Government of Western Australia
Department of Health

Summary of 'Adverse Event Following Immunisation' Reports, Western Australia, 2012

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Background

This annual report of adverse events following immunisation (AEFI) in WA summarises passive surveillance data received by the Western Australian Vaccine Safety Surveillance (WAVSS) system.

WAVSS is a Western Australian Department of Health (WA DoH) initiative to monitor vaccine safety and was established in March 2011, in collaboration with Child and Adolescent Health (CACH) and the Central Immunisation Clinic. WAVSS was developed on the Victorian Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC) model. WAVSS accepts reports of suspected AEFI from health providers but also directly from the public.

AEFIs are defined as unwanted or unexpected events following the administration of a vaccine. The fact that an adverse event occurred following immunisation is not conclusive evidence that the event was caused by a vaccine. Factors such as medical history, diagnostic tests, and other medication given near the time of vaccination must be examined to help to determine the cause of adverse events.

In Western Australia (WA) there is a statutory requirement for health professionals to report an AEFI to the WA DoH, as specified in Regulation 4 of the Health Regulations, 1995. (For more detail see http://www.public.health.wa.gov.au/3/498/3/adverse_events_following_immunisation.pm). All AEFI reports received by the WA DoH are forwarded to the Therapeutic Goods Administration (TGA) on a daily basis (Monday to Friday). In addition, the TGA receives AEFI reports directly from clinicians, pharmaceutical companies that manufacture vaccines and the public. On a monthly basis, the TGA provides the WA DoH with data on all reports of 'suspected' AEFI that they have received for residents of WA and these are cross-checked with WAVSS and entered where missing.

In 2012, the TGA launched an online Database of Adverse Event Notifications (DAEN). The DAEN contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia. The DAEN is available to members of the public as part of TGA initiatives to be more transparent about its activities. For more information on the DAEN visit http://www.tga.gov.au/safety/daen.htm.

Method

For this summary, AEFI reports were eligible for inclusion in the analysis if:

- a vaccine(s) was recorded as 'suspected' of being involved in the reported adverse event
- the residential address of the individual was recorded as WA
- the vaccination occurred between 1 January 2012 and the 31 December 2012; if the vaccine date was not recorded, the date of symptoms onset was taken as the date of vaccination.

Classification of the type of AEFI reaction(s):

An individual AEFI report can consist of multiple symptoms, signs and tentative diagnoses. For the purpose of this summary, AEFIs were grouped into the following categories:

- Febrile convulsions
- Afebrile convulsions/seizures
- Other febrile reactions (i.e. fever but no convulsion/seizure reported)
- Local reactions (e.g. redness, swelling, and/or pain at the injection site but no fever or convulsion) - Note: in cases in which multiple vaccines were given where possible the vaccine associated with the local reaction was attributed as being associated with the adverse event.
- Other reactions, i.e. not in one of the four categories above (includes but is not limited to reports of rash, joint swelling, dizziness, myalgia, headache, nausea and vomiting).

"Hospitalised patients" were defined as those where the AEFI was suspected to have led to a hospital admission of at least one night or in which the AEFI was believed to prolong a hospital stay.

Notes on interpretation of the summary data

1. Young children often receive multiple vaccines during a single health care encounter and because in these circumstances it is usually not possible to attribute a subsequent AEFI to a single vaccine, all the vaccines administered during the clinic visit are usually listed as 'suspected' of involvement in the AEFI.

2. The reported symptoms, signs and diagnoses in each adverse event were temporally associated with vaccination, but are not necessarily causally associated with one or more of the vaccines administered.

3. The data below include all reports received by WAVSS for 2012 as at 16 January 2013. These data are subject to change.

Surveillance data analysis

AEFI reports

A total of 297 individual AEFI reports were received by WAVSS for persons vaccinated in 2012, compared with 323 in 2011, and 1,075 in 2010. Of the 297 reports, 7 were reviewed and determined to be unrelated to vaccination, these were removed from further analysis.

From the remaining 290 reports 566 adverse events were described (compared with 557 from 2011): 370 met established case definitions and 196 were recorded verbatim (note that a vaccinee may describe multiple AEFI reactions).

A total of 473 vaccines had been administered (compared with 533 in 2011), with a median number of 1 vaccine per person reported (range 1-5 vaccines per person).

A comparison of the number of reports received by month vaccinated in 2012 to 2011 is seen in Figure 1 below. The months with the highest number of AEFI reports were March and April 2012, coinciding with the influenza vaccination program launch and roll-out. The reactions reported in these months are seen mainly in adult's ≥18 years (Figure 2). An increase in reports in August of 2012 is mainly seen in 5-17 year olds and may be related to school-based vaccinations given in Term 3 (dtPa and HepB2).

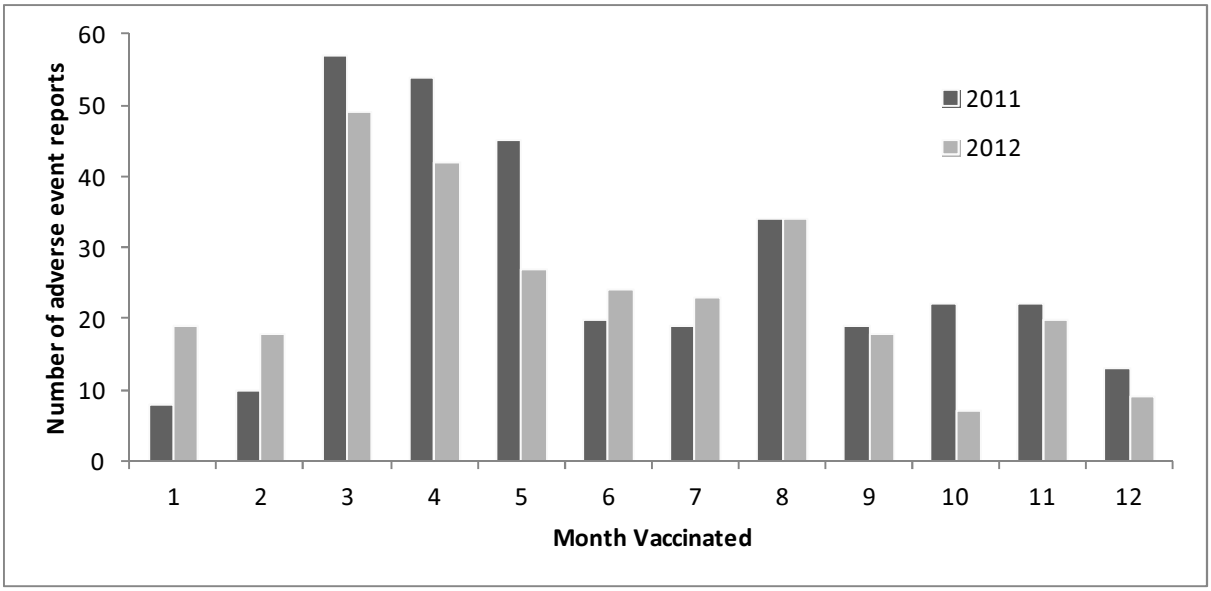

Figure 1 – Reports of adverse events following immunisation, Western Australia, 2011-2012, by month of vaccination.

Characteristics of AEFI reports received in 2012 are summarised in Table 1 and compared to those received in 2011. A total of 23 AEFIs reported being hospitalised, with a median length of stay of 2 days (range 1-37 days).

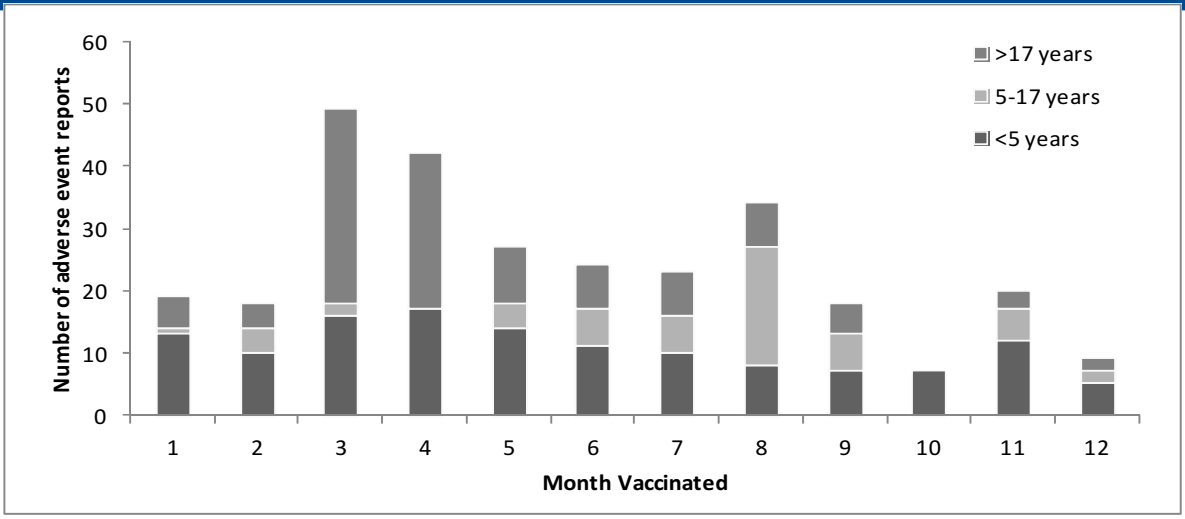

Figure 2 – Reports of adverse events following immunisation, Western Australia, 2012, by month of vaccination and age group in years.

Table 1 – Characteristics of AEFIs reported in 2011 vs 2012

	2011	2012
TOTAL	323	290
Male	130 (40%)	126 (43%)
Female	193 (60%)	163 (56%)
ATSI	9 (3%)	12 (4%)
Non-ATSI	223 (69%)	238 (82%)
Unknown	91 (28%)	40 (14%)
<5 years	135 (42%)	130 (45%)
5-17 years	62 (19%)	55 (19%)
≥18 years	126 (39%)	105 (36%)
Reporter type: Health provider	257 (80%)	214 (74%)
Parent/public	59 (18%)	66 (23%)
Other	7 (2%)	10 (3%)
Immunisation provider: GP	118 (37%)	77 (27%)
Nurse	142 (44%)	154 (53%)
Managed by: Healthdirect	14 (4%)	19 (7%)
Nurse assessment	54 (17%)	70 (24%)
GP assessment	150 (46%)	119 (41%)
Central Immunisation Clinic	12 (4%)	11 (4%)
Emergency Department	46 (14%)	62 (21%)
Admitted to Hospital	25 (8%)	23 (8%)
Reported by: Fax	149 (46%)	121 (42%)
Online	136 (42%)	106 (37%)
Post	16 (5%)	22 (8%)
Telephone	19 (6%)	41 (14%)

Table 2 – Classification of the type of AEFI reaction(s), 2011 vs 2012

	2011	2012
Afebrile convulsions/seizures	4	4
Febrile convulsions	4	7
Local reaction	122	91
Other febrile reaction	75	69
Other reactions	118	119
Grand Total	**323**	**290**

Of all AEFI reports, 45% (130/290) were reported among children aged less than five years, compared with 42% (135/323) in 2011 and 78% (839/1075) in 2010. In 2012 more than 750,000 doses of National Immunisation Program childhood vaccines were distributed in WA. The rate of AEFIs in children <7 years per 10,000 doses recorded on the Australian Childhood Immunisation Record (ACIR) is provided in Table 3. The highest rate of AEFI per 10,000 doses is seen with Quadracel and then TIV, numbers are comparable to 2011.

Table 3 – Rate of AEFI in children <7 years per 10,000 doses administered as recorded on ACIR by vaccine, 2011 and 2012.

	2011			2012		
VACCINE (DISEASE(S))	Doses administered in <7 yrs	AEFIs Reported to WAVSS in <7 yrs	Rate of AEFI per 10,000 doses	Doses administered in <7 yrs	AEFIs Reported to WAVSS in <7 yrs	Rate of AEFI per 10,000 doses
Infanrix Hexa (DTP-HepB-Polio-HIB)	91024	51	5.6	92974	45	4.8
Prevenar (Pneumococcal)	99295[a]	57	5.7	104014	53	5.1
RotaTeq (Rotavirus)	80946	40	4.9	83824	46	5.5
TIV (Influenza)	10100	14	13.9	10717	11	10.3
Priorix (Measles, Mumps, Rubella)	60793	53	8.7	62068	34	5.5
Hiberix (Haemophilus influenza B)	29878	17	5.7	30528	18	5.9
NeisVac-C (Meningococcal C)	31508	18	5.7	32722	17	5.2
Vaqta Paed Ad (Hepatitis A)	3395	3	8.8	3358	1	3.0
Varilrix (Varicella)	29983	11	3.7	30904	7	2.3
Quadracel (DTPa-Polio)	30090	43	14.3	28828	46	16.0

[a]Includes both Prevenar7 and Prevenar13 figures

AEFIs associated with influenza vaccines

Administration of an influenza vaccine (inactivated trivalent influenza vaccine [TIV]) was recorded, either singly or in combination with other vaccines, in 24% (70/290) of the AEFI reports, compared with 21% (67/323) in 2011 and 89% (795/1075) of reports in 2010.

Table 4 shows the brand and age breakdown of the reports. Fourteen percent (n=10) of adverse reports to influenza vaccines occurred in children <5 years of age (Table 1) this is similar to 2011 (10%) and markedly down on 2010 in which 82% of all reports were influenza vaccine-related reports in children <5 years. In 2012 approximately 340,000 doses of influenza vaccine were distributed in WA.

The most commonly reported type of adverse event following receipt of influenza vaccine, alone or in combination with other vaccines, was an 'other reaction'.

Table 4 – Age breakdown of all adverse reaction reports to 2012 influenza vaccines, by brand, Western Australia, 2012.

	<5 years	5-17 years	≥18 years	TOTAL
Brand unspecified			1	1
Fluarix®	1		3	4
Fluvax®		1	9	10
Influvac®	1		1	2
Influvac junior®	1			1
Intanza®			18	18
Vaxigrip®	6	2	25	33
Vaxigrip Junior®	1			1
Grand Total	**10**	**3**	**57**	**70**

A total of 5 reports associated with influenza vaccines indicated the patient had been hospitalised for at least one night.

Non-influenza vaccines identified in AEFI reports

Influenza vaccines were the most commonly reported vaccine on an AEFI report in 2012, the other most frequently identified vaccines specified on AEFI reports were:

- DTPa (n=61, 21% of all reports)
- Pneumococcal PCV13 (n=53, 18% of all reports)
- dTpa-IPV (46, 16%)
- Rotavirus vaccine (46, 16%)
- DTPa-IPV-HepB-Hib (45, 16%)
- MMR (34, 12%)

Of the adverse events following receipt of all vaccines other than influenza (alone or in combination with other vaccines), there were 7 febrile convulsions (6 in children <5 years and 1 aged 5-17 years), 4 afebrile convulsions (3 in children <5 years and 1 aged 5-17 years), 72 local reactions, 54 other febrile reactions, and 83 other reactions. A total of 18 reports following receipt of all vaccines other than influenza indicated the patient had been hospitalised.

There were two reports of anaphylaxis but no reports of Guillain Barre Syndrome or death to vaccines administered in 2012.

WAVSS clinical activity

Of the 290 AEFIs reported against vaccines received in 2012 a total of 28 children were invited to and attended a WAVSS clinic at either the Central Immunisation Clinic or Princess Margaret Hospital for Children. 39% (11/28) were vaccinated at the clinic. A further three were invited but failed to attend clinic.

Also seen in clinics in 2012 were 7 children who experienced an AEFI following vaccination in 2011, 2 in 2010 and 17 children referred by their GP or parent for allergy or concerns related to vaccination. Bringing the total number of children seen to 54.

Twenty adults were referred to the adult immunology clinic at Sir Charles Gairdner Hospital (SCGH).

Publications

- Kelly H, Carcione D, Dowse GK, Effler P. The vaccine-attributable risk of febrile convulsions following influenza vaccine. The Pediatric Infectious Disease Journal. 2012; 31 (7): 792.
- Mak DB, Carcione D, Joyce S, Tomlin S, Effler PV. Paediatric influenza vaccination program suspension: effect on childhood vaccine uptake. Aust NZ J Publ Heal 2012: 36 (5); 494-495. – LETTER
- Mak DB, Bulsara MK, Wrate MJ, Carcione D, Chantry M, Effler PV. Factors determining vaccine uptake in Western Australian adolescents. Journal of Paediatrics and Child Health. 2012; DOI: 10.1111/jpc.12030.
- Carcione D, Blyth CC, Richmond PC, Mak DB, Effler PV. Safety Surveillance of Influenza Vaccine in Pregnant Women. Australian New Zealand Journal of Obstetrics and Gynaecology. 2012; - LETTER, in press.

Discussion

WAVSS was a recommendation that came out of the WA Parliamentary Enquiry (Stokes Review) into the handling of AEFIs following 2010 seasonal influenza vaccination in children. With the assistance of SAEFVIC the WA DoH was able to launch WAVSS to health providers and the public in 2011. This report summarised the AEFIs experienced following vaccination in 2012.

The numbers of reports received following vaccination given in 2012 were similar to that reported in 2011 and a third of that reported in 2010.

The post-licensure surveillance of AEFI is important to detect uncommon events that may not have been identified in previous clinical trials undertaken for licensure. AEFI surveillance in Australia relies on passive reporting from immunisation providers and the public. Although passive reports of AEFI can rarely provide definitive evidence of a causal association between a vaccine and particular risks, spontaneous AEFI reporting enables the early detection of signals that can then be more rigorously investigated.