanrix hexa® vaccine for all children at 2, 4 and 6 months of age,[3–5] due to an

international shortage of *Haemophilus influenzae* type b (Hib) (PedvaxHib® (monovalent) and Comvax® (Hib-HepB)) vaccines.[6] In March 2008, Queensland, South Australia and Victoria changed from using 2 combination vaccines (quadrivalent DTPa-IPV and Hib-HepB) to the single hexavalent DTPa-IPV-HepB-Hib vaccine. In February 2009, Western Australia stopped using PedvaxHib® for Indigenous children so that all children received the single hexavalent DTPa-IPV-HepB-Hib vaccine. The Northern Territory continued using Comvax®until October 2009, when it also changed to the hexavalent vaccine. All other jurisdictions had already been using the hexavalent vaccine since November 2005.

- In 2008, Western Australia commenced a seasonal influenza vaccination program for all children aged 6 months – 5 years (born after 1 April 2003). Children should receive 2 doses of vaccine given at least 1 month apart followed by 1 dose annually.

Previous changes to the National Immunisation Program (NIP) schedule[7–9] also impact on the interpretation of trend data, and have been described in detail in previous reports published regularly since 2003.[10–22] These are:

(i) in 2003, the commencement of the meningococcal C conjugate vaccine (MenCCV) immunisation program and the removal of the 18-month dose of DTPa vaccine;[8]

(ii) from 2004, the progressive introduction of a dose of dTpa for adolescents;[8]

(iii) in January 2005, the commencement of the 7-valent pneumococcal conjugate vaccine (7vPCV) program for infants and the 23-valent polysaccharide vaccine (23vPPV) for adults aged ≥65 years;[7]

(iv) in November 2005, varicella for infants and at 12–13 years of age for those with no evidence of previous vaccination or varicella infection, and the replacement of oral poliovirus vaccine with inactivated poliovirus vaccine (IPV) for children. All IPV-containing vaccines include diphtheria-tetanus-acellular pertussis (DTPa) antigens (i.e. quadrivalent vaccines) and some also include hepatitis B (HepB) and/or *Haemophilus influenzae* type b (Hib) antigens (i.e. pentavalent and hexavalent vaccines). The specific combination vaccines administered at 2, 4, and 6 months of age at times varied between states and territories during the period covered by this report, but all jurisdictions provide DTPa-IPV quadrivalent vaccine at 4 years of age;[9]

(v) in April 2007, the national human papillomavirus (HPV) immunisation program commenced for all girls aged 12–18 years, and was extended to the 19–26 year age group in July 2007;[7] and

(vi) in July 2007, rotavirus vaccines were added to the NIP for all infants in Australia,[7] following the earlier introduction in the Northern Territory in October 2006.

Methods

AEFI are notified to the Therapeutic Goods Administration (TGA) by state and territory health departments, health professionals, vaccine manufacturers and members of the public.[8,9] All reports are assessed using internationally consistent criteria[23] and entered into the Australian Adverse Drug Reactions System (ADRS) database. All reports for vaccines and complementary medicines, plus all serious reports for drugs, are forwarded to the Adverse Drug Reactions Advisory Committee (ADRAC) for review at regular meetings. This is an expert committee of the TGA composed of independent medical experts who have expertise in areas of importance to the evaluation of medicine safety.

Adverse events following immunisation data

De-identified information on all AEFI reported to the TGA from 1 January 2000 to 28 February 2010 and stored in the ADRS database were released to the National Centre for Immunisation Research and Surveillance. Readers are referred to previous AEFI surveillance reports for a description of the surveillance system and methods used to evaluate reports to the TGA.[13,14]

AEFI records* contained in the ADRS database were eligible for inclusion in the analysis if a vaccine was recorded as 'suspected'† of involvement in the reported adverse event and *either;*

(a) the vaccination occurred between 1 January 2000 and 31 December 2009 *or;*

* The term 'AEFI record' is used throughout this report because a single AEFI notification/report to the Medicine Safety Monitoring Unit can generate more than 1 record in the ADRS database. This may occur if there is a time sequence of separate adverse reactions in a single patient, such as systemic and local reactions.

† Records are classified as 'suspected' if the report contains sufficient information to be valid and the relationship between reported reactions and drugs are deemed as biologically plausible.

(b) for records where the vaccination date was not recorded, the date of onset of symptoms or signs occurred between 1 January 2000 and 31 December 2009.

Study definitions of adverse events following immunisation outcomes and reactions

AEFI were defined as 'serious' or 'non-serious' based on information recorded in the ADRS database and criteria similar to those used by the World Health Organization[23] and the US Vaccine Adverse Events Reporting System.[24] In this report, an AEFI is defined as 'serious' if the record indicated that the person had recovered with sequelae, been admitted to a hospital or hospitalisation was prolonged, experienced a life-threatening event, or died.

The causality ratings of 'certain', 'probable' and 'possible' are assigned to individual AEFI records by the TGA. They describe the likelihood that a suspected vaccine or vaccines was/were associated with the reported reaction at the level of the individual vaccine recipient. Factors that are considered in assigning causality ratings include the timing (minutes, hours etc) and the spatial correlation (for injection site reactions) of symptoms and signs in relation to vaccination, and whether one or more vaccines were administered, and are outlined in more detail elsewhere.[13] However, in many instances a causal association between vaccines administered to an individual and events that subsequently occurred cannot be clearly ruled in or out. In addition, children in particular often receive several vaccines at the same time. Therefore, all administered vaccines are usually listed as 'suspected' of involvement in a systemic adverse event as it is usually not possible to attribute the AEFI to a single vaccine.

Typically, each AEFI record lists several symptoms, signs and/or diagnoses that have been re-coded by TGA staff from the reporter's description into standardised terms using the Medical Dictionary for Regulatory Activities (MedDRA®).[25] AEFI reports of suspected anaphylaxis and hypotonic-hyporesponsive episodes (HHE) were reviewed by ADRAC and classified using the Brighton Collaboration case definitions.[26,27]

To analyse reported AEFI, MedDRA® coding terms were grouped to create a set of reaction categories. Firstly, reaction categories were created that were analogous to the AEFI listed and defined in *The Australian Immunisation Handbook* (9th edition).[9] Where MedDRA® coding terms could not be categorised into *Handbook* categories, additional categories were created for those that were listed in more than 1% of AEFI records (e.g. headache, dizziness, change in heart or respiratory rate or rhythm). Reaction terms listed in less than 1% of records were grouped into broader categories based on the organ system where the reaction was manifested (e.g. gastrointestinal, neurological).

Data analysis

All data analyses were performed using SAS software version 9.1.3.[28] The distribution of AEFI records was analysed by age, gender and jurisdiction. Average annual population-based reporting rates were calculated for each state and territory and by age group using population estimates obtained from the Australian Bureau of Statistics.

AEFI reporting rates per 100,000 administered doses were estimated where reliable information was available on the number of doses administered – for influenza and pH1N1 vaccines in adults aged ≥18 years, for 23vPPV in ≥65 year-olds and for 10 vaccines funded through the NIP for children aged <7 years.

Denominator data to estimate influenza and 23vPPV AEFI reporting rates were obtained from a national adult coverage survey conducted in 2006 (unpublished), and for pH1N1 using the Pandemic Vaccination Survey.[29] For 23vPPV the number of people vaccinated per year was derived from the number of people fully vaccinated in 2006 divided by 5. The number of administered doses of each of the 10 childhood vaccines was calculated from the Australian Childhood Immunisation Register (ACIR), a national population-based register of approximately 99% of children aged <7 years.[30]

Notes on interpretation

Caution is required when interpreting the AEFI data presented in this report. Due to reporting delays and late onset of some AEFI, the data are considered preliminary, particularly for the 4th quarter of 2009. Data published in previous reports for 2000–2009[10–22] differ from that presented in this report for the same period because the data in this report have been updated to include delayed notifications of AEFI to the TGA prior publication.

The information collated in the ADRS database is intended primarily for signal detection and hypothesis generation. While AEFI reporting rates can be estimated using appropriate denominators, they cannot be interpreted as incidence rates due to under-reporting and biased reporting of suspected AEFI, and the variable quality and completeness of information provided in individual AEFI notifications.[10–22,31]

It is important to note that this report is based on vaccine and reaction term information collated in the ADRS database and not on comprehensive clinical notes or case reviews. Individual database records list symptoms, signs and diagnoses that were used to define a set of reaction categories based on the case definitions provided in the 9th edition of *The Australian Immunisation Handbook*.[9] These reaction categories are similar, but not identical, to the AEFI case definitions.

The reported symptoms, signs and diagnoses in each AEFI record in the ADRS database are temporally associated with vaccination but are not necessarily causally associated with a vaccine or vaccines.

Results

The ADRS database included a total of 2,396 AEFI records where the date of vaccination (or onset of adverse event, if vaccination date was not reported) occurred between 1 January and 31 December 2009. Of these, 1,312 records (55%) related to pH1N1 influenza vaccine, accounting for the increase of 46% over the total records for 2008.

In 2009, 43% of AEFI (n=1,025) were reported to the TGA via states and territories, with others reported directly. Of those directly reported to TGA, 28% (n=664) were reported by members of the public, 23% (n=552) by doctors or health professionals, 5% (n=110) by hospitals, and 2% (n=45) by drug companies (Table 1). The proportion reported by members of the public was much greater in 2009 than in 2008 (n=51, 3%), with 94% of the reports by members of the public following pH1N1 influenza vaccine.

Reporting trends

The overall AEFI reporting rate for 2009 was 11.0 per 100,000 population, compared with 7.2 per 100,000 population in 2008, and the highest in the decade 2000 to 2009.

Table 1: Reporter types for adverse events following immunisation (AEFI), ADRS database, 2008 and 2009

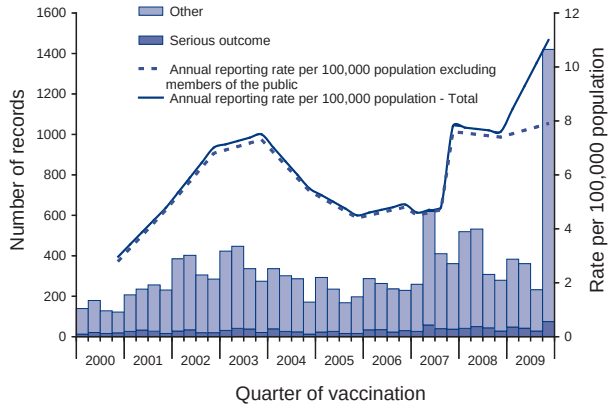
	State or territory									
Reporter type	ACT	NSW	NT	Qld	SA	Tas	Vic	WA	Other*	Total
2008										
Hospital	0	9	0	17	2	0	424†	8	0	460
Drug company	0	0	0	0	0	0	0	0	34	34
Doctors/medical	5	83	2	63	19	29	53	32	5	291
Public	0	7	0	18	0	2	1	3	20	51
State/territory	58	241	41	134	232	0	33	63	0	802
Total	63	340	43	232	253	31	511	106	59	1,638
2009										
Hospital	8	19	0	15	6	0	49	12	1	110
Drug company	0	0	0	0	0	0	0	0	45	45
Doctors/medical	10	190	0	106	36	33	87	80	10	552
Public	21	147	0	138	78	16	157	80	27	664
State/territory	45	94	40	164	198	0	440	35	9	1,025
Total	84	450	40	423	318	49	733	207	92	2,396
2009 (without Panvax®)										
Hospital	8	10	0	12	3	0	41	6	0	80
Drug company	0	0	0	0	0	0	0	0	33	33
Doctors/medical	4	51	0	42	9	16	27	43	7	199
Public	0	3	0	18	0	0	3	8	5	37
State or territory	35	81	33	19	135	0	398	34	0	735
Total	47	145	33	91	147	16	469	91	45	1,084

* Records where the jurisdiction in which the AEFI occurred was not reported or was unclear. AEFI records in this category were notified mainly by pharmaceutical companies, members of the public, and general practitioners.

† 2008 SAFEVIC (Victoria) reports were counted as hospital but 2009 reports are state or territory.

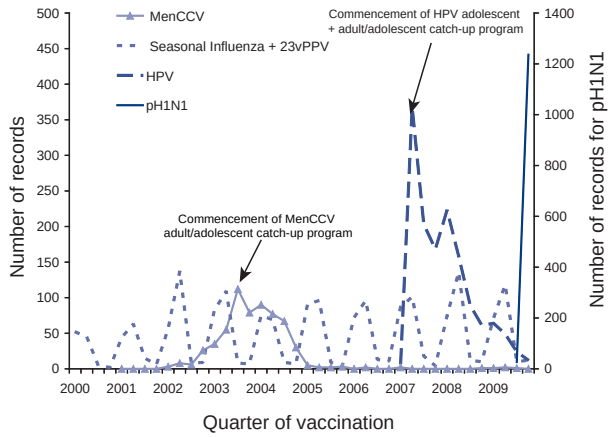
Figure 1 shows the sharp rise in AEFI in the last quarter of 2009 and Figure 2a shows that this rise was due to reports following receipt of pH1N1 influenza vaccine, introduced on 30 September. The impact of previous changes to the NIP on reported AEFI in adolescents and adults are also evident in Figure 2a, such as the commencement of the MenCCV program in 2003 and HPV program in 2007. Figures 2b and 2c show the impact on AEFI reports of other changes to the vaccination programs for children, including the removal of the 18-month DTPa dose in 2003, and commencement of 7vPCV in 2005 and rotavirus vaccine in 2007. Reporting rates usually increased with the commencement of a new vaccination program and then stabilised at lower rates.

Figure 1: Adverse events following immunisation, ADRS database, 2000 to 2009, by quarter of vaccination



Note: For reports where the date of vaccination was not recorded, the date of onset was used as a proxy for vaccination date.

Figure 2a: Frequently suspected vaccines, adverse events following immunisation for individuals aged >7 years, ADRS database, 2000 to 2009, by quarter of vaccination



The usual seasonal pattern of AEFI reporting, with peaks in the first half of the year, was also apparent in 2009 (Figure 2a). The seasonal peaks generally correspond to the months when more vaccinations are administered in Australia, particularly among 4– and 5-year-old children receiving measles-mumps-rubella (MMR) and DTPa-containing vaccines prior to commencing school in February, and older Australians receiving 23vPPV and influenza vaccine during the autumn months (March to June) (Figures 2a and 2b).

Figure 2b: Frequently suspected vaccines, adverse events following immunisation for children aged 1 to <7 years, ADRS database, 2000 to 2009, by quarter of vaccination

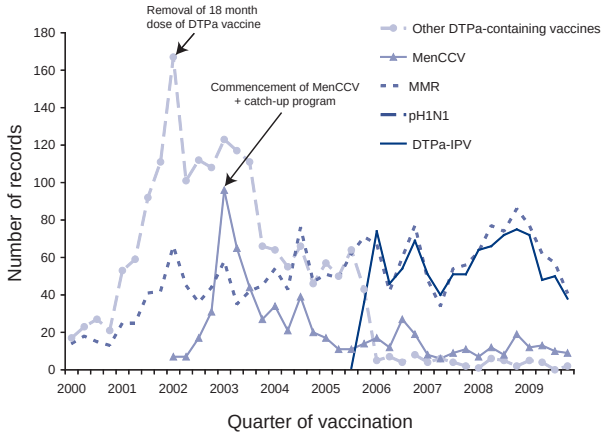
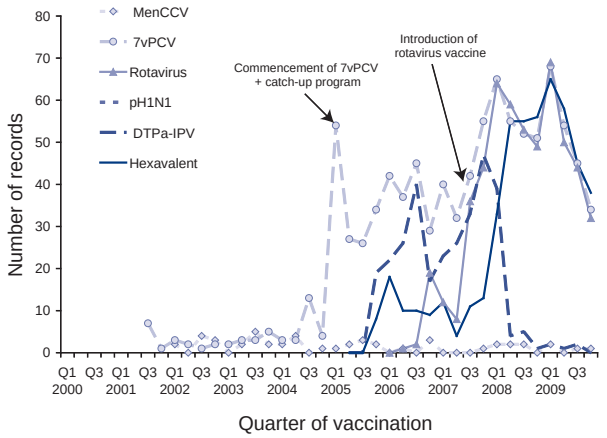


Figure 2c: Frequently suspected vaccines, adverse events following immunisation for children aged <1 years, ADRS database, 2000 to 2009, by quarter of vaccination



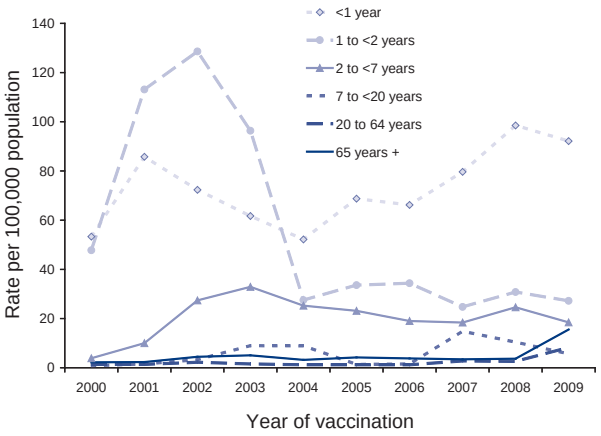
* Meningococcal C conjugate vaccine (MenCCV) was introduced into the NIP schedule on 1 January 2003; 7-valent pneumococcal conjugate vaccine (7vPCV) on 1 January 2005; DTPa-IPV and DTPa-IPV-HepB-Hib (hexavalent) vaccines in November 2005; rotavirus (RotaTeq® and Rotarix®) vaccines on 1 July 2007; and pH1N1 influenza vaccine on 30 September 2009.

Age distribution

In 2009, the highest AEFI reporting rate per 100,000 population was in infants <1 year of age, the age group that received the highest number of vaccines (Figure 3). Compared with 2008, AEFI reporting rates decreased slightly among the < 1 year age group (6% decrease from 98.5 to 92.1 per 100,000 population), the 1 to < 2 year age group (12% decrease, from 30.8 to 27.2 per 100,000 population), the 2 to < 7 year age group (25% decrease, from 24.6 to 18.5 per 100,000 population) and for older children and adolescents (46% decrease, from 10.4 to 5.6 per 100,000 population). The decline in AEFI reporting rates for older children and adolescents were mainly attributable to a reduction in the numbers of reports related to HPV vaccine following cessation of the catch-up component of the HPV program.

However, AEFI reporting rates increased for the 20–64 year age group (2.6 to 8.2 per 100,000 population) and the >65 year age group (3.7 to 15.5 per 100,000 population), mainly associated with the introduction of the pH1N1 influenza vaccine.

Figure 3: Reporting rates of adverse events following immunisation per 100,000 population, ADRS database, 2000 to 2009, by age group and year of vaccination



Geographical distribution

AEFI reporting patterns varied between states and territories for vaccines received during 2009 (Table 2) as reported previously.[11,13,14,17,19–21] The Australian Capital Territory, South Australia and the Northern Territory had the highest reporting rates (23.9, 19.6 and 17.8 per 100,000 population, respectively) while New South Wales had the lowest rate (6.3 per 100,000 population). With the exception of the Northern Territory, AEFI reporting rates increased in all jurisdictions in 2009, largely related to the commencement of pH1N1 vaccination in September 2009. After excluding pH1N1, there was a decrease in reporting rates in all jurisdictions and in all age groups.

Table 2: Adverse events following immunisation (AEFI), ADRS database, January to December 2009, by jurisdiction

State or territory	AEFI records		Annual reporting rate per 100,000 population*			
	n	%	Overall	'Certain'/ 'probable' causality rating†	'Serious' outcome‡	Aged <7 years
Australian Capital Territory	84	4	23.9	2.8	1.7	101.7
New South Wales	450	19	6.3	0.5	0.4	9.9
Northern Territory	40	2	17.8	4.4	4.4	55.0
Queensland	423	18	9.6	0.8	0.6	9.4
South Australia	318	13	19.6	1.1	1.4	50.2
Tasmania	49	2	9.7	2.6	0.6	22.1
Victoria	733	31	13.5	1.5	1.1	67.1
Western Australia	207	9	9.3	1.3	0.8	26.3
Other§	92	4	na	na	na	na
Total	2,396	100	11.0	1.1	0.9	31.1

* Average annual rates per 100,000 population calculated using mid-2009 population estimates (Australian Bureau of Statistics).

† See previous report[13] for criteria used to assign causality ratings.

‡ AEFI records defined as 'serious' (i.e. recovery with sequelae, hospitalisation, life-threatening or death.

§ Records where the jurisdiction in which the AEFI occurred was not reported or was unclear. AEFI records in this category were notified mainly by pharmaceutical companies (n=45), members of the public (n=27), and general practitioners (n=8).

Outcomes

Thirty-five per cent of reported AEFI in 2009 were defined as 'non-serious' while 8% were defined as 'serious' (i.e. recovery with sequelae, requiring hospitalisation, experiencing a life-threatening event or death) (Table 3), and is similar to the proportions of serious AEFI observed in previous years.[11,19] A further 19% were recorded as not fully recovered at the time of reporting and 55% of these were following receipt of pH1N1 influenza vaccine. A total of 244 (10%) AEFI records were assigned causality ratings of either 'certain' (n=216, 9%) or 'probable' (n=28, 1%). Fewer 'serious' AEFI were assigned certain or probable causality ratings compared with 'non-serious' AEFI (7% versus 14%) (Table 3). The number of reported AEFI, severity of outcome and causality, for each vaccine, are shown in Table 4.

There was a relatively high number (918, 38%) of AEFI records in 2009 for which severity could not be definitively determined due to insufficient data, usually the absence of follow-up data on whether a full recovery had occurred. Eighty-two per cent of these were following the receipt of pH1N1 influenza vaccine and 50% were reported by members of the public. The most commonly reported adverse reactions were allergic reactions (25%), headache (20%), fever and injection site reaction (19% each), pain (14%), malaise (13%), myalgia and nausea (12% each), abdominal pain (6%), dizziness (8% each) and weakness (2%).

Six deaths were recorded as temporally associated with receipt of vaccines; five in adults following receipt of pH1N1 influenza vaccine and one in a child following seasonal influenza vaccination. The adults ranged in age from 47 to 90 years. Three of the adults had co-morbidities including cardiac, pulmonary and renal disease. The child had an intercurrent respiratory illness. All deaths were investigated and classified as not related to vaccination.

Vaccines

Thirty-three different vaccines were included in the 2,396 AEFI records received in 2009 (Table 4). The percentage of records where only 1 vaccine was reported differed by vaccine, typically varying according to whether multiple vaccines are routinely co-administered for the patient's age. The percentage of AEFI records assigned causality ratings of 'certain' or 'probable' also varied, in accordance with the frequency of injection site reactions, for which the attribution of causality is more straightforward. There were also variations in the proportions with outcomes defined as 'serious'.

Table 3: Outcomes of adverse events following immunisation (AEFI), ADRS database, 2009

Outcome	AEFI records		'Certain'/ 'probable' causality rating†		Age group‡			
					<7 years		≥7 years	
	n	%	n	%§	n	%§	n	%§
Non-serious	841	35	118	14	314	37	519	62
Not recovered at time of report	444	19	62	14	95	21	341	77
Not known (missing data) – total	918	38	50	5	120	13	785	86
Not known (missing data)‖	463	19	39	8	110	24	351	76
Serious:	193	8	14	7	80	41	110	57
recovered with sequelae	3		0		0		3	
hospital treatment – admission	172		13		75		95	
life-threatening event	12		1		4		7	
death	6		0		1		5	
Total	2,396	100	244	10	609	25	1,755	73

* Percentages relate to the total number of AEFI records (n=2,396).

† Causality ratings were assigned to AEFI records using criteria described previously.[13]

‡ AEFI records where both age and date of birth were not recorded are not shown (32 missing).

§ Percentages relate to the number of AEFI records with the specific outcome, e.g. of 841 AEFI records with a 'non-serious' outcome, 14% had causality ratings of 'certain' or 'probable' and 37% were for children aged <7 years.

‖ AEFI records with missing data reported by health professionals only (excluding reports from members of the public)

Table 4: Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI), ADRS database, 2009

Suspected vaccine type*	AEFI records	One suspected vaccine or drug only†		'Certain'/ 'probable' causality rating‡		'Serious' outcome§		Age group‖ <7 years		Age group‖ ≥7 years	
	n	n	%¶	n	%¶	n	%¶	n	%¶	n	%¶
pH1N1	1,312	1,287	98	46	4	56	4	23	2	1,265	96
DTPa-IPV	218	80	37	64	29	12	6	213	98	5	2
MMR	213	22	10	9	4	18	8	197	92	16	8
7vPCV	212	2	1	1	1	37	17	210	99	2	1
DTPa-IPV-HepB-Hib	206	10	5	4	2	32	16	204	99	2	1
Rotavirus**	202	30	1	4	2	36	18	199	99	2	1
Influenza	162	134	83	27	17	0	19	17	10	144	89
HPV	153	110	72	13	9	13	9	1	1	149	97
23vPPV	82	67	82	35	43	4	5	2	2	80	98
dTpa	79	60	76	18	23	5	6	0	–	78	99
Hepatitis B	71	22	31	10	14	4	6	10	14	61	86
MenCCV	52	4	8	1	2	5	10	48	92	4	8
Hib	46	1	2	0	–	7	15	45	98	1	2
Varicella	41	23	56	1	2	6	15	23	56	18	44
DTPa	12	4	33	2	17	4	33	11	92	0	–
Hib-Hepatitis B	10	0	–	0	–	1	10	9	90	1	10
dT	9	6	67	4	44	1	11	0	–	9	100
Hepatitis A	9	2	22	1	11	0	–	4	44	5	56
BCG	7	7	100	4	57	2	29	6	86	1	14
Hepatitis A + B	7	5	71	1	14	2	29	0	–	7	100
Typhoid	7	1	14	0	–	2	29	1	14	5	71
Yellow fever	6	5	83	0	–	2	33	0	–	6	100
Hepatitis A-Typhoid	5	1	20	2	40	2	40	1	20	4	80
IPV	4	1	25	1	25	0	–	4	100	0	–
Japanese encephalitis	4	3	75	0	–	1	25	1	25	3	75
Men4PV	4	0	–	0	–	0	–	4	100	0	–
DTPa-IPV-HepB	3	0	–	0	–	2	67	3	100	0	–
dTpa-IPV	2	0	–	0	–	2	100	0	–	2	100
Rabies	2	2	100	1	50	0	–	1	50	1	50
10vPCV	2	0	–	0	–	0	–	2	100	0	–
Cholera	1	1	100	0	–	1	100	0	–	1	100
Tetanus	1	1	100	0	–	0	–	0	–	0	–
Q fever	1	1	100	0	–	0	–	0	–	1	100
Total‡‡	2,396	1,893	79	244	10	193	8	609	25	1,755	73

* See appendix for abbreviations of vaccine names.

† AEFI records where only 1 vaccine was suspected of involvement in a reported adverse event.

‡ Causality ratings were assigned to AEFI records using criteria described previously.[13]

§ 'Serious' outcomes are defined in the Methods section (see also Table 2).

‖ AEFI records are not shown if both age and date of birth were not reported.

¶ Percentages are calculated for the number of AEFI records where the vaccine was suspected of involvement in the AEFI, e.g. HPV was 'suspected' in 153 AEFI records; this was the only suspected vaccine in 72% of the 153 AEFI records, 9% had 'certain' or 'probable' causality ratings, 9% were defined as 'serious' and 97% were for those aged ≥7 years.

** Rotavirus vaccine was added to the National Immunisation Program schedule on 1 July 2007.[7]

‡‡ Total number of AEFI records analysed, not the total in each column as categories are not mutually exclusive and an AEFI record may list more than 1 vaccine.

The most frequently reported individual vaccine was pH1N1 with 1,312 records (55%) (Table 4). Vaccines containing diphtheria, tetanus and acellular pertussis antigens (including combination DTPa-containing vaccines and dTpa (adult/adolescent formulation)) were the next most commonly reported (520; 22% of records) (Table 4), with DTPa-IPV (218 records; 9%) and hexavalent DTPa-IPV-HepB-Hib (206 records; 9%) the most frequently reported vaccines in this group. In the <1 year age group, reports that included DTPa-IPV decreased and reports of DTPa-IPV-HepB-Hib increased, in line with the changes in usage of those vaccines as outlined in the Introduction (Figure 2c). The other frequently reported vaccines were MMR (213 records; 9%), 7vPCV (212 records; 9%), and rotavirus (202 records; 8%). The pH1N1 influenza vaccine, seasonal influenza vaccine and 23vPPV were among the more common vaccines listed as suspected of involvement in reported AEFI, particularly where only 1 vaccine was listed as suspected (Table 4).

In comparison to the number reported in 2008, AEFI reports were substantially reduced for the HPV vaccine (153 in 2009 vs 497 in 2008) following the peak in the catch-up program in 2008–2009, and for Hib-HepB (10 in 2009 vs 63 in 2008) following its reduced availability. Reports following 23vPPV were also lower in 2009 (82 vs 137), but data on vaccine use in 2009 comparison with 2008 are not available. Reports increased for Hib (46 vs 33) and DTPa-IPV-HepB-Hib (206 vs 169, Figures 2b and 2c) in line with increased usage, while dTpa reports also increased in 2009 (79 vs 44).

Reactions

The distribution and frequency of reactions listed in AEFI records for vaccines received in 2009 are shown in Tables 5 and 6. In Table 5, only the reaction categories analogous to those listed in *The Australian Immunisation Handbook*[9] are shown. In Table 6, other reaction categories are listed in descending order of frequency.

The most frequently reported adverse events were allergic reaction (26%) followed by injection site reaction (ISR) (25% of 2,396 AEFI records), fever (18%), headache (15%), malaise (11%), nausea (10%), myalgia (10%) and pain (9%) (Tables 5 and 6). ISR was the most commonly reported individual adverse event following receipt of DTPa-IPV (86%; 188/218), 23vPPV (80%; 66/82), MMR (60%; 128/213), and influenza vaccine (35%; 56/162), administered alone or in combination with other vaccines. Fourteen per cent of both pH1N1 (178/1312) and HPV (22/153) vaccine-related AEFI records listed ISR.

More severe AEFI included reports of convulsion (n=46), HHE (n=34), anaphylactic reaction (n=18), Guillain-Barré syndrome (GBS; n=12), thrombocytopenia (n=7), death (n=6; described previously in this report) and encephalitis (n=1).

The 46 reports of convulsion included 9 febrile convulsions. Nineteen were for children aged <7 years and 35% were from Victoria. The most commonly suspected vaccines in reposts of convulsion were HPV (n=18), 7vPCV (n=10), DTPa-IPV-HepB-Hib (n=9), rotavirus (n=7) and pH1N1 (n=5). The majority of HHE (22/34) were notified by Victoria. DTPa-containing vaccines were suspected for 29 reports, with hexavalent DTPa-IPV-HepB-Hib in 24 reports and DTPa-IPV in three. Other vaccines given concomitantly with hexavalent vaccine (7vPCV (n=25) and rotavirus (n=21)) were also frequently included in reports of HHE. Seven of the 18 reports of anaphylaxis in 2009 occurred following receipt of only pH1N1 influenza vaccine, while others occurred following receipt of DTPa-IPV (n=3), MMR (n=3), HPV (n=2), seasonal influenza vaccine (n=2), 23vPPV (n=2), HepB (n=1), rotavirus (n=1), DTPa-IPV-HepB-Hib (n=1) and adult dTpa (n=1). The 12 records coded as GBS included 10 reports following receipt of pH1N1 influenza vaccine and two following seasonal influenza vaccine.

Reactions shown in Table 6 include headache, malaise, myalgia, nausea, pain, dizziness and gastrointestinal reactions. Many of the reaction terms shown in this table were reported for pH1N1, HPV and rotavirus vaccines. Reactions mentioned in less than 1% of AEFI records in 2009 are shown in the lower portion of Table 6, grouped by organ system categories.

The number of reports in each reaction category has changed over time (Figure 4). Reports of headache and allergic reactions peaked in 2003, 2007 and again in 2009, coinciding with the national school-based MenCCV immunisation program in 2003, the HPV school program in 2007 and the commencement of pH1N1 vaccination from September 2009. Much of the variation in reporting of ISR related to specific changes in the immunisation schedules for vaccines that are known to have higher rates of ISR, including DTPa-containing vaccines, MenCCV, 23vPCV and HPV vaccine.[10–22,32,33] Increases in reports of fever are associated with the new vaccines added to the NIP in the reporting period, including rotavirus and HPV in 2007.

Table 5: Reaction categories of interest* mentioned in records of adverse events following immunisation (AEFI), ADRS database, 2009

Reaction category*	AEFI records	Only reaction reported†		'Certain'/'probable' causality rating‡		Age group§			
						<7 years		≥7 years	
	n	n	%‖	n	%‖	n	%‖	n	%‖
Allergic reaction¶	634	94	15	24	4	131	21	497	78
Injection site reaction	600	121	20	202	34	238	40	358	60
Fever	430	10	2	6	1	131	30	295	69
Rash**	130	49	38	3	2	61	47	67	52
Arthralgia	83	5	6	0	–	1	1	80	96
Syncope	73	18	25	4	5	5	7	68	93
Lymphadenopathy/itis††	51	7	14	5	10	7	14	44	86
Convulsions	46	19	41	3	7	19	41	27	59
Abnormal crying	44	2	5	0	–	44	100	–	–
Hypotonic-hyporesponsive episode	34	20	59	3	9	34	100	–	–
Arthritis	26	4	15	1	4	3	12	22	85
Anaphylactic reaction	18	9	50	4	22	4	22	14	78
Guillain-Barré syndrome	12	11	92	0	–	0	–	12	100
Abscess	11	4	36	7	64	5	45	6	55
Intussusception	8	5	63	0	–	7	88	0	–
Thrombocytopenia	7	4	57	0	–	3	43	4	57
Death	6	4	67	0	–	1	17	5	83
Brachial neuritis	4	2	50	0	–	0	–	3	75
Parotitis	2	0	–	0	–	0	–	2	100
Orchitis	2	0	–	0	–	1	50	1	50
Encephalitis	1	1	100	0	–	0	–	1	100
Osteitis	1	0	–	0	–	0	–	1	100
Encephalopathy	1	0	–	0	–	0	–	1	100
Total‡‡	2,396	1,893	79	244	10	609	25	1,755	73

* Reaction categories were created for the AEFI of interest listed and defined in *The Australian Immunisation Handbook*, (9th edition, p 58–65 and 360–3)[9] as described in the Methods section.

† AEFI records where only 1 reaction was reported.

‡ Causality ratings were assigned to AEFI records using criteria described previously.[13]

§ Not shown if neither age nor date of birth were recorded.

‖ Percentages relate to the number of AEFI records in which the specific reaction term was listed, e.g. of 600 AEFI records listing injection site reaction, 20% listed only 1 type of reaction while 34% had a causality rating of 'certain' or 'probable' and 40% were for children aged <7 years.

¶ Allergic reaction includes skin reactions including pruritus, urticaria, periorbital oedema, facial oedema, erythema multiforme etc. (excludes skin reactions presented elsewhere in this table); and/or gastrointestinal (e.g. diarrhoea, vomiting) symptoms and signs but does not include other abdominal symptoms like abdominal pain, nausea, flatulence, abnormal faeces, haematochesia etc. Does not include anaphylaxis.

** Includes general terms of rash but does not include pruritic rash.

†† Includes lymphadenitis following BCG vaccination and the more general term of 'lymphadenopathy'.

‡‡ Total number of AEFI records analysed, not the total in each column as categories are not mutually exclusive and an AEFI record may list more than 1 reaction term.

Table 6: 'Other'* reaction terms listed in records of adverse events following immunisation (AEFI), ADRS database, 2009

Reaction term*	AEFI records	Only reaction reported†		'Certain'/'probable' causality rating‡		Age group§			
						<7 years		≥7 years	
	n	n	%‖	n	%‖	n	%‖	n	%‖
Headache	362	13	4	9	2	7	2	345	95
Malaise	256	6	2	6	2	44	17	207	81
Nausea	237	1	0.4	6	3	7	3	229	97
Myalgia	233	14	6	2	1	8	3	222	95
Pain	217	9	4	7	3	4	2	208	96
Respiratory	212	23	11	6	3	66	31	146	69
Neurological/psychological	176	8	5	4	2	66	38	110	62
Dizziness	169	6	4	6	4	2	1	167	99
Circulatory	102	6	6	2	2	18	18	81	79
Reduced sensation	102	19	19	9	9	–		100	98
Abdominal pain	98	1	1	3	3	16	16	80	82
ENT	91	10	11	3	3	4	4	85	93
Gastrointestinal – RVV¶	87	9	10	3	3	87	100	–	–
Somnolence	53	3	6	2	4	23	43	30	57
Increased sweating	69	2	3	3	4	2	3	67	97
Erythema	49	8	16	1	2	15	31	33	67
Pallor	41	1	2	4	10	15	37	26	63
Flushing	39	2	5	3	8	3	8	36	92
Weakness	37	–	–	1	3	–	–	37	100
Vision impaired	34	–	–	1	3	1	3	33	97
Oedema	31	2	6	2	6	7	3	23	74
Tremor	29	3	10	2	7	3	10	26	90
Spinal chord/peripheral nerve	28	13	46	–	–	1	4	27	96
Haematological/metabolic	25	5	20	3	3	3	12	22	88
Aphasia	15	1	7	–	–	–	–	15	100
Other	301	27	9	9	3	51	17	244	81
eye or ear	43	1	2	1	2	6	14	37	86
cardiovascular	32	3	9	2	6	8	25	24	75
infection	27	9	33	1	4	6	22	20	74
general non-specific	27	4	15	–	–	5	19	21	78
renal/urogenital	20	–	–	1	5	3	15	17	85
gastrointestinal**	16	1	6	–	–	2	13	13	81
respiratory	14	–	–	–	–	–	–	14	100
skin††	14	3	21	–	–	5	36	9	64
musculoskeletal	11	1	9	1	9	–	–	10	91
metabolic/endocrine	9	–	–	–	–	5	56	4	44
haematological	8	2	25	1	13	–	–	8	100
psychological	7	1	14	–	–	1	14	6	86
miscellaneous	6	–	–	–	–	–	–	6	100
neurological	6	2	33	–	–	2	33	4	67
pregnancy/congenital	6	–	–	–	–	1	17	5	83

* Reaction terms not listed in *The Australian Immunisation Handbook*[9] but included in AEFI records in the ADRAC database. The top part of the table shows reaction terms included in 1% or more of AEFI records; the bottom part of the table shows reaction terms, grouped by organ system, that were included in less than 1% of AEFI records.

† AEFI records where only 1 vaccine was suspected of involvement in a reported adverse event.

‡ Causality ratings were assigned to AEFI records using criteria described previously.[13]

§ 'Serious' outcomes are defined in the Methods section (see also Table 2).

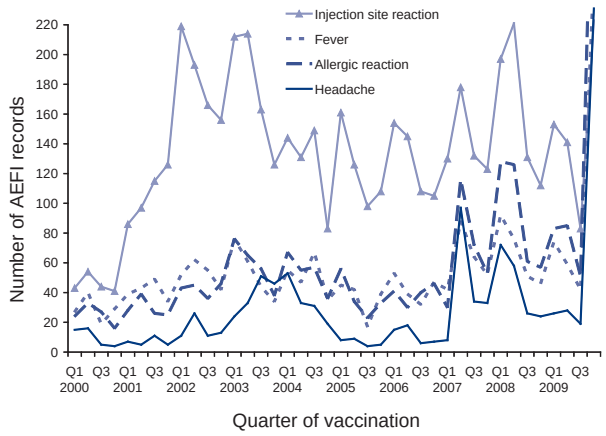
‖ AEFI records are not shown if both age and date of birth were not reported.

¶ Gastrointestinal – RVV includes all the GI reactions following rotavirus vaccination.

** Other, gastrointestinal does not include GI reactions and Gastrointestinal – RVV signs and symptoms.

†† Other, skin includes purpura, petechiae, blister, burning, dermatitis, dry skin etc. but does not include skin reactions.

Figure 4: Selected frequently reported adverse events following immunisation, ADRS database, 2000 to 2009, by quarter of vaccination



Dose-based adverse events following immunisation reporting rates

Seasonal influenza vaccine and adults aged ≥18 years

In 2009, there were 135 adverse events following influenza vaccination of people aged ≥ 18 years. The AEFI reporting rate was 2.5 per 100,000 administered doses, similar to the rate in 2008 (Table 7). As seen in previous years, the overall AEFI reporting rates were higher for vaccinees aged 18–64 years than among older people. However, there was an increase in the reporting rate of serious AEFI in all age groups and particularly among older people (aged ≥65 years). The most frequently reported adverse events were ISR, allergic reaction, fever, myalgia, malaise, dizziness, nausea and headache (reporting rate 0.9, 0.8, 0.5, 0.4 and 0.3 (malaise, dizziness, nausea and headache each) per 100,000 doses, respectively). The reporting rate for each of these reactions was higher in the 18–64 year age group. There were 2 reports of GBS following seasonal influenza vaccination in 2009 giving a reporting rate of 0.04 per 100,000 doses, well within the expected reporting rates.

Pneumococcal vaccine and adults aged ≥65 years

There were 57 AEFI reports for older adults that included 23vPPV, with 2 reports coded as serious and 47 reports of ISR. The AEFI reporting rate was 13.3 per 100,000 doses, with 0.5 per 100,000 doses serious and 10.9 per 100,000 doses for ISR reports. This was lower than the rate reported for 2008 (18.9 per 100,000 doses with 1.2 serious).[11]

Scheduled vaccines for children aged <7 years

There were a total of 609 AEFI records for children aged <7 years for vaccines administered in 2009, which was a 13% decrease compared with 2008 (n=699).

Of the 609 AEFI records in 2009, 552 records included at least one of the 10 vaccines for which ACIR data could be used to estimate AEFI reporting rates per 100,000 administered doses (Table 8). Vaccines for which reliable denominator data were not available included pH1N1 (n=23), seasonal

Table 7: Reporting rate of adverse events following immunisation (AEFI) per 100,000 doses of seasonal influenza and pH1N1 influenza vaccine,* 18 years and over, ADRS database, 2009

AEFI category†	Age group	AEFI records‡		Vaccine doses*	Rate per 100,000 doses§					
					2009		2008		2007	
		All	Serious	n	All	Serious	All	Serious	All	Serious
Seasonal Influenza	≥18 years	135	27	4,746,900	2.8	0.6	2.7	0.2	2.3	0.3
	18–64 years	101	15	2,626,400	3.8	0.6	3.4	0.2	3.0	0.4
	≥65 years	34	12	2,120,500	1.6	0.6	1.7	0.2	1.4	0.1
pH1N1 influenza vaccine	≥18 years	1,209	49	3,533,800	34.2	1.4	na		na	
	18–64 years	846	26	2,238,100	37.8	1.2	na		na	
	≥65 years	363	23	1,295,700	28.0	1.8	na		na	

* Number of administered doses of seasonal influenza vaccine estimated from the 2006 Australian Institute of Health and Welfare national survey (unpublished) and Number of administered doses of pH1N1 influenza vaccine estimated from the 2010 AIHW Pandemic Vaccination survey (published in August 2010 – Cat. No. PHE 128).

† AEFI category includes all records, and those defined as 'serious' where influenza vaccine was suspected of involvement in the reported adverse event. The definition of a 'serious' outcome is given in the Methods section.

‡ Number of AEFI records in which vaccine was 'suspected' and the vaccination was administered in 2009.

§ The estimated reporting rate of adverse events per 100,000 administered doses of respective vaccines.

influenza (n=17), hepatitis B (n=10), BCG (n=6), hepatitis A (n=4), and 23vPPV (n=2) (Table 4). The overall reporting rate for the 10 NIP vaccines was 14.1 per 100,000 administered doses, while the reporting rate for serious AEFI was 1.8 per 100,000 doses (Table 8).

AEFI reporting rates across jurisdictions were consistently similar to, or lower than, those for the same period in 2008 for most age groups, reaction categories and vaccines (Table 8). The largest declines were for varicella (43%; reporting rates 8.3 per 100,000 doses in 2009 compared with 14.9 in 2008) and DTPa-IPV (34%; 72.1 vs 92.1). Reporting rates also declined for rotavirus (12%; 38.2 vs 43.1) and MMR (8%; 34.0 vs 38.5).

The AEFI reporting rates for pentavalent DTPa-IPV-HepB and Hib-HepB vaccines are less reliable due to the small number of reports.

New pandemic pH1N1 2009 influenza vaccine

There were a total of 1,312 AEFI reports received for 2009 where pH1N1 influenza vaccine was listed as a suspected vaccine (Table 4). It was the only suspected vaccine in 1,287 (98%) reports, 46 (4%) had causality ratings of 'certain' or 'probable' and 56 (4%) were defined as 'serious' (Table 4). Five deaths were recorded as temporally associated with receipt of pH1N1 influenza vaccine (described earlier in this report). Twenty-five per cent of reports (n=332) came from Queensland, 23% (n=305) from New South Wales, 20% (n=264) from Victoria, 13% (n=171) from South

Table 8: Reporting rates of adverse events following immunisation (AEFI) per 100,000 vaccine doses,* children aged less than 7 years, ADRS database, 2009

	AEFI records†	Vaccine doses*	Reporting rate per 100,000 doses‡		
	n	n	2009	2008	2007
Vaccine					
DTPa-containing vaccines	420	1,122,430	37.4	46.3	33.0
DTPa-IPV	213	295,237	72.1	92.1	45.4
Pentavalent (DTPa-IPV-HepB)	3	10,566	28.4	22.5	43.7
Hexavalent (DTPa-IPV-HepB-Hib)	204	816,627	25.0	25.0	10.7
Haemophilus influenzae type b	45	276,878	16.3	19.4	18.3
Haemophilus influenzae type b-hepatitis B	9	5,500	163.6	39.6	30.8
Measles-mumps-rubella	197	579,066	34.0	38.5	23.3
Meningococcal C conjugate	48	292,754	16.4	17.5	12.2
Pneumococcal conjugate	210	826,947	25.4	27.0	20.6
Rotavirus vaccine	199	521,181	38.2	43.1	40.2
Varicella	23	277,496	8.3	14.9	10.9
Age group					
<1 year	249	2,217,680	11.2	13.0	9.7
1 to <2 years	71	1,035,641	6.9	8.2	6.5
2 to <7 years	232	648,931	35.8	52.9	38.5
AEFI category§					
Total	552	3,902,252	14.1	17.8	13.3
'Certain' or 'probable' causality rating	80	3,902,252	2.1	4.9	4.2
'Serious' outcome	69	3,902,252	1.8	2.3	1.6

* Number of vaccine doses recorded on the Australian Childhood Immunisation Register (ACIR) and administered between 1 January and 31 December 2009.

† 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 31 December 2009. More than 1 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.

§ Records where at least one of the 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.[13] A 'serious' outcome is defined as recovery with sequelae, hospitalisation, life-threatening event or death.[13]

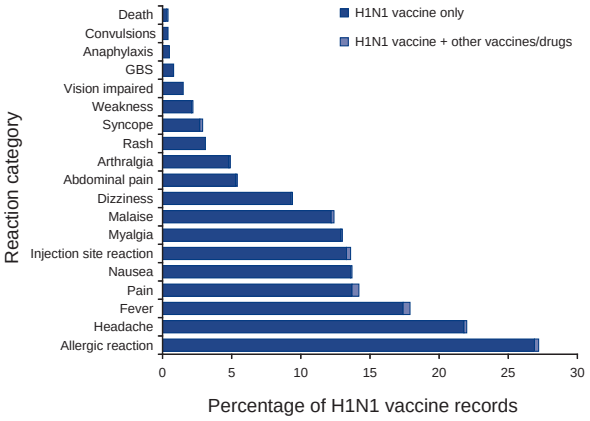
Australia, 8% (n=116) from Western Australia, 3% each from the Australian Capital Territory (n=37) and Tasmania (n=33) and 0.5% (n=7) from the Northern Territory.

The AEFI reporting rate for people aged ≥18 years was 34.2 per 100,000 administered doses (Table 7). The overall AEFI reporting rates were higher for vaccinees aged 18–64 years than among older people. However, the reporting rate of serious AEFI was highest (1.8 per 100,000 doses) among older people (aged ≥65 years).

The majority of the AEFI (48%; n=627) were reported by members of the public, 22% (n=290) by states and territories, 15% (n=191) by GPs, 9% (n=118) by nurses, 2% each by hospitals (n=30) and pharmacists (n=27), 1% (n=12) by drug companies, and 1.2% (n=17) by specialists.

The most frequently reported categories of reactions associated with administration of pH1N1 influenza vaccine are shown in Figure 5. They included non-anaphylactic allergic reactions (27%; n=357); headache (22%); fever (18%); ISR, pain and nausea (14% each); myalgia (13%); malaise (12%); and dizziness (9%). There were a total of 7 reports of anaphylactic reaction and 5 reports of convulsion (including 2 febrile convulsions; aged 1 and 4 years). Both the febrile convulsion cases were following only pH1N1 influenza vaccine and symptoms appeared within 12 hours post vaccination. All the anaphylactic reactions occurred immediately after pH1N1 administration. Among the 7 records of anaphylaxis, two were reported to have a history of asthma and one had known allergies to eggs. There were 10 cases reported as GBS following pH1N1 influenza vaccination.

Figure 5: Most frequently reported adverse events following pH1N1 immunisation,* ADRS database, 2009



* Percentage of 1,312 AEFI records where pH1N1 vaccine was listed as suspected of involvement in the reported AEFI.

Discussion

The majority of AEFI reported to the TGA in 2009 were mild, transient and well recognised vaccine side-effects. There was, however, a large increase (55%) in the number of AEFI reports received for 2009 compared with 2008, mainly related to the commencement of the pH1N1 immunisation program in September 2009, which contributed 54% of the total AEFI reports for 2009. Of particular note was the large increase in reports from members of the public direct to the TGA, from 3% of the total in 2008 to 28% in 2009, 94% of which were for pH1N1 influenza vaccine. The reporting rate for pH1N1 was 34.2 per 100,000 doses administered in persons aged ≥18 years, higher than that for seasonal influenza vaccine (2.8). Rates for those aged ≥65 years were 28.0, 1.6 and 13.3 for pH1N1, seasonal influenza and polysaccharide pneumococcal vaccines respectively. The high AEFI reporting rate for pH1N1, including high rates from members of the public, are likely due at least in part to the fact that the H1N1 influenza vaccination program used strategies to encourage consumers and health professionals to report adverse events to allow TGA to closely monitor the safety of the vaccine,[34] as well as the known effect of enhanced reporting for new vaccines.

The safety of the pH1N1 influenza vaccine has been examined closely both internationally and in Australia. The World Health Organization reported that approximately 30 different pH1N1 influenza vaccines have been developed using a range of methods.[35] All progressed successfully through vaccine trials to licensure, showing satisfactory safety profiles. However, these clinical trials were not powered to detect rare adverse vaccine reactions that occur with a frequency of less than one in 1,000, emphasising the need for post-licensure surveillance. In general, the safety profile, including that for the Australian vaccine, has been similar to those of seasonal influenza vaccines, with predominantly mild transient events and a small number of serious reactions reported.[36]

The data presented here for pH1N1 influenza vaccine in 2009 include very few AEFI in children, as the pH1N1 vaccine was licensed for children only in December 2009. The majority of the 1,132 reports were mild vaccine side-effects similar to that identified in pre-licensure clinical trials.[36] These included mainly non-anaphylactic allergic reactions, fever and injection site reactions. A range of mild non-specific symptoms including headache, nausea, dizziness, malaise and weakness were also commonly reported (Tables 5 and 6; Figure 5). This constellation of symptoms

is known to be associated with any new event of vaccination rather than any specific vaccine; data presented here are consistent with this experience. While GBS was associated with a previous swine influenza vaccine in 1976,[37] international assessment of the current pH1N1 vaccines has found either no association,[34] or a slightly higher rate of GBS in vaccinees up to one per million vaccine doses, which is consistent with estimates for seasonal influenza vaccine.[38] Initial national analysis by the TGA has shown no indication of an increased rate of GBS, or anaphylaxis, another serious reaction of concern, associated with pH1N1 influenza vaccine in Australia.[39] None of the 5 deaths reported following receipt of pH1N1 influenza vaccine were regarded as likely to be causally associated with the vaccine.

After excluding reports for pH1N1, there was a 30% reduction in the number of AEFI reported to the TGA in 2009 compared with 2008 (Table 1). The majority of these (68%) were reported by states and territories and only 3% were reported by members of the public. Decreases were seen in all jurisdictions and in all age groups. The decreases were greater in adolescents, associated with the tapering off of the HPV catch-up campaign and possibly reduced reporting associated with greater familiarity with that vaccine. Decreases among children aged <7 years are likely to be a combination of a stable vaccination schedule during 2008 and 2009, and reporting delay, which usually results in an underestimation of reports in the latest year of approximately 5%.

Conclusion

There was a substantial increase in AEFI reported in 2009 associated with the introduction of the new pH1N1 influenza vaccine in September. A large number of reports were received from members of the public. However, the majority of AEFI reports were of mild, transient and well-recognised vaccine side-effects.

The regular analysis and publication of national AEFI surveillance data collated in the ADRAC database remains an important aspect of Australia's immunisation program.

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Abbreviations of vaccine types

7vPCV	7-valent pneumococcal conjugate vaccine
10vPCV	10-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine
BCG	Bacille Calmette-Guérin (i.e. tuberculosis)
dT	diphtheria-tetanus – adolescent and adult formulation
DTPa	diphtheria-tetanus-pertussis (acellular) – paediatric formulation
dTpa	diphtheria-tetanus-pertussis (acellular) – adolescent and adult formulation
dTpa-IPV	combined dTpa and inactivated poliovirus
DTPa-HepB	combined diphtheria-tetanus-pertussis (acellular) and hepatitis B
DTPa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus (quadrivalent)
DTPa-IPV-HepB	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus and hepatitis B (pentavalent)
DTPa-IPV-HepB-Hib	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus, hepatitis B and *Haemophilus influenzae* type b vaccine (hexavalent)
HepB	hepatitis B
Hib	*Haemophilus influenzae* type b
Hib-HepB	combined *Haemophilus influenzae* type b and hepatitis B
HPV	human papillomavirus
IPV	inactivated poliovirus vaccine
Men4PV	meningococcal polysaccharide tetravalent vaccine
MenCCV	meningococcal C conjugate vaccine
MMR	measles-mumps-rubella
pH1N1	pandemic H1N1 influenza 2009