Annual report

Surveillance of adverse events following immunisation in Australia annual report, 2015

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Abstract

This report summarises Australian passive surveillance data for adverse events following immunisation (AEFI) for 2015 reported to the Therapeutic Goods Administration and compares them to long-term trends. There were 2,924 AEFI records for vaccines administered in 2015; an annual AEFI reporting rate of 12.3 per 100,000 population. There was a decline of 7% in the overall AEFI reporting rate in 2015 compared with 2014. This decline in reported adverse events in 2015 compared to the previous year was mainly attributable to fewer reports following the HPV vaccine and replacement of monovalent vaccines (Hib, MenCCV and varicella) with combination vaccines such as Hib–MenC, and MMRV. AEFI reporting rates for most individual vaccines were lower in 2015 compared with 2014. The most commonly reported reactions were injection site reaction (26%), pyrexia (17%), rash (16%), vomiting (8%) and headache (7%). The majority of AEFI reports (85%) were described as non-serious events. There were two deaths reported, but no clear causal relationship with vaccination was found.

Introduction

This report summarises national passive surveillance data for adverse events following immunisation (AEFI) reported to the Therapeutic Goods Administration (TGA) by 28 February 2016. The report focuses on AEFI reported for vaccines administered during 2015 and compares trends in AEFI reporting during 1 January 2000 – 31 December 2015.

An adverse event following immunisation is defined as any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine.[1] The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.[1]

Thus, AEFI may be caused by a vaccine(s) or may be coincidental. Adverse events may also include conditions that occur following the incorrect handling and/or administration of a vaccine(s). The post-marketing surveillance of AEFI is particularly important to detect signals of rare, late onset or unexpected events, which are difficult to detect in pre-registration vaccine trials.

Reports summarising national AEFI surveillance data have been published regularly since 2003. [2-15] Trends in reported adverse events following immunisation are heavily influenced by changes to vaccine funding and availability provided through the National Immunisation Program (NIP). These changes impact on the interpretation of trend data and have been described in detail in reports published since 2003.[2-15] Appendix 1 shows the chronological listing of the changes.

Below is a glossary of the abbreviations on vaccines referred to in this report.

Recent changes that impact on AEFI surveillance data presented in this 2015 report are:

- In March 2015, seasonal influenza vaccine was funded for Aboriginal and Torres Strait Islander children aged 6 months to less than 5 years.
- From March to June 2015, the dTpa vaccine for women during the third trimester of pregnancy was funded by New South Wales, South Australia, Western Australia, the Australian Capital Territory, Victoria and Tasmania. The Northern Territory had funded it since September 2013 and Queensland since July 2014.
- In April 2015, new immunisation requirements for family assistance payments were announced by the federal government (the 'No Jab, No Pay' policy), to come into effect on 1 January 2016. Only parents of children (aged less than 20 years) who are 'fully immunised' or on a recognised catch-up schedule, remain eligible to receive the Child Care Benefit, Child Care Rebate, and/or the Family Tax Benefit Part A end-of-year supplement.

- In March 2015, a booster dose of DTPa was recommended for babies at 18 months of age (commenced under NIP in March 2016).

Refer to Appendix 1

Methods

AEFI are notified to the TGA by state and territory health departments, health professionals, vaccine companies and the public.[16,17] All reports are assessed using internationally consistent criteria[18] and entered into the Australian Adverse Drug Reactions System (ADRS) database. Reports are used in data mining and signal detection activities. Where there is insufficient information in a report to determine causality for a serious adverse event, the TGA will contact the reporter on up to three occasions to elicit further information.

AEFI data

De-identified information on all AEFI reported to the TGA from 1 January 2000 to 31 December 2015 and stored in the ADRS database, were released to the National Centre for Immunisation Research and Surveillance (NCIRS) in March 2016. A description of the surveillance system is available in previous AEFI surveillance reports.[3,6]

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 2015, or

(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 2015.

Study definitions of AEFI outcomes and reactions

AEFI were defined as 'serious' or 'non-serious' based on information in the report sent to the TGA and criteria similar to those used by the World Health Organization[18] and the US Vaccine Adverse Events Reporting System.[19] In this report, an AEFI is defined as 'serious' if it meets one or more of the following criteria: (1) results in death; (2) is life-threatening; (3) requires inpatient hospitalisation or prolongation of existing hospitalisation; (4) results in persistent or significant disability/incapacity; (5) is a congenital anomaly/birth defect or; (6) is a medically important event or reaction.

Typically, each record lists several reaction terms that are symptoms, signs and/or diagnoses that have been coded by TGA staff from the reporter's description into standardised terms using the Medical Dictionary for Regulatory Activities (MedDRA®).[20,21]

In reports published previously, in order to analyse the data, MedDRA® coding terms were grouped to create a set of reaction categories that were broadly analogous to the reactions listed in previous Australian Immunisation Handbooks.[16,17] However, the methodological framework of reporting of adverse events was revised in 2014 and a new format for AEFI analyses using MedDRA

Abbreviations of vaccine types	
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 diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus (quadrivalent)
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
Hib-MenC	combined Haemophilus influenzae type b and meningococcal C conjugate vaccine
HPV	human papillomavirus
MenB	meningococcal B vaccine
MenCCV	meningococcal C conjugate vaccine
MMR	measles-mumps-rubella
MMRV	measles-mumps-rubella-varicella
pH1N1	pandemic H1N1 influenza 2009
7vPCV	7-valent pneumococcal conjugate vaccine
13vPCV	13-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine

* The term 'AEFI record' is used throughout this report because a single AEFI notification/report to the Office of Product review can generate more than one 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.
** Vaccines are classified as 'suspected' if the report contains sufficient information to be valid and the relationship between reported reactions and the vaccine is deemed at least possible.

preferred terms (PTs) was adopted.[22] For this report, MedDRA PTs are used for analysis similar to the previous two published reports.[2,15] Grouping of reactions using PTs is more comparable with data from other countries and internationally accepted.[23-25] In conjunction with the currently used national vaccine-specific reporting form,[26] using PTs allows better reflection of post-marketing surveillance data on vaccines in Australia.

Data analysis

All data analyses were performed using SAS software version 9.4.[27] Average annual population-based reporting rates were calculated for each state and territory and by age group using 2015 population estimates obtained from the Australian Bureau of Statistics.[28] All rates are presented as average annual rates per 100,000 population. Reporting rates per 100,000 administered doses were estimated where information was available on the number of doses administered. This was done for vaccines funded through the NIP for children aged <7 years. The number of administered doses of each of the vaccines given to this age group was obtained from the Australian Immunisation Register (AIR), a national population-based register,[29] a national register that records vaccinations given to people of all ages in Australia.[30] In the future, as reporting in older age groups (>7 years) becomes more complete, denominator data on vaccine doses administered in older age groups will be analysed for the purposes of AEFI reporting.

Notes on interpretation

Caution is required when interpreting this report's data. Due to reporting delays and late onset of some AEFI, the data are considered preliminary, particularly for the fourth quarter of 2015. Data published in previous reports may differ from that presented in this report for the same period, because this report has been updated to include delayed notifications to the TGA that were not included in prior publications. Data can also differ because reports may be updated and recoded when follow-up information is received or when vaccine-specific analyses are conducted.

The information collated in the ADRS database is intended primarily for signal detection and hypothesis generation. While reporting rates can be estimated using appropriate denominators, they cannot be interpreted as incidence rates due to under-reporting and biased reporting of suspected events, and the variable quality and completeness of information provided in individual notifications.[3-14,31]

This report is based on vaccine information and MedDRA preferred terms (similar to previous two published reports)[2,15] collated in the ADRS database and not on comprehensive clinical notes or case reviews. 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.

Comparison with online Database of Adverse Events Notifications (DAEN)

In August 2012, the TGA made available to the public on its website a searchable database, the Database of Adverse Event Notifications (DAEN), containing reports of all adverse event reports for medicines and vaccines.[32] The data in this report have not been downloaded from DAEN. This report uses data sent to NCIRS by the TGA and includes more detailed information than provided by the DAEN. The numbers published in this report may be different to the numbers in the DAEN database, due to different dates of data extraction and amendment to reports where further information has become available. In addition, this report provides several features that are not available from the DAEN database, including long-term trends and population and dose-based reporting rates, described in the context of changes in vaccine policy and utilisation, and reporting practices.

Results

The ADRS database included a total of 2,924 records where the date of vaccination (or onset of adverse event, if vaccination date was not reported) was between 1 January and 31 December 2015. Of these, 53% were females (n=1,562), 45% (n=1,337) males and 1% (n=25) missing data on gender.2% (n=72) were reported as Aboriginal and Torres Strait Islander Peoples.

In 2015, approximately 81% of AEFI (n=2,368) were reported to the TGA via states and territories, while the rest were reported directly to the TGA by healthcare professionals (13% n=374), members of the public (4% n=105), vaccine companies (2% n=70) and hospitals (2% n=53).

Reporting trends

The overall reporting rate for 2015 was 12.3 per 100,000 population compared with 13.2 per 100,000 in 2014. The highest peak for all years was observed in 2010 (17.4 per 100,000) predominantly due to reports in children following vaccination with the pandemic and 2010 seasonal trivalent influenza vaccines.[12]

The vast majority of reported events in 2015 (from all reporter types) were of a non-serious nature, similar to the previous years (Figure 1).[10,11] Figures 2a, 2b and 2c demonstrate marked variations in reporting levels in association with previous changes to the NIP from 2000 onwards. The decrease in reports in 2015 was predominantly associated with replacement of monovalent vaccines with combination vaccines in children (Figures 2a and 2b) and also a decline in reports of adverse events following immunisation with HPV vaccines in adolescents (Figure 2c).

A seasonal pattern of AEFI reporting was apparent in 2015 as in previous years, with the highest number of AEFI notifications for vaccinations administered in the first half of the year (Figure 1). This corresponds to the months when influenza vaccine is given and older Australians receive 23vPPV (March to June). However, more AEFI reports following influenza vaccine were received in each of the last five years than years prior to 2009 (pre-pandemic era) (Figure 2c).

Age distribution

The highest population-based AEFI reporting rate per 100, 000 population occurred in infants <1 year of age, the age group that received the largest number of vaccines (Figure 3). Compared with 2014, AEFI reporting rates in children decreased in the 1 to <2 year age group from 117.3 to 108.7. A decline was also observed in the 7 to <20 year age group from 19.7 to 15.1 (Figure 3).

There were no significant differences in reporting rates per 100,000 doses for most individual vaccines in 2015 compared to 2014 (Table 1). For children <7 years of age, rates for varicella, Hib and MenC should be interpreted with caution since these monovalent vaccines were replaced by combination vaccines in July 2013 and hence very few doses were recorded in 2015.

Geographical distribution

Population-based reporting patterns varied among states and territories during 2015 (Table 2). Reporting rates were not significantly different (with overlapping confidence intervals) across jurisdictions in 2015 compared with 2014[2].

Vaccines

There were 2,924 AEFI records received in 2015 (Table 3). The percentage of records where only one vaccine was reported as being the suspected vaccine differed by vaccine administered, typically varying according to whether multiple vaccines were routinely co-administered according to the patient's age. There were slight variations in numbers with outcomes defined as 'serious', which have remained low as in previous years.

The most frequently reported individual vaccine was seasonal influenza vaccine with 599 records (20%) followed by hexavalent DTPa-IPV-HepB-Hib (n=513; 18%), 13vPCV (n=484, 17%), MMR (n=481; 16%), and rotavirus vaccine (n=469; 16%) (Table 3).

Reactions

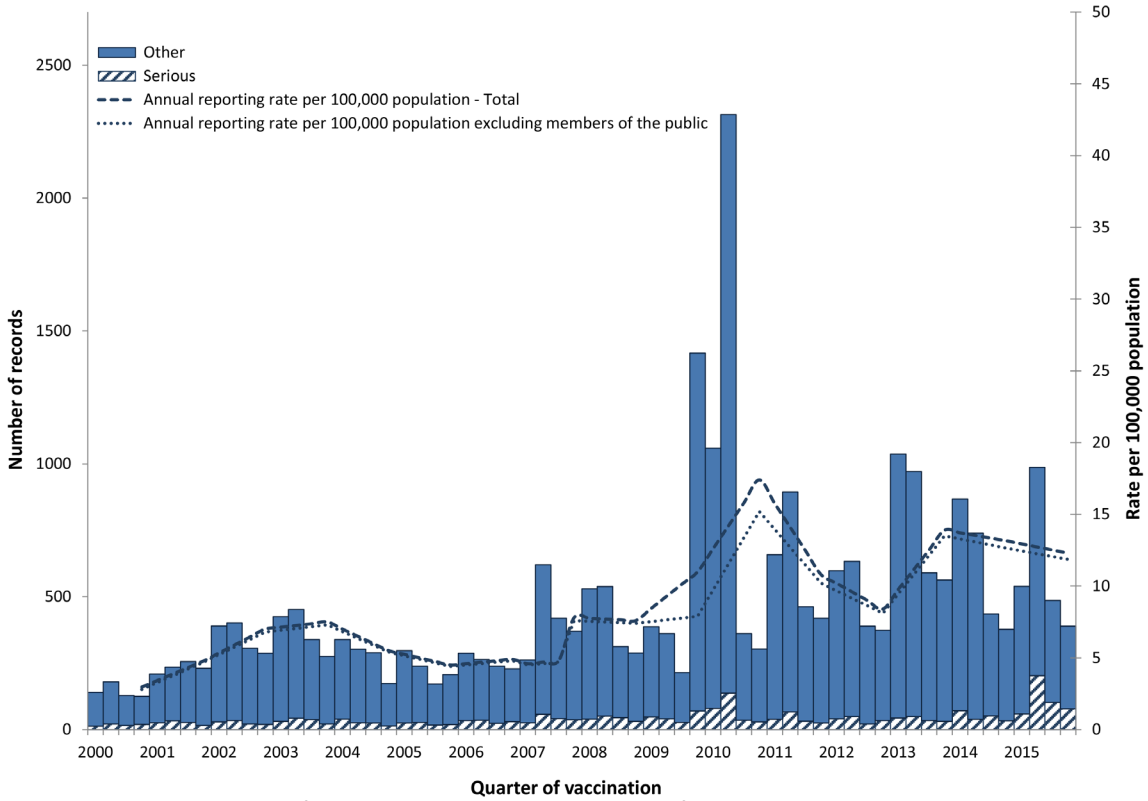
In 2015, out of the 2,924 records, the most frequently reported adverse events were injection site reactions (ISRs) (n=764; 26%), pyrexia (n=497; 17%), rash (n=481; 16%), vomiting (n=225; 8%), headache (n=196; 7%), extensive swelling of vaccinated limb (n=196; 6%) and diarrhoea (n=146; 5%) (Table 4, Figure 4). Among other reactions of interest were: hypotonic-hyporesponsive episode (n=55; 1.9%), convulsions (n=52; 1.8%), intussusception (n=25; 0.9%) and Guillain-Barré Syndrome (n=6; 0.2%) (Table 4). Anaphylaxis (n=22) was reported for less than 1 per cent of AEFI records in 2015.

The number of reports for each reaction has changed over time (Figure 4). The variation in reporting of ISRs is related to changes in the immunisation schedule for vaccines that are known to have higher rates of ISR, including DTPa-containing vaccines, 23vPPV and HPV vaccine.[3-14,33,34] Increases in reports of fever were largely associated with: time periods when new vaccines were added to the NIP in the reporting period, such as 7vPCV and HPV; the extension of seasonal influenza vaccine on the NIP to include persons <65 years at high risk of influenza in 2010; 13vPCV replacing 7vPCV in July 2011; and the extension of HPV to males in 2013.

Severity of outcomes

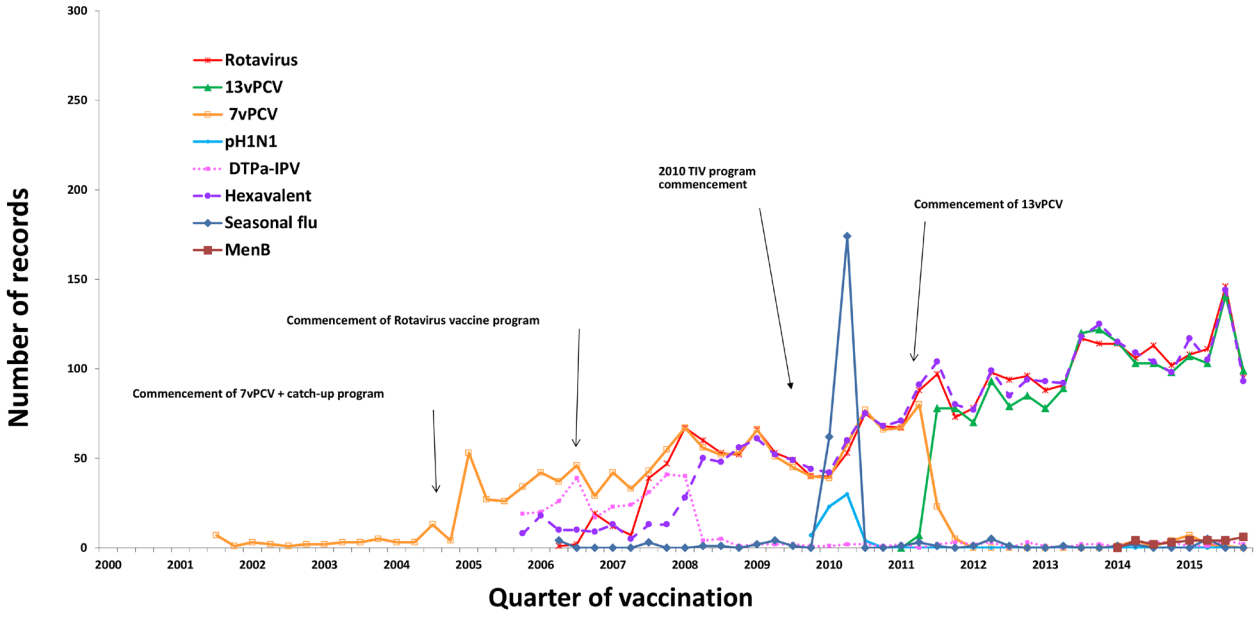
The majority of reported events in 2015 were defined as 'non-serious' (n=2482, 85%). There was a slight increase in percentage of 'serious' events in this reporting period compared to the previous reporting period (Figure 1). This could be due to active surveillance using AusVaxSafety being rolled out more widely throughout Australia, resulting in detection and reporting of events. [35,36]

Figure 1: Adverse events following immunisation, ADRS database, 2000 to 2015, by quarter of vaccination



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

Figure 2a: Adverse events following immunisation for children aged <1 year, ADRS database, 2000 to 2015, by quarter of vaccination

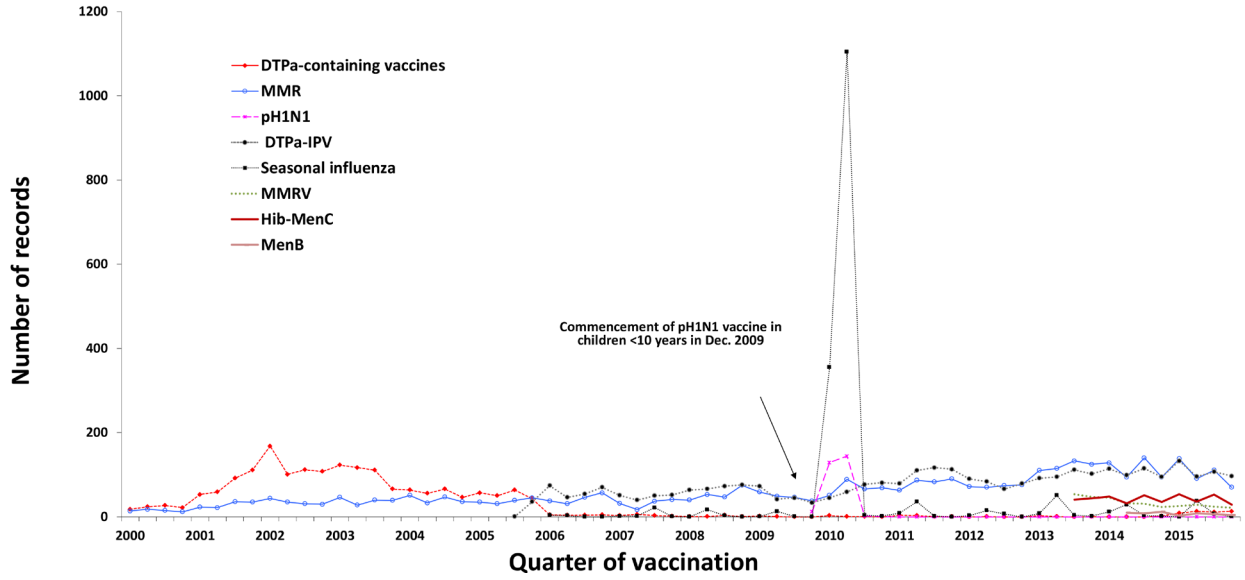


*safety signal for fever and febrile convulsion found to be due to Fluvax 2010 TIV in children.

DTPa-IPV and DTPa-IPV-HepB-Hib (hexavalent) vaccines were introduced into the NIP schedule in November 2005; rotavirus (RotaTeq® and Rotarix®) vaccines on 1 July 2007; pH1N1 influenza vaccine for children 6 months to 10 years in December 2009; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Aboriginal and Torres Strait Islander Peoples programs to at-risk populations; and the 13-valent pneumococcal conjugate vaccine (13vPCV) on 1 July 2011. Also, MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under the NIP.

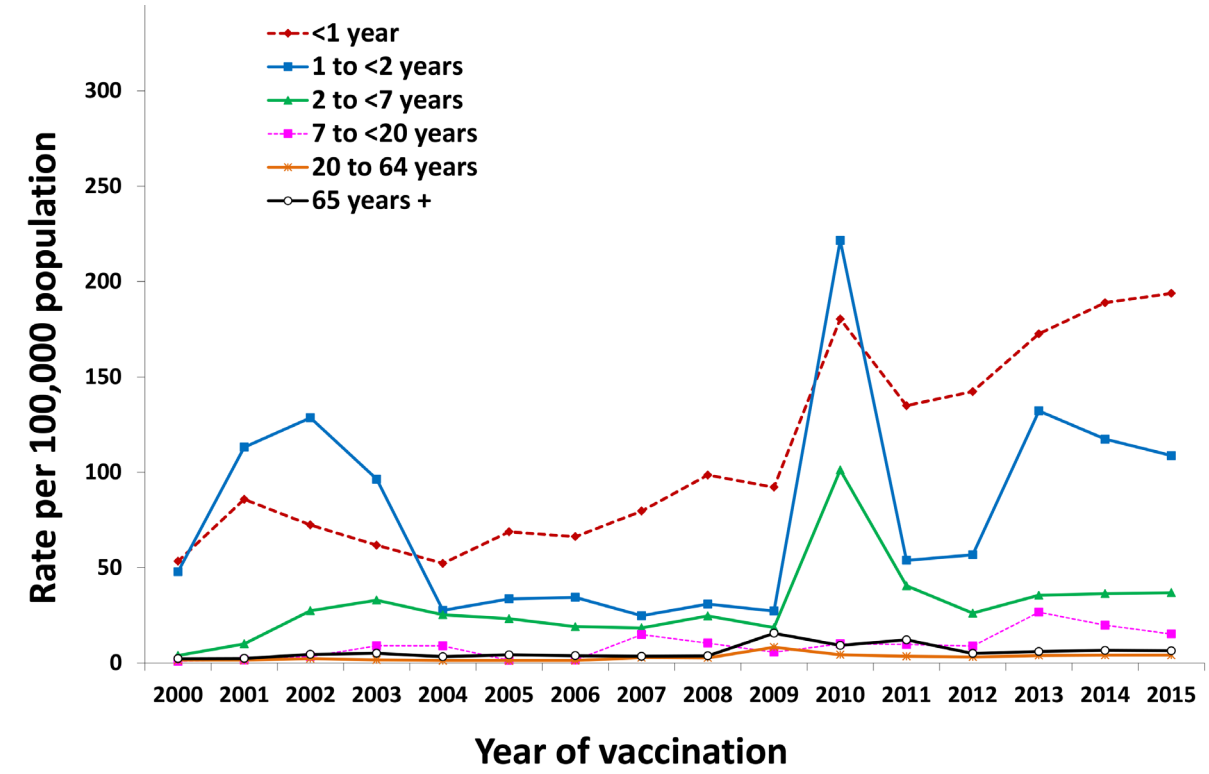
Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA, was used as a proxy for vaccination date.

Figure 2b: Adverse events following immunisation for children aged 1 to <7 years in frequently reported vaccines, ADRS database, 2000 to 2015, by quarter of vaccination



* safety signal for fever and febrile convulsion found to be due to bioCSL Fluvax 2010 TIV in children.
DTPa-IPV was introduced into the NIP schedule in November 2005 replacing DTPa and OPV; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Aboriginal and Torres Strait Islander Peoples programs to at-risk populations; MMRV and Hib–MenC vaccines on July 2013, and HPV program extended to boys in February 2013. Also, MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under the NIP.
Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA, was used as a proxy for vaccination date.

Figure 3: Reporting rates of adverse events following immunisation per 100,000 population, ADRS database, 2000 to 2015, by age group and year of vaccination



* Associated with administration of bioCSL Fluvax 2010 TIV and associated stimulated reporting.
** The peak in syncope coincided with the enhanced HPV surveillance program in which there was stimulated reporting of syncope for the first 6 months of 2013.
Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA, was used as a proxy for vaccination date. Also, grouping for reactions are different for this report though these reactions have been mapped back to 2000 as mentioned in the Methods section.

Table 1: Vaccine types listed as 'suspected' in records of adverse events following immunisation by age groups (<7, 7–17, 18–64 and ≥65 years), ADRS database, 2015

Vaccines*	AEFI records† (n)	Vaccine Doses	Reporting rate per 100,000 doses§ (95% CI)	
			2015	2014
<7 years			**Rate (95% Confidence Interval)**	
DTPa-containing vaccines	946	1171740	80.7 (75.7–86.0)	76.5 (71.6–81.6)
Hexavalent (DTPa-IPV-HepB-Hib)	505	862264	58.6 (53.6–63.9)	53.2 (48.5–58.3)
DTPa-IPV	441	309476	142.5 (129.5–156.4)	143.2 (130.3–157.4)
Pneumococcal conjugate -13PCV	479	874250	54.8 (50.0–59.9)	51.1 (46.6–56.0)
Rotavirus vaccine	465	713714	65.2 (59.4–71.4)	61.6 (56.2–67.7)
Measles-mumps-rubella (MMR)	443	575154	77.0 (70.0–84.5)	80.7 (73.8–88.3)
Hib-MenC	199	307737	64.7 (56.0–74.3)	61.0 (52.7–70.6)
Measles-mumps-rubella-varicella (MMRV)	101	303134	33.3 (27.1–40.5)	45.8 (38.8–54.1)
Seasonal influenza	51	79120	64.5 (48.0–84.8)	–
Meningococcal B	40	18995	210.6 (150.4–286.8)	–
Varicella	7	9187	76.2 (30.6–157.0)	94.9 (52.6–171.4)
Meningococcal C conjugate	7	4996	140.1 (56.3–288.7)	124.1 (72.1–213.7)
Haemophilus influenzae type b	5	8051	62.1 (20.2–144.9)	38.6 (16.1–92.8)
Total (<7 years)	**1497**	**4,066,078**	**36.8 (35.0-38.7)**	**37.1 (35.3–39.0)**
7–17 years				
HPV	359	n/a	–	–
dTpa	234	n/a	–	–
Varicella	105	n/a	–	–
Seasonal influenza	48	n/a	–	–
Meningococcal B	9	n/a		
Hepatitis B	7	n/a	–	–
Total (7–17 years)	**553**	**n/a**	**–**	**–**
18–64 years			**–**	
Seasonal influenza	366	n/a	–	–
dTpa	105	n/a	–	–
23vPPV	38	n/a	–	–
Hepatitis B	31	n/a	–	–
MMR	24	n/a	–	–
Q fever	10	n/a	–	–
Meningococcal B	8	n/a		
Total (18–64 years)	**597**	**n/a**	**–**	
≥65 years			**–**	
23vPPV	117	n/a	–	–
Seasonal influenza	111	n/a	–	–
dTpa	5	n/a	–	–
Meningococcal B	3	n/a		
Total (≥65 years)	**226**	**n/a**	**–**	**–**

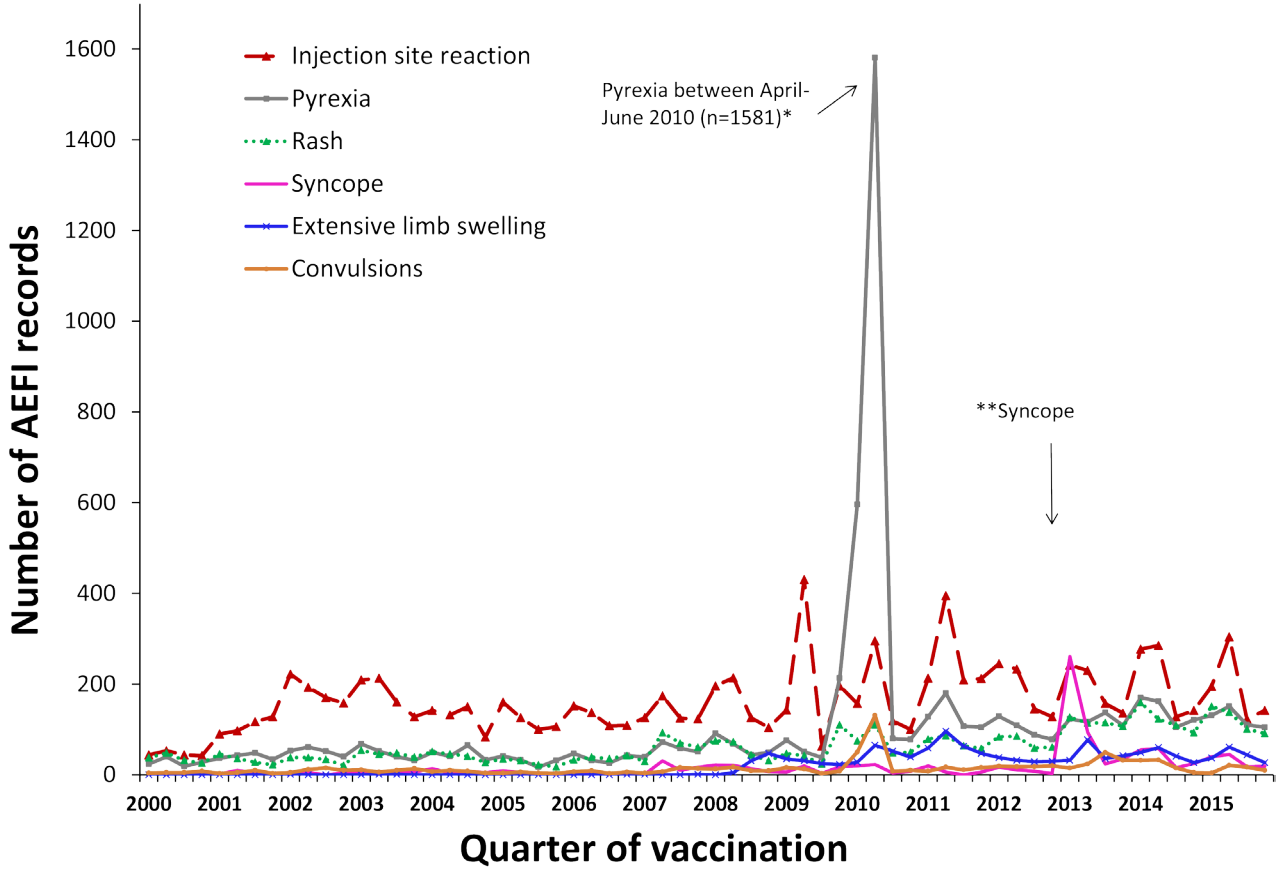
* Records where at least one of the vaccines shown in the table was suspected of involvement in the reported adverse event.
† Number of AEFI records in which the vaccine was coded as 'suspected' of involvement in the reported adverse event and the vaccination was administered between 1 January and 31 December 2015. More than one vaccine may be coded as 'suspected' if several were administered at the same time.
‡ Number of vaccine doses recorded on the AIR/ACIR and administered between 1 January and 31 December 2015.
§ The estimated reporting rate per 100,000 vaccine doses recorded.
n/a Not applicable.

Table 2: Adverse events following immunisation (AEFI) records, ADRS database, January to December 2015, by jurisdiction

State or territory	AEFI records		Annual reporting rate per 100,000 population*			
	N	(%)	'Serious' †	Aged <7 years	Overall Rate	(95% Confidence Interval)
Australian Capital Territory	95	(3.2)	1.8	252.9	24.3	(19.7–29.7)
New South Wales	510	(17.4)	1.1	74.1	6.7	(6.1–7.3)
Northern Territory	54	(1.8)	1.2	205.7	22.1	(16.6–28.8)
Queensland	553	(18.9)	1.3	123.7	11.6	(10.6–12.6)
South Australia	220	(7.5)	1.7	154.8	12.9	(11.3–14.8)
Tasmania	48	(1.6)	0.8	110.5	9.3	(6.8–12.3)
Victoria	1216	(41.6)	3.1	228.7	20.5	(19.3–21.6)
Western Australia	229	(7.8)	2.6	94.8	8.8	(7.7–10.1)
Total	**2924**	**(100.0)**	**1.9**	**133.5**	**12.3**	**(11.8–12.7)**

*Average annual rates per 100,000 population calculated using mid-2015 population estimates (Australian Bureau of Statistics).
†AEFI records defined as 'serious' (i.e. recovery with sequelae, hospitalisation, life-threatening or death).

Figure 4: Selected frequently reported adverse events following immunisation, ADRS database, 2000 to 2015, by quarter of vaccination



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

Table 3: Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI), ADRS database, 2015

Suspected vaccine type	AEFI records		One suspected vaccine only†		'Serious' §		Age group|| <7 years		Age group|| ≥7 years	
	N	(%)	n	(%)¶	n	(%)¶	n	(%)¶	n	(%)¶
Influenza	599	(20.5)	516	(86.1)	112	(18.7)	51	(8.5)	525	(87.6)
DTPa-IPV-HepB-Hib	513	(17.5)	34	(6.6)	143	(27.9)	505	(98.4)	5	(1.0)
13vPCV	484	(16.6)	16	(3.3)	139	(28.7)	479	(99.0)	3	(0.6)
MMR	481	(16.5)	80	(16.6)	64	(13.3)	443	(92.1)	32	(6.7)
Rotavirus	469	(16.0)	43	(9.2)	141	(30.1)	465	(99.1)	0	(0.0)
DTPa-IPV	453	(15.5)	244	(53.9)	37	(8.2)	441	(97.4)	8	(1.8)
HPV	374	(12.8)	147	(39.3)	32	(8.6)	7	(1.9)	364	(97.3)
dTpa	358	(12.2)	161	(45.0)	27	(7.5)	10	(2.8)	344	(96.1)
Hib-MenC	202	(6.9)	13	(6.4)	45	(22.3)	199	(98.5)	2	(1.0)
23vPPV	184	(6.3)	126	(62.7)	14	(7.6)	14	(3.8)	168	(96.2)
Varicella	123	(4.2)	29	(23.6)	8	(6.5)	7	(5.7)	115	(93.5)
MMRV	108	(3.7)	85	(78.7)	26	(24.1)	101	(93.5)	6	(5.6)
Meningococcal B	60	(2.1)	52	(86.7)	9	(15.0)	40	(66.7)	20	(33.3)
Hepatitis B	56	(1.9)	29	(51.8)	5	(8.9)	13	(23.2)	39	(69.6)
Hepatitis A	28	(1.0)	6	(21.4)	2	(7.1)	13	(46.4)	15	(53.6)
BCG	23	(0.8)	18	(78.3)	4	(17.4)	21	(91.3)	1	(4.3)
dT	22	(0.8)	15	(68.2)	1	(4.5)	0	(0.0)	22	(100.0)
Typhoid	18	(0.6)	6	(33.3)	2	(11.1)	5	(27.8)	13	(72.2)
Hepatitis A-Typhoid	13	(0.4)	7	(53.8)	2	(15.4)	0	(0.0)	13	(100.0)
MenCCV	11	(0.4)	3	(27.3)	1	(9.1)	7	(63.6)	4	(36.4)
Q fever	11	(0.4)	10	(90.9)	0	(0.0)	0	(0.0)	11	(100.0)
Zoster	10	(0.3)	10	(100.0)	1	(10.0)	0	(0.0)	8	(80.0)
Rabies	7	(0.2)	4	(57.1)	2	(28.6)	1	(14.3)	6	(85.7)
Hib	7	(0.2)	1	(14.3)	1	(14.3)	5	(71.4)	2	(28.6)
Hepatitis A + B	7	(0.2)	3	(42.9)	0	(0.0)	0	(0.0)	7	(100.0)
Yellow fever	6	(0.2)	3	(50.0)	0	(0.0)	1	(16.7)	5	(83.3)
Japanese encephalitis	3	(0.1)	1	(33.3)	1	(33.3)	2	(66.7)	1	(33.3)
Tetanus	3	(0.1)	3	(100.0)	0	(0.0)	0	(0.0)	3	(100.0)
Cholera	1	(0.0)	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
Total**	**2924**	**(100.0)**	**1678**	**(57.4)**	**442**	**(15.1)**	**1497**	**(51.2)**	**1377**	**(47.1)**

* See appendix for abbreviations of vaccine names.
† AEFI records where only one vaccine was suspected of involvement in a reported adverse event.
‡Causality ratings were assigned to AEFI records using criteria described previously.2,3
§'Serious' is defined in the Methods section.
|| Includes only AEFI records where an age or date of birth has been reported.
¶ Percentages are calculated for the number of AEFI records where the vaccine was suspected of involvement in the AEFI.
** 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 one vaccine.

Table 4: Selected reported adverse events and reactions of interest* classified by MedDRA Preferred Terms in records of adverse events following immunisation (AEFI), ADRS database, 2015¥

MedDRA Preferred Terms (Adverse events)	AEFI records	Only reaction reported†		'Serious'		Age group‡ <7 years		Age group‡ ≥7 years	
	N	n	(%)||	n	(%)||	n	(%)||	N	(%)||
Injection site reaction**	764	361	(47.3)	41	(5.4)	394	(51.6)	362	(47.4)
Pyrexia	497	34	(6.8)	77	(15.5)	331	(66.6)	158	(31.8)
Rash***	481	189	(39.3)	58	(12.1)	330	(68.6)	144	(29.9)
Vomiting	225	27	(12.0)	37	(16.4)	138	(61.3)	85	(37.8)
Headache	196	6	(3.1)	20	(10.2)	13	(6.6)	180	(91.8)
Extensive limb swelling	169	95	(56.2)	10	(5.9)	103	(60.9)	66	(39.1)
Diarrhoea	146	24	(16.4)	32	(21.9)	113	(77.4)	31	(21.2)
Pain	139	19	(13.7)	12	(8.6)	24	(17.3)	113	(81.3)
Urticaria	138	64	(46.4)	12	(8.7)	87	(63.0)	51	(37.0)
Syncope	122	86	(70.5)	22	(18.0)	24	(19.7)	95	(77.9)
Nausea	116	2	(1.7)	10	(8.6)	8	(6.9)	104	(89.7)
Irritability	104	2	(1.9)	19	(18.3)	103	(99.0)	0	(0.0)
Lethargy	100	0	(0.0)	12	(12.0)	48	(48.0)	49	(49.0)
Dizziness	95	4	(4.2)	9	(9.5)	3	(3.2)	86	(90.5)
Pruritus	80	2	(2.5)	6	(7.5)	20	(25.0)	59	(73.8)
Malaise	77	1	(1.3)	5	(6.5)	8	(10.4)	66	(85.7)
Erythema	76	10	(13.2)	9	(11.8)	40	(52.6)	35	(46.1)
Myalgia	55	6	(10.9)	0	(0.0)	3	(5.5)	50	(90.9)
Hypotonic-hyporesponsive episode	55	42	(76.4)	22	(40.0)	55	(100.0)	0	(0.0)
Abdominal pain	54	3	(5.6)	9	(16.7)	22	(40.7)	31	(57.4)
Paraesthesia	53	3	(5.7)	5	(9.4)	0	(0.0)	51	(96.2)
Convulsions****	52	31	(59.6)	39	(75.0)	51	(98.1)	0	(0.0)
Chills	51	1	(2.0)	9	(17.6)	5	(9.8)	46	(90.2)
Presyncope	44	29	(65.9)	5	(11.4)	8	(18.2)	33	(75.0)
Decreased appetite	39	0	(0.0)	6	(15.4)	26	(66.7)	13	(33.3)
Cough	38	1	(2.6)	5	(13.2)	14	(36.8)	24	(63.2)
Dyspnoea	37	0	(0.0)	9	(24.3)	5	(13.5)	32	(86.5)
Fatigue	36	0	(0.0)	2	(5.6)	2	(5.6)	34	(94.4)
Arthralgia	35	1	(2.9)	0	(0.0)	4	(11.4)	29	(82.9)
Pallor	30	2	(6.7)	6	(20.0)	16	(53.3)	13	(43.3)
Intussception	25	24	(96.0)	15	(60.0)	24	(96.0)	0	(0.0)
Somnolence	23	1	(4.3)	1	(4.3)	13	(56.5)	10	(43.5)
Anaphylactic reaction	22	21	(95.5)	10	(45.5)	3	(13.6)	16	(72.7)
Hyperhidrosis	21	0	(0.0)	3	(14.3)	2	(9.5)	18	(85.7)
Hypoaesthesia	20	2	(10.0)	4	(20.0)	0	(0.0)	20	(100.0)
Haematochezia	18	9	(50.0)	9	(50.0)	18	(100.0)	0	(0.0)
Chest discomfort	18	0	(0.0)	5	(27.8)	0	(0.0)	18	(100.0)
Tachycardia	16	1	(6.3)	5	(31.3)	7	(43.8)	8	(50.0)
Oropharyngeal pain	14	0	(0.0)	3	(21.4)	0	(0.0)	14	(100.0)
Rhinorrhoea	13	1	(7.7)	0	(0.0)	7	(53.8)	5	(38.5)
Tremor	7	1	(14.3)	0	(0.0)	0	(0.0)	7	(100.0)
Guillain-Barre Syndrome	6	6	(100.0)	5	(83.3)	1	(16.7)	5	(83.3)
Lymphadenitis	5	2	(40.0)	0	(0.0)	2	(40.0)	3	(60.0)

¥ A complete list of adverse reactions as classified by individual Preferred Terms is available on request.
* Selected reported adverse events reported during Jan-Dec 2015. Note: for injection site reaction, rash and convulsions, PTs were grouped as described below.
** Injection site reaction includes the following MedDRA PTs: injection site reaction, injection site swelling, injection site pain, injection site mass, injection site erythema, injection site cellulitis, injection site rash, injection site induration, injection site abscess, injection site pruritus, injection site nodule, injected limb mobility decreased, injection site urticaria, injection site inflammation, injection site bruising, injection site infection, and injection site warmth.
*** Rash includes the following MedDRA PTs: rash, rash generalised, rash erythematous, rash pruritic, rash maculo-papular, rash macular, rash vesicular, rash papular, rash morbilliform, and rash pustular.
**** Convulsion includes the following MedDRA PTs: febrile convulsion, and convulsion, grand mal convulsion, and partial seizures.
† AEFI records where only one reaction was reported.
§ 'Serious' outcomes are defined in the Methods section.
‡ Includes only AEFI records where an age or date of birth has been reported.
|| Percentages relate to the number of AEFI records in which the specific reaction term was listed.

Two deaths were reported as temporally associated with receipt of vaccines in 2015.

- A 76-year-old male who had been unwell for a week prior to influenza vaccination. He also had history of chronic obstructive pulmonary disease (COPD), diabetes and acute respiratory failure.
- A 73-year-old male with history of severe COPD, diabetes, high cholesterol and lung cancer received influenza vaccine more than two weeks prior to hospitalisation. The causes of death were pneumonia, severe COPD and squamous cell carcinoma of the lung.

In both of these cases, a clear causal relationship with vaccination was unable to be determined due to confounding factors.

Discussion

This report uses a similar methodology of analysis to that used in the previous two annual reports.[2,15] As per the previous report, this method allows for clearer reporting of adverse events using MedDRA PTs, as used in the DAEN. This change in methodology needs to be taken into account when comparing with data on specific reaction terms and categories from annual reports prior to 2013.

In 2015, there appeared to be an overall decline in AEFI reporting rate compared with the previous year. The decline was likely due to it being the third year of the extension of National HPV Vaccination Program to males and also that the HPV male catch-up component ceased in 2014. There is usually an increase in reporting of adverse events when a program is newly rolled out. Previous data have shown that an early increase in AEFI reporting occurred each time a new vaccine was introduced, as immunisation providers are more likely to report milder, less serious AEFIs for vaccines with which they are not as familiar. A reduction and stabilisation of reporting rates over time occurs thereafter.[2,4,5,7,10,12-15,37]

The drop in number of adverse events could also partially be attributed to very few reports of adverse events following administration of individual pathogen vaccines such as varicella, MenC and Hib in this reporting period. This was anticipated as the combined Hib–MenC vaccine replaced the respective monovalent MenC and Hib vaccines in July 2013. Also, from July 2013, the 2nd dose of MMR vaccine was brought forward to 18 months of age and delivered as a combination MMRV vaccine.

From 2015, the seasonal influenza vaccine was provided free for all Aboriginal and Torres Strait Islander children aged 6 months to 5 years.[38] During this first year of the program's implementation, an adverse event following seasonal influenza vaccine was reported in only one Aboriginal and Torres Strait Islander child aged 6 months to 5 years and was not serious.

The dTpa vaccine was recommended and funded for women during the third trimester of pregnancy in this reporting period. As well, a booster dose of DTPa was recommended (though funded only from March 2016) at 18 months of age. In 2015, there had been no impact of this recommendation on numbers of AEFI.

Overall, in Australia, injection-site reaction, pyrexia and rash were the most commonly reported reactions in 2015. Vaccines such as DTPa-containing vaccines, pneumococcal conjugate (13vPCV), MMR and rotavirus had higher reporting rates than other vaccines for children aged <7 years in the current reporting period. However, these rates were not significantly higher than for the previous reporting period.

Conclusion

The reported AEFIs decreased in 2015 compared with 2014. The majority of AEFIs reported to the TGA were mild, transient events. The data reported here are consistent with an overall high level of safety for vaccines included in the NIP schedule.

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Appendix 1: Changes in immunisation policy and the National Immunisation Program (2005–2015)[2,4,5,7,10,12-14,39]

Year	Intervention
2015	From March 2015, seasonal influenza vaccine funded for Aboriginal and Torres Strait Islander children aged 6 months to less than 5 years. From March to June 2015, the dTpa vaccine for women during the third trimester of pregnancy was funded by New South Wales, South Australia, Western Australia, the Australian Capital Territory, Victoria and Tasmania. The Northern Territory had funded it since September 2013 and Queensland since July 2014. In March 2015, a booster dose of DTPa recommended at 18 months of age (funded in March 2016). In April 2015, new immunisation requirements for family assistance payments were announced by the federal government (the 'No Jab, No Pay' policy), to come into effect on 1 January 2016. Only parents of children (aged less than 20 years) who are 'fully immunised' or on a recognised catch-up schedule remain eligible to receive the Child Care Benefit, Child Care Rebate, and/or the Family Tax Benefit Part A end-of-year supplement.
2014	4vHPV catch-up program for males aged 14–15 years ceased in December 2014. In July 2014, dTpa was funded by Queensland for women during the third trimester of pregnancy.
2013	From 1 February 2013, 4vHPV was extended to males aged 12–13 years, delivered through a school-based program, with a catch-up program for males aged 14–15 years in 2013 and 2014. From July 2013, the 2nd dose of MMR vaccine, previously given at 4 years, was brought forward to 18 months of age and delivered as a combination MMRV vaccine. From July 2013, combined Haemophilus influenzae type b (Hib) and meningococcal serogroup C (MenC) vaccine, Menitorix®, was funded for infants aged 12 months. This combination vaccine replaced the single dose of monovalent meningococcal C conjugate vaccine (MenCCV) and booster dose of monovalent Hib vaccine previously scheduled at 12 months of age. At the end of December 2013, the secondary school Year 7 hepatitis B vaccine catch-up program ceased, as all younger age cohorts were eligible for infant immunisation under the NIP (commenced 2000). In September 2013, dTpa was funded by NT for women during the third trimester of pregnancy and for parents of infants aged <7 months under cocoon strategy
2012	From 1 October 2012, a fourth dose of Prevenar 13®, (13vPCV, a 13-valent pneumococcal conjugate vaccine) was listed on the National Immunisation Program (NIP) for Aboriginal and Torres Strait Islander children, aged 12-18 months, residing in Queensland, South Australia, Western Australia and the Northern Territory. This replaced the booster dose of Pneumovax23®, (23vPPV, a 23-valent pneumococcal polysaccharide vaccine) administered between 18 and 24 months of age for Aboriginal and Torres Strait Islander children from these jurisdictions.
2011	From 1 July 2011, Prevenar 13® replaced Prevenar® on the NIP for children at 2, 4 and 6 months of age in all states and territories, except the Northern Territory which adopted 13vPCV from 1 October 2011. 1 October 2011 to 30 September 2012 – all children aged between 12 - 35 months who had completed a primary pneumococcal vaccination course with 7vPCV, were eligible to receive a free, supplementary dose of Prevenar 13® On 25 March 2011, TGA issued a recall of Batch N3336 of the 23 valent pneumococcal polysaccharide vaccine 23vPPV, Pneumovax® 23. April 2011 - health professionals were advised not to administer a second or subsequent dose of Pneumovax 23 vaccine. December 2011 - Revised recommendations regarding which patients should be re-vaccinated under the NIP were provided.
2010	Annual vaccination with seasonal trivalent influenza vaccine (TIV, containing 3 influenza strains: A/H1N1, A/H3N2 and B) was funded under the NIP for people aged ≥6 months with medical risk factors (previously subsidised through the Pharmaceutical Benefits Scheme) and all Aboriginal and Torres Strait Islander Peoples aged ≥15 years (previously all Aboriginal and Torres Strait Islander Peoples ≥50 years and 15–49 years with medical risk factors). On 23 April 2010, the use of the 2010 seasonal TIV in children <5 years of age was suspended by Australia's Chief Medical Officer due to an increased number of reports of fever and febrile convulsions post vaccination. A subsequent investigation identified that Fluvax® and Fluvax junior® (CSL Biotherapies), but neither of the other two available brands registered for use in young children, were associated with an unacceptably high risk of febrile convulsions. 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 made in August 2010.

Year	Intervention
2009	By late 2009, all states and territories were using the single hexavalent DTPa-IPV-Hib-HepB (Infanrix hexa®) vaccine for all children at 2, 4 and 6 months of age, due to an international shortage of Haemophilus influenzae type b (Hib) (PedvaxHib® [monovalent] and Comvax®[Hib-HepB]) vaccines. Pandemic H1N1 2009 influenza vaccine (Panvax®) was rolled out across Australia from 30 September 2009 for people aged ≥10 years. From December 2009, the pandemic vaccine was made available to children aged 6 months to 10 years.
2008	Western Australia commenced a seasonal influenza vaccination program for all children aged 6 months to <5 years (born after 1 April 2003). In March 2008, Queensland, South Australia and Victoria changed from using two combination vaccines (quadrivalent DTPa-IPV and Hib-HepB) to the single hexavalent DTPa-IPV-HepB-Hib vaccine.
2007	From April 2007, funded immunisation against human papillomavirus for all Australian girls aged 12–13 years was delivered through a school-based program, with a temporary catch-up program through schools or primary care providers for females aged 13–26 years, until December 2009. From July 2007, immunisation against rotavirus at 2 and 4 months of age (Rotarix®) or at 2, 4 and 6 months of age (Rotateq®) was funded.
2005	From January 2005, universal funded infant 7-valent pneumococcal conjugate vaccine (7vPCV) program replaced the previous targeted childhood program, with a catch-up program for children aged <2 years. Universal 23-valent pneumococcal polysaccharide vaccine (23vPPV) for adults aged ≥65 years replaced previous subsidy through the Pharmaceutical Benefits Scheme. From November 2005, universal funded immunisation against varicella at 18 months of age, with a school-based catch-up program for children at 10–13 years of age not previously vaccinated and without a history of varicella infection (no funded catch-up for children 2–10 years of age). IPV was funded to replace OPV, in combination vaccines.