Surveillance summaries

Supplementary report: surveillance of adverse events following immunisation among children aged less than 7 years in Australia, 1 January to 30 June 2010

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Introduction

This report summarises national passive surveillance data reported to the Therapeutic Goods Administration (TGA) to 31 August 2010 for adverse events following immunisation (AEFI) reported for children aged < 7 years who received vaccines between 1 January and 30 June 2010. The report includes all vaccines administered to children in this age group with a focus on the vaccines included in the funded National Immunisation Program (NIP) schedule.[1]

There were two recent changes to vaccine funding and availability that had impacts on the AEFI surveillance data presented in this report:

i. annual vaccination with seasonal trivalent influenza vaccine (TIV with 3 strains: A/H1N1, A/H3N2 and B), which was introduced as funded under the NIP for at-risk children for the first time in 2010;[2] and
ii. the introduction of pandemic H1N1 (pH1N1) 2009 influenza vaccine (Panvax), which was rolled out across Australia from 30 September 2009 for people aged ≥ 10 years and for children aged 6 months to 10 years from December 2009.[3]

A number of other important changes to vaccine funding and availability also occurred in 2009. The Northern Territory started using a new 10-valent pneumococcal conjugate vaccine (Synflorix®) from October 2009 at 2, 4, 6 and 12 months of age instead of the 3-dose 7-valent pneumococcal conjugate vaccine (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 had switched to the hexavalent DTPa-IPV-Hib-HepB (Infanrix hexa®) vaccine for all children at 2, 4 and 6 months of age,[4–6] due to an international shortage of *Haemophilus influenzae* type b (Hib) (PedvaxHib® [monovalent] and Comvax® [Hib-HepB]) vaccines.[7]

This report also summarises AEFI reports that were collected and contributed to detection of an unexpected increase in adverse events predominantly fever and febrile convulsions, in young children following the use of one type of 2010 seasonal influenza vaccine (Fluvax® or Fluvax junior® CSL Biotherapies) leading to the suspension of use of seasonal influenza vaccine in children aged 5 years or under.[8]

Methods

Case definition and coding

The data reported here are provisional only. It is important to note that an AEFI is defined as a medical event that is temporally, but not necessarily causally, associated with immunisation. Readers are referred to previous reports for a description of the national AEFI passive surveillance system,[9] methods used to analyse the data and information regarding limitations and interpretation of the data.[9–12] Often, several vaccines and reaction codes are listed in an AEFI record so the number of vaccines and reaction codes will exceed the total number of AEFI records. For the purpose of this report, an AEFI is defined as 'serious' if there is a code of life-threatening severity or an outcome code indicating recovery with sequelae, admission to hospital, prolongation of hospitalisation, or death.

Denominator calculations from Australian Childhood Immunisation Register

Average annual population-based AEFI reporting rates were calculated using mid-2009 population estimates. Reporting rates per 100,000 doses were calculated for 10 vaccines on the NIP schedule for which reliable dosing data were available from the Australian Childhood Immunisation Register (ACIR), for children aged from 2 months to < 7 years. In addition to those vaccines, national dose estimates for pH1N1 and seasonal influenza vaccines were calculated using an adjustment for the known under-reporting of these vaccines to the

ACIR in 2010. Adjustments were based on estimated under-reporting of 55% for seasonal influenza vaccine (personal communication, Gary Dowse, Communicable Disease Control Directorate, Western Australian Department of Health) and 45% for pH1N1 influenza vaccine from March to June 2010 (personal communication, Dr Christine Selvey, Queensland Health). In addition, dose estimates for January to February 2010 for pH1N1 influenza vaccine were taken from an Australian Institute of Health and Welfare survey.[13] Estimates for different seasonal influenza vaccines were not calculated, as ACIR reporting issues differed for some vaccine brands. It should be noted that for influenza vaccines, there is a considerable level of uncertainty around the dose number estimates and the rates per dose should be regarded as only approximate estimates.

Severity score, type of reaction and vaccine type

Severity classification followed previous guidelines.[9] Given the large number of individual vaccines reported, detailed information and type of reaction are not presented for all vaccine types. However, more detailed data for reports following influenza vaccines, whether given alone or with other vaccines are provided.

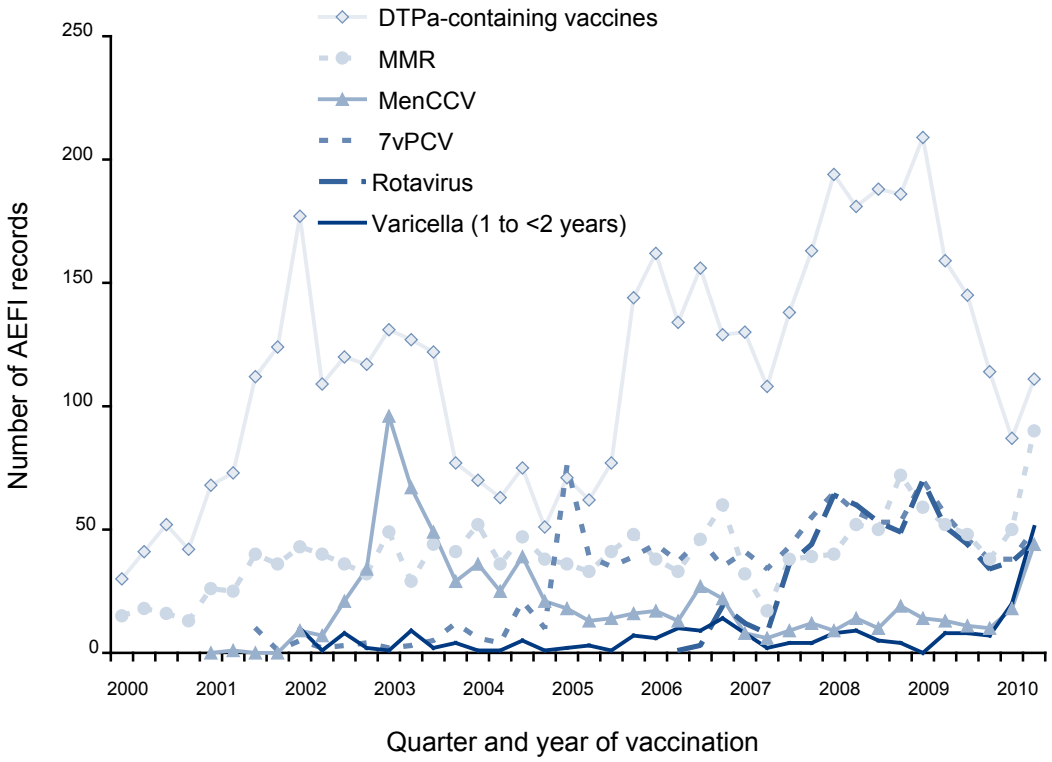
Results

There was a total of 2,225 AEFI records (annualised reporting rate of 227.1 per 100,000 population) for children aged < 7 years for vaccines administered in the first 6 months of 2010. This was a more than 7-fold increase from 305 records (32.0 per 100,000 population) for the corresponding period in 2009.

Overall number of AEFI reports increased for all vaccine types (Figure 1) and jurisdictions in the second quarter of 2010 compared with the first quarter of 2010. Sixty-seven per cent of AEFI (n = 1,498) were reported to the TGA via states and territories and the remainder were reported direct to the TGA: 17% (n = 379) by members of the public, 13% (n = 295) by doctors/health professionals, 2% (n = 44) by hospitals, and 0.4% (n = 8) by pharmaceutical companies. The number of AEFI reports by members of the public was much greater in the first 6 months of 2010 than in 2009 (n = 6, 2%), with 95% of reports by members of the public relating to seasonal influenza and pH1N1 influenza vaccines.

Seventeen per cent (n = 370) of the reported AEFI were for children aged < 1 year, 27% (n = 615) were for those aged 1 to < 2 years, and 56% (n = 1,240) were for the 2 to < 7 year age group. The male to female ratio was 1.1:1, similar to previous years.[10,14]

Figure 1: Reports of adverse events following immunisation for vaccines other than influenza for individuals aged < 7 years, ADRS database, 2000 to 30 June 2010, by quarter of vaccination



Of the 2,225 records, accurate total population dose numbers administered from ACIR were available for 365 records associated with 10 NIP vaccines (Table 1). The overall AEFI rate for those reports was 19.5 per 100,000 doses, with 2.1 per 100,000 classified as 'serious', slightly higher than for the same period in 2009 (overall 14.7 per 100,000 doses and serious 1.8 per 100,000 doses). By age group, reporting rates per 100,000 doses were higher in 2010 for children aged 1 to < 2 years (27.8 vs 7.1) and 2 to < 7 years (42.2 vs 38.3), but not for children aged < 1 year (9.8 vs 11.2). The increase in AEFI reporting rates for children 1 to < 2 and 2 to < 7 are probably related to the fact that these vaccines were often co-administered with either seasonal influenza or pH1N1 influenza vaccine during 2010 (153 of the 365 records had one of the influenza vaccines co-administered with other NIP vaccines) for which increased reporting occurred. There were increases in the reporting rates of some individual vaccines in 2010 (Table 1), which were again probably related to these vaccines being co-administered with the influenza vaccines in 2010.

Adverse events following immunisation reports not including influenza vaccines

There were only 212 AEFI records for children aged < 7 years in the first 6 months of 2010 (reporting rate of 21.7 per 100,000 population), which did not include influenza vaccines or co-administration of influenza with other vaccines, which is less than in 2009 (n = 301; reporting rate 31.0 per 100,000 population).

Table 1: Reporting rates of adverse events following immunisation per 100,000 vaccine doses for vaccines other than influenza vaccines, children aged < 7 years, ADRS database, 1 January to 30 June 2010

	AEFI records* (n)	Vaccine doses† (n)	Reporting rate per 100,000 doses‡		
			Jan–June 2010	Jan–June 2009	Jan–June 2008
Vaccine (NIP vaccines)§					
DTPa-containing vaccines	193	516,284	37.4	39.7	45.1
DTPa-IPV	103	132,037	78.0	76.1	77.6
Pentavalent (DTPa-IPV-HepB)	3	163	1,840.5	46.5	11.2
Hexavalent (DTPa-IPV-HepB-Hib)	86	384,084	22.4	25.9	24.4
Haemophilus influenzae type b	64	129,404	49.5	17.7	17.4
Haemophilus influenzae type b-hepatitis B	1	542	184.5	83.7	40.6
Measles-mumps-rubella	140	265,008	52.8	35.3	33.1
Meningococcal C conjugate	58	136,630	42.5	18.7	15.6
Pneumococcal conjugate	83	380,005	21.8	27.2	28.4
Varicella	76	131,218	57.9	7.5	16.4
Rotavirus	81	314,588	25.7	33.3	37.2
Age group					
< 1 year	107	1,094,919	9.8	11.2	12.8
1 to < 2 years	136	489,499	27.8	7.1	7.4
2 to < 7 years	122	289,261	42.2	38.3	50.5
AEFI category§					
Total	365	1,873,679	19.5	14.7	16.9
'Certain' or 'probable' causality rating	23	1,873,679	1.2	2.2	5.1
'Serious' outcome	40	1,873,679	2.1	1.8	2.3

* Number of adverse events following immunisation (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 2010. More than 1 vaccine may be coded as 'suspected' if several were administered at the same time.

† Number of vaccine doses recorded on the Australian Childhood Immunisation Register (ACIR) and administered between 1 January and 30 June 2010.

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

§ Records where at least one of the 10 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.[9] A 'serious' outcome is defined as recovery with sequelae, hospitalisation, life-threatening event or death. Of the 365 reports contained in this table, 153 reports also included some influenza vaccine co-administered with other National Immunisation Program vaccines.

Nine per cent (n = 20) of the 212 AEFI records had outcomes defined as 'serious' (i.e. recovery with sequelae, hospitalisation, life threatening event or death). Serious AEFI reported included pyrexia (n = 6), diarrhoea (n = 6), injection site reactions (n = 5), intussusception (n = 4), allergic reactions (n = 3), seizure (n = 1) and death (n = 1). There were no reports of life-threatening events and 18 children were admitted to hospital.

One death was recorded as temporally associated with the receipt of vaccines other than influenza vaccine. It was an infant following receipt of hexavalent, 7vPCV and rotavirus vaccines; who had an apnoeic episode and sudden infant death syndrome 5 days post vaccination. The death was investigated by the TGA and while temporally related to vaccination was not classified as causally related to vaccination.

Adverse events following immunisation reports including influenza vaccines

Of the 2,225 records, 1,695 (76%) included receipt of seasonal influenza vaccine and 318 (14%) included pH1N1 influenza vaccine (Table 2, Figure 2), which was a sharp contrast to the first 6 months of 2008 and 2009, where there were only 18 and 20 reports, respectively, for influenza vaccines.

2010 seasonal influenza vaccine

The majority of the reports for seasonal influenza vaccine were for either Fluvax® or Fluvax junior® (CSL Biotherapies) (n = 1,388; 82%) while another 16% did not specify the vaccine brand and were coded only as influenza vaccine (Figure 2). There were 32 adverse event reports following vaccination with Influvac® (Solvay Biosciences), eight with Vaxigrip® (Sanofi Pasteur) and four with Fluarix®(GlaxoSmithKline).

The reporting rate for seasonal influenza vaccine, using a dose administered estimate adjusted for under-reporting to the ACIR, was 3,939 per 100,000 doses, approximately 150-fold higher than the average for non-influenza vaccines. Seventy-one per cent were reported via states and territories. A large proportion of the total number of reports for seasonal influenza vaccine were from Western Australia (41%); compared with only 22% of reports for other vaccine types from that State. The increased proportion of reports from Western Australia is consistent with the greater use of seasonal influenza vaccine in that State due to their vaccine program for children < 5 years of age.[15] Eighty-two per cent of the reports following seasonal influenza vaccine were defined as 'non-serious', 6% (n = 94) were defined as 'serious' and an additional 12% were not categorised because of the non-availability of data on hospitalisation and outcome.

Figure 2: Reports of adverse events following immunisation for influenza-related vaccines for individuals aged < 7 years, ADRS database, 2007 to 30 June 2010, by year of vaccination

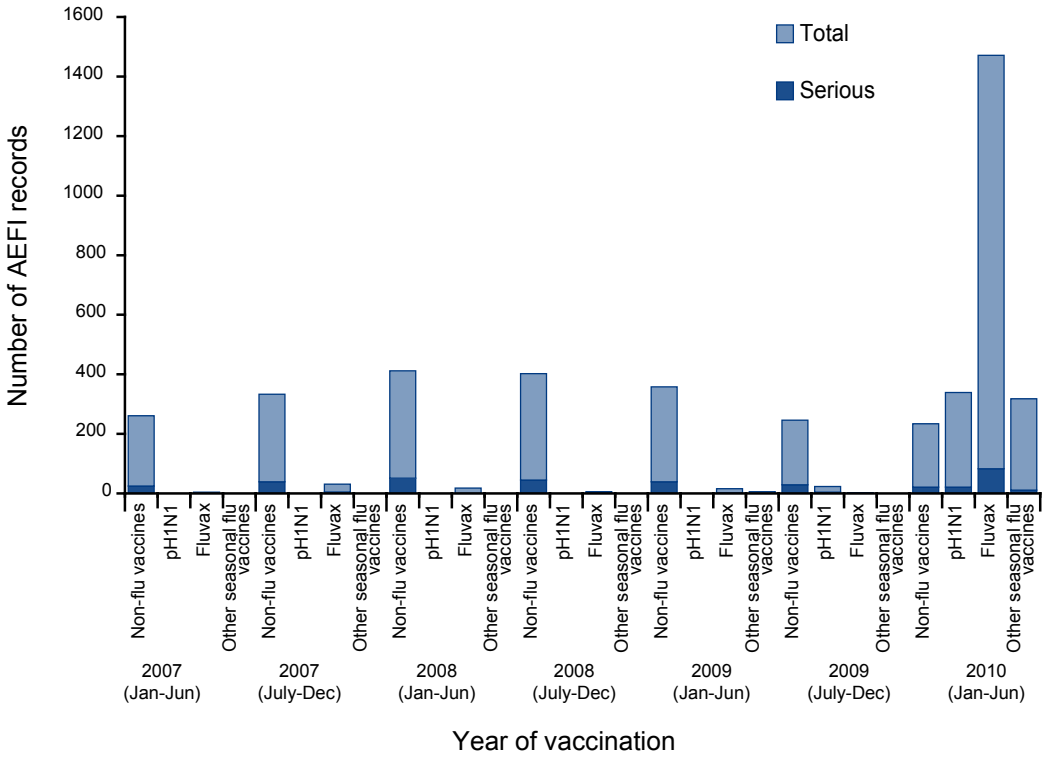


Table 2: Reporting rates of adverse events following immunisation (AEFI) per 100,000 vaccine doses for influenza-containing vaccines, children aged < 7 years, ADRS database, 1 January to 30 June 2010

	AEFI records* (n)	Vaccine doses† (n)	Reporting rate per 100,000 doses‡ Jan–June 2010
Age group			
<1 year			
Trivalent seasonal influenza vaccine	244	3,745	6,515.0
Fluvax or Fluvax junior only	204	na	na
Other seasonal influenza vaccines§	4	na	na
Influenza vaccines not specified	36	na	na
pH1N1 influenza vaccine	53	36,154	155.2
1 to <2 years			
Trivalent seasonal influenza vaccine	461	7,908	5,830.0
Fluvaxor Fluvax junior only	385	na	na
Other seasonal influenza vaccines§	14	na	na
Influenza vaccines not specified	62	na	na
pH1N1 influenza vaccine	109	73,325	148.7
2 to <7 years			
Trivalent seasonal influenza vaccine	990	30,729	3,222.0
Fluvax or Fluvax junior only	799	na	na
Other seasonal influenza vaccines§	26	na	na
Influenza vaccines not specified	165	na	na
pH1N1 influenza vaccine	156	299,710	52.1
AEFI category‖			
Total			
Trivalent seasonal influenza vaccine	1,695	42,384	3,999.0
Fluvax or Fluvax junior only	1,388	na	na
Other seasonal influenza vaccines§	44	na	na
Influenza vaccines not specified	263	na	na
pH1N1 influenza vaccine	318	407,189	78.1
'Certain' or 'probable' causality rating			
Trivalent seasonal influenza vaccine	21	42,384	49.5
Fluvax or Fluvax junior only	12	na	na
Other seasonal influenza vaccines§	0	na	na
Influenza vaccines not specified	0	na	na
pH1N1 influenza vaccine	9	407,189	2.2
'Serious' outcome			
Trivalent seasonal influenza vaccine	94	42,384	221.8
Fluvax or Fluvax junior only	83	na	na
Other seasonal influenza vaccines§	3	na	na
Influenza vaccines not specified	8	na	na
pH1N1 influenza vaccine	21	407,189	5.2

* The number of adverse events following immunisation (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 2010. More than 1 vaccine may be coded as 'suspected' if several were administered at the same time.

† Number of vaccine doses were estimated using an adjustment for the known under-reporting of these vaccines to the Australian Childhood Immunisation Register (ACIR) in 2010 as explained in the text.

‡ The estimated AEFI reporting rate per 100,000 vaccine doses. Should be regarded as approximate only, due to uncertainty about the level of under-reporting to the ACIR.

§ Includes all non CSL influenza vaccine types where vaccine type is specified.

‖ Records where the vaccine 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.[9] A 'serious' outcome is defined as recovery with sequelae, hospitalisation, life-threatening event or death.

The spectrum of reactions for seasonal influenza vaccine was similar to that for non-influenza vaccines (Table 3), with the exception of a substantially higher proportion with fever (94% compared to 54% for non-influenza vaccines), allergic reaction (54% vs 29%) and malaise (15% vs 10%). A higher proportion of reports following seasonal influenza vaccine came from members of the public (14% compared with 5% for non-influenza vaccines).

One death was recorded as temporally associated with the receipt of seasonal influenza vaccine. A 2-year-old child was found deceased on the morning following receipt of seasonal influenza vaccine (Fluvax junior®, CSL Biotherapies). A post-mortem determined that a causal relationship between vaccination and death was not established.

Monovalent pH1N1 vaccine

There were 318 reports following pH1N1 influenza vaccine, a rate of 78 per 100,000 doses using a dose administered estimate adjusted for under-reporting to the ACIR. This was more than 4-fold greater than the reporting rate for non-influenza vaccines. Thirty-four per cent of the cases were reported by Queensland, 25% by New South Wales and 12% by Western Australia. Forty-four per cent were reported by members of the public (compared with 14% for TIV and 5% for non-influenza) and 40% by states

Table 3: Reaction categories of interest* mentioned in records of adverse events following immunisation, ADRS database, 2009

Reaction category*	Fluvax ± other vaccines	pH1N1 ± other vaccines	Other seasonal influenza ± other vaccines	Influenza vaccine not specified ± other vaccines
Fever	1,309	249	34	248
Allergic reaction†	753	170	15	136
Malaise	214	49	2	32
Nerve/psychological	203	42	7	30
Headache	112	19	2	20
Seizure	105	37	1	9
Tremor	84	21	1	15
Abnormal crying	85	20	1	9
Nausea	34	6	2	15
Myalgia	41	8	0	8
Abdominal pain	33	7	0	14
Injection site reaction	42	18	0	5
Pain	28	7	0	8
Rash‡	33	19	0	4
Dizziness	9	4	0	1
Vision impaired	4	0	0	2
Weakness	5	0	0	1
Syncope	4	6	0	0
Arthralgia	4	0	0	0
Anaphylaxis	2	1	0	0
Death	1	0	0	0
HHE§	1	3	0	0
Total‖	1,388	318	44	263

* Reaction categories were created for the adverse events following immunisation (AEFI) of interest listed and defined in *The Australian Immunisation Handbook,* 9th edition, pp 58–65 and 360–363.[1]

† Allergic reaction includes skin reactions including pruritus, urticaria, periorbital oedema, facial oedema, erythema multiforme, etc, and/or gastrointestinal (e.g. diarrhoea, vomiting) symptoms and signs (excludes 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.

§ Hypotonic-hyporesponsive episode.

‖ 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.

and territories. Only 7% of the reports following pH1N1 influenza vaccine were coded as serious compared with 11% following non-influenza vaccines. Distribution of reaction types for pH1N1 influenza vaccine is presented in Table 3. The spectrum of reactions for the pH1N1 influenza vaccine was similar to that for seasonal influenza vaccine, showing higher rates than non-influenza vaccines for fever (78% vs 54%), allergic reaction (53% vs 29%) and malaise (15% vs 10%).

Discussion

There was a more than 7-fold increase in both the number of AEFI report and population-based reporting rates for specific AEFI in the first 6 months of 2010. This was due to the substantial increase in reporting of adverse events following vaccination with the two available influenza vaccines: seasonal trivalent influenza vaccines and the pandemic (pH1N1) influenza vaccine. Forty-one per cent of the adverse events following seasonal influenza vaccine were reported by Western Australia. Western Australia has had a funded state-based seasonal influenza vaccination program for all children aged 6 months to < 5 years since 2008, and in 2010 Western Australia had the highest number of children aged 6 months to < 5 years vaccinated with CSL's 2010 seasonal trivalent influenza vaccine. This State was the first to detect the safety signal related to the 2010 seasonal influenza vaccine of substantially higher rates of fever and febrile convulsions.[8,16,17]

AEFI reporting rates for non-influenza vaccines were slightly higher in the first 6 months of 2010 compared with previous years (Table 1). However, after excluding reports where influenza vaccines were co-administered, the rate was 30% lower in the first 6 months of 2010 compared with 2009. 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 large number of reports from members of the public in comparison with previous years indicates a high level of public interest in both the pH1N1 and seasonal influenza vaccines. This was for at least two reasons: 1) the pandemic H1N1 influenza vaccination program used strategies to encourage consumers and health professionals to report adverse events to the TGA to monitor the vaccine safety[18] and 2) the public announcement of the suspension of the use of seasonal influenza vaccine in April 2010 due to high rates of fever.

The safety of pH1N1 influenza vaccines has been examined closely both nationally and internationally. The World Health Organization reports that approximately 30 different pH1N1 vaccines have been developed using a range of methods.[19] 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, which occur with a frequency of less than 1 in 1,000. In general, the safety profile, including that for the Australian vaccine, have been similar to that of other vaccines, with predominantly mild transient events and a small number of serious reactions reported.[20,21]

The investigation that occurred when increased reports of AEFI in young children following 2010 seasonal TIV (predominantly fever and febrile convulsions) has been described in detail in two reports from the TGA.[16,17] The number of AEFI reports presented here may vary slightly from published TGA reports[16–18,21] due to differences in age groups and time frames for reporting.

Epidemiological studies determined that the 2010 seasonal influenza vaccine produced by CSL Biotherapies (Fluvax® and Fluvax junior®) was associated with unexpected and excessively increased rate of febrile convulsions within 24 hours of administration (incidence rate 500–700 febrile convulsions per 100,000 doses). The use of the 2010 seasonal TIV in children < 5 years of age was suspended in April 2010,[8] after which reporting of AEFI from seasonal influenza vaccine were observed to decline. The recommendation to resume the use of seasonal influenza vaccine in children aged 6 months to 5 years (using brands other than Fluvax® and Fluvax junior®) was subsequently made in August.[22]

Conclusion

In the first half of 2010, the overall AEFI reporting rate per 100,000 doses for children aged < 7 years was much higher than for the same period in 2009. This was entirely attributable to reports arising from the 2010 seasonal trivalent influenza vaccine as well as the pH1N1 influenza vaccine. There was a substantial increase in the number of reports received from members of the public compared with 2009. The majority of AEFI reports were of mild, transient and well-recognised vaccine side-effects, however, the occurrence of an increased number of serious AEFI, predominantly febrile convulsions and fever post 2010 seasonal TIV from CSL Biotherapies led to the suspension of use of that vaccine in children < 5 years of age.

Acknowledgements

The National Centre for Immunisation Research and Surveillance is supported by the Department of Health and Ageing, the New South Wales Health Department and The Children's Hospital at Westmead.

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