# Surveillance of adverse events following immunisation, NSW, 2015

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**Abstract: Aim:** This report summarises passive surveillance data for adverse events following immunisation (AEFI) in NSW from 1 January 2015 to 31 December 2015. **Methods:** Analysis of de-identified data on all adverse events following immunisation reported to the Therapeutic Goods Administration (TGA) for persons from NSW. **Results:** There were 510 AEFI reported for vaccines administered from 1 January to 31 December 2015. Of all AEFI, 3% were reported in Aboriginal and Torres Strait Islander people. The overall AEFI reporting rate was 6.7 per 100 000 population in 2015, compared with 6.9 in 2014. This decline in reporting rates in 2015 compared with the previous year is not statistically significant. Overall, the most commonly reported reactions were associated with seasonal influenza (22%), followed by HPV vaccine (19%), dTpa (15%), MMR (15%), DTPa-IPV-HepB-Hib (12%) and PCV13 (11%). Only 17% of the reported adverse events were categorised as serious. There were no deaths reported in this period. **Conclusion:** There were no vaccine safety signals or concerns observed in this reporting period. Overall, there was a slight decline in the number of reports observed in 2015 compared with 2014.

**Abbreviations of vaccine types**

| | |
|---|---|
| BCG | Bacille Calmette-Guérin |
| 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-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-MenC | combined *Haemophilus influenzae* type b and meningococcal C vaccine |
| HPV | human papillomavirus |
| IPV | inactivated poliovirus vaccine |
| Men4PV | meningococcal polysaccharide tetravalent vaccine |
| MenCCV | meningococcal C conjugate vaccine |
| MMR | measles-mumps-rubella |
| MMRV | measles-mumps-rubella-varicella |
| 7vPCV | 7-valent pneumococcal conjugate vaccine |
| 13vPCV | 13-valent pneumococcal conjugate vaccine |
| 23vPPV | 23-valent pneumococcal polysaccharide vaccine |

## Introduction

This is the seventh in a series of annual reports of adverse events following immunisation (AEFI) in New South Wales (NSW). This report summarises passive surveillance data reported from NSW for 2015 and describes reporting trends over the 16-year period 2000–2015.

An AEFI is defined as any untoward medical occurrence that follows immunisation.[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-licensure surveillance of AEFI is particularly important to detect rare, late onset and unexpected events, and new vaccine safety signals that are difficult to detect in pre-licensure vaccine trials.

Trends in reported AEFI are heavily influenced by changes to vaccines provided through the National Immunisation Program (NIP). Changes in previous years have been reported elsewhere.[2–12] Recent changes that impact on AEFI surveillance data presented in this report are:

- April 2015: New immunisation requirements for family assistance payments were announced by the federal government. With the 'No Jab, No pay' policy coming into effect as of 1 January 2016, only parents of children (aged less than 20 years) who are 'fully immunised' or on a recognised catch-up schedule will continue to receive the Child Care Benefit, Child Care Rebate, and/or the Family Tax Benefit Part A end-of-year supplement. Children with medical contraindications or natural immunity for certain diseases will continue to be exempt from the requirements; however, conscientious objection will no longer be a valid exemption from immunisation requirements.
- March 2015:
  - Seasonal influenza vaccine funded for Aboriginal and Torres Strait Islander children aged 6 months to less than 5 years. The recommended upper age for children requiring two doses in the first year they receive influenza vaccine changed from less than 10 years to less than 9 years.
  - The dTpa vaccine was recommended by the National Health and Medical Research Council (NHMRC) and funded by NSW Health for women during the third trimester of pregnancy and for new mothers in maternity units of public hospitals (if not vaccinated in the third trimester) under the NSW maternal pertussis strategy.
  - A booster dose of DTPa recommended at 18 months of age (funded in March 2016).
- December 2014: Secondary school HPV vaccine catch-up program for Year 9 male students ceased.

## Methods

Adverse events following immunisation are notifiable to NSW public health units by medical practitioners and hospital CEOs under the NSW *Public Health Act 2010*. Cases with any outstanding information and all serious AEFI are followed up by public health units and Health Protection NSW. All notifications are forwarded to the Therapeutic Goods Administration (TGA). The TGA also receives reports directly from vaccine manufacturers, members of the public and other sources.[13,14]

### *Adverse events following immunisation data*

Reports from all sources across Australia are assessed by the TGA using internationally consistent criteria[15] and entered into the Australian Adverse Drug Reaction Reporting System (ADRS) database. The term 'AEFI record' is used throughout this report to signify occurrence of an AEFI because a single adverse event can result in more than one notification and generate more than one record in the ADRS database. Duplication of adverse event reports/cases is more likely to occur in situations where there are sequential adverse reactions in a single patient or if multiple vaccines are involved.

Typically, each AEFI record lists several symptoms, signs and diagnoses that have been coded by TGA staff from the description provided by the reporter into standardised terms using the Medical Dictionary for Regulatory Activities (MedDRA®).[16]

In reports published previously,[8,9] analysis was conducted using MedDRA® terms grouped into 'reaction categories' that were broadly analogous to the reactions listed in previous *Australian Immunisation Handbooks*.[13,14] However, the methodological framework for analysing and reporting on adverse events was revised in 2012 after which AEFI analysis has been conducted using MedDRA Preferred Terms (PTs).[17] Grouping of reactions using PTs is more comparable with data from other countries and is internationally accepted.[18–20] In conjunction with the national vaccine-specific reporting form,[21] the use of PTs allows for a better description of post-marketing surveillance data on vaccine safety in Australia.

### *Definitions of AEFI outcomes and reactions*

This report includes only AEFI records that are classified as 'suspected' to be causally related to immunisation. An AEFI record is classified as 'not suspected' and excluded from the ADRS database if: (1) there is no reasonable temporal association between the use of a drug and the clinical event; (2) the record does not contain enough information for an adequate assessment or the information is contradictory; or (3) if a clinical event is explained as likely to have arisen from other causes.

AEFIs 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[16] and the US Vaccine Adverse Events Reporting System (VAERS).[22] 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; and/or (6) is a medically important event or reaction.

### Data analysis

De-identified information on AEFI reports from the TGA's ADRS database was released to NCIRS for analysis and reporting. 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; the vaccination occurred between 1 January 2015 and 31 December 2015; and the residential address of the individual was recorded as NSW.

All data analyses were performed using SAS (version 9.4, SAS Institute, Cary, NC, USA).[23] Average annual population-based reporting rates were calculated using population estimates obtained from the Australian Bureau of Statistics.[24]

AEFI reporting rates per 100 000 administered doses were estimated where information on dose numbers was available from the Australian Childhood Immunisation Register (ACIR) for NIP vaccines for children aged less than 7 years; and NSW Health data on vaccines administered in schools for 12–17 year olds.

From 30 September 2016, the Australian Childhood Immunisation Register (ACIR) became the Australian Immunisation Register (AIR), a national register that records vaccinations given to people of all ages in Australia.[25] Also, note that data on adolescents does not include doses given outside the school program.

### Notes on interpretation

The data reported here are provisional only, particularly for the fourth quarter of 2015, because of reporting delays and the late onset of some reported AEFIs. Numbers are updated for previous years. The information collated in the ADRS database is intended primarily to detect signals of adverse events and to inform hypothesis generation. While AEFI reporting rates can be estimated using appropriate denominators, they cannot be interpreted as incidence rates due to under-reporting, biased reporting of suspected events, and the variable quality and completeness of information provided in individual notification reports.[12]

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.

## Results

There was a total of 510 AEFI records for NSW in the ADRS database with a date of vaccination in 2015. Of these, 53% ($n = 272$) were females, 45% ($n = 232$) males and 1% ($n = 6$) missing data. Also, 3% ($n = 17$) were reported in Aboriginal and Torres Strait Islander people.

Of all reports, 40% ($n = 203$) were for children aged less than 7 years and 58% ($n = 298$) were for people aged 7 years and over. Approximately 2% ($n = 9$) had age missing in the database.

Forty-eight per cent ($n = 246$) of AEFIs were reported to the TGA via NSW Health and the remainder were reported directly to the TGA; 27% ($n = 139$) by doctors/other health care providers, 13% ($n = 67$) by members of the public, 7% ($n = 34$) by drug companies and 5% ($n = 24$) by hospitals.

### Reporting trends

The overall AEFI reporting rate for 2015 was 6.7 per 100 000 population, compared with 6.9 in 2014.

Figure 1 shows a decline in the reported events and annual reporting rate per 100 000 population during 2015 compared with 2014, although this decline was not statistically significant. The vast majority of reported events were of a non-serious nature similar to previous years.[8,12,26]

Figures 2a, 2b and 3 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 individual pathogen vaccines with combination vaccines in children (Figures 2a and 2b) and also a decline in reports of AEFI with HPV vaccines in adolescents (Figure 3).

The usual seasonal pattern of AEFI reporting from older Australians receiving 23vPPV and influenza vaccine during the autumn months (March–June) is evident in Figure 3.

### Age group and vaccine

Figure 4a shows that the reporting rates were highest in 2–6 year olds during 2015 (21.2 per 100 000 doses) and appeared to have slightly increased compared with 2014 (20.8 per 100 000 doses), although this increase was not statistically significant. Also, no statistically significant changes were observed in less than 1 year and 1 year olds in 2015 compared with 2014.

Since vaccine dose information was not available for 7 years and over, population-based AEFI reporting rates were estimated as shown in Figure 4b. There was a 12% decline in the 7–19-year age group during 2015 compared with 2014 (from 10.9 per 100 000 population to 9.6 per 100 000 population), which has contributed to the overall drop in rate for the current reporting period.

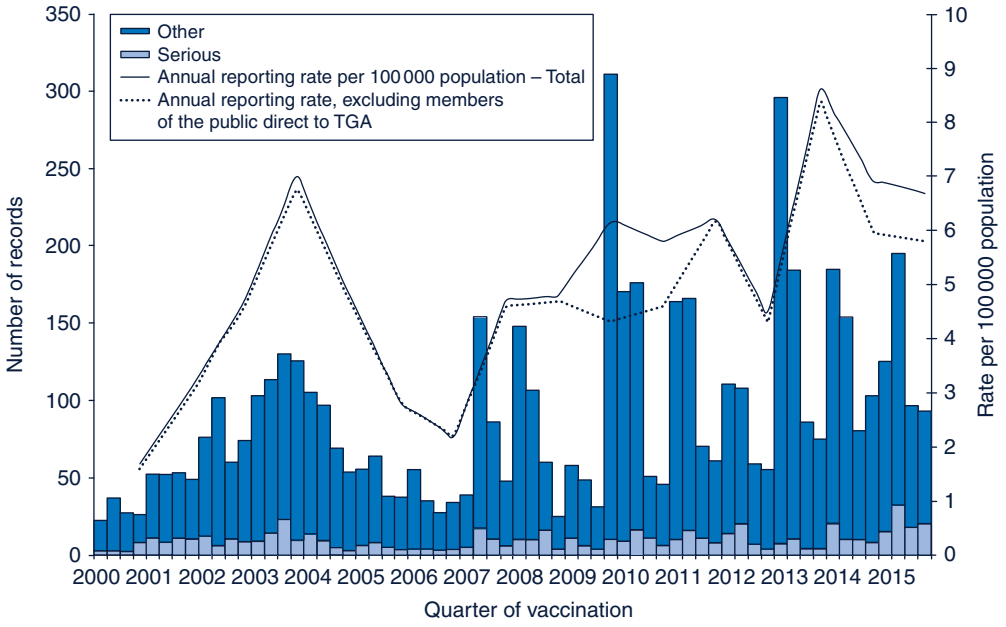


**Figure 1. Reports of adverse events following immunisation, NSW, 2000–2015, by quarter of vaccination.**

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

**Source: Adverse Drug Reactions Reporting System database, TGA.**

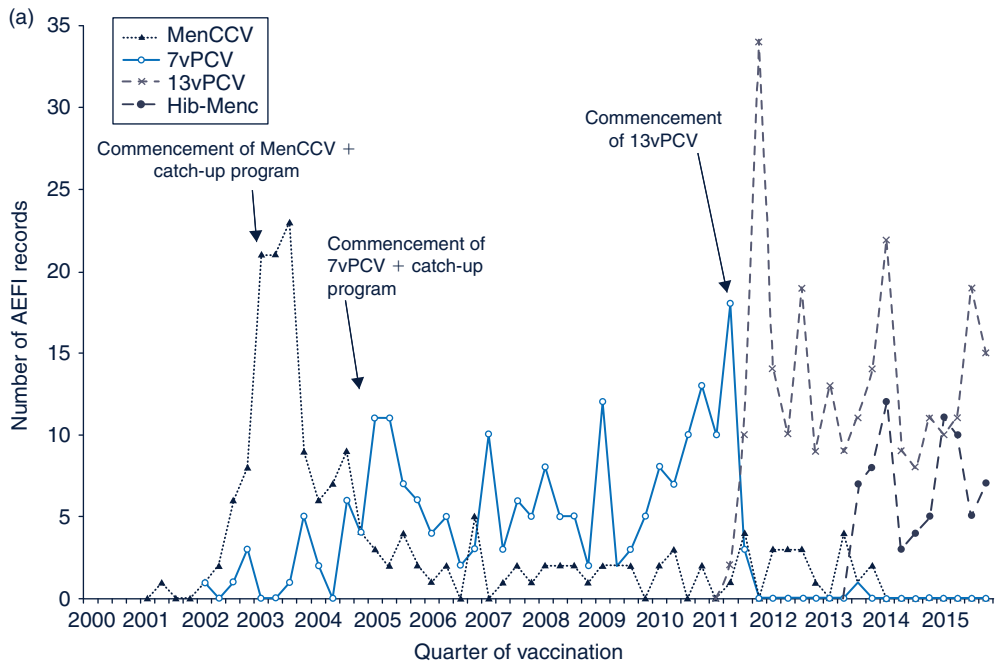


**Figure 2a. Adverse events following immunisation in children aged less than7 years for selected vaccines, NSW, 2015, by quarter of vaccination.**

NB: Meningococcal C conjugate vaccine (MenCCV) was introduced into the National Immunisation Program schedule on 1 January 2003, 7-valent pneumococcal conjugate vaccine (7vPCV) on 1 January 2005, 13-valent pneumococcal conjugate vaccine (13vPCV) on 1 July 2011 and HibMenC on 1 July 2013.

**Source: Adverse Drug Reactions Reporting System database, TGA.**

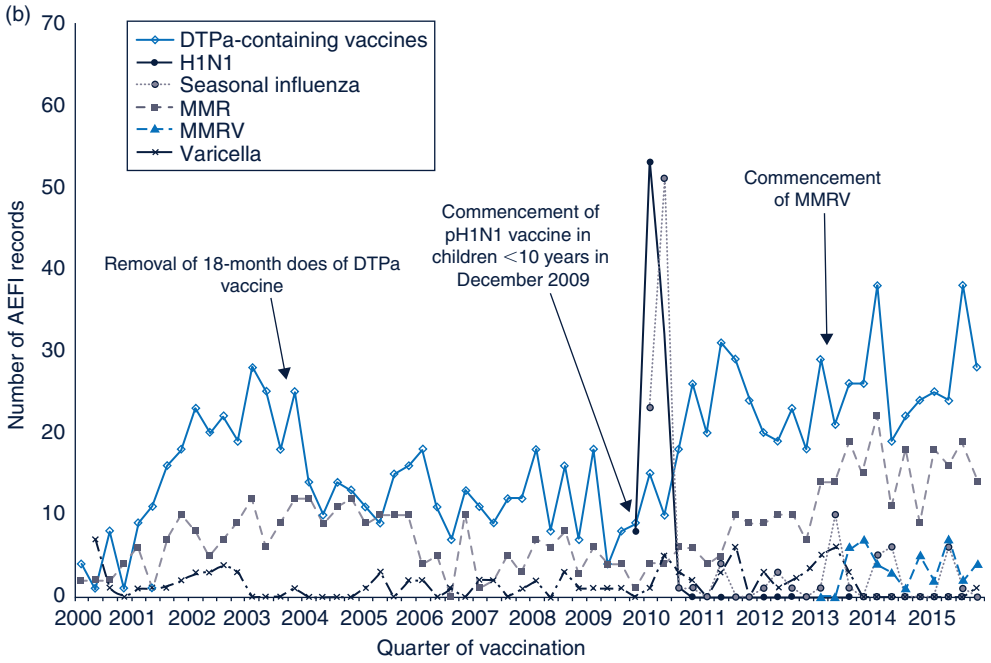


**Figure 2b. Adverse events following immunisation in children aged less than 7 years for selected vaccines, NSW, 2000–2015, by quarter of vaccination.**

NB: DTPa-IPV was introduced into the NIP schedule in November 2005 replacing DTPa and OPV; seasonal trivalent influenza vaccine was extended to medically at-risk children in 2010; MMRV vaccine was introduced on 1 July 2013.

**Source: Adverse Drug Reactions Reporting System database, TGA.**

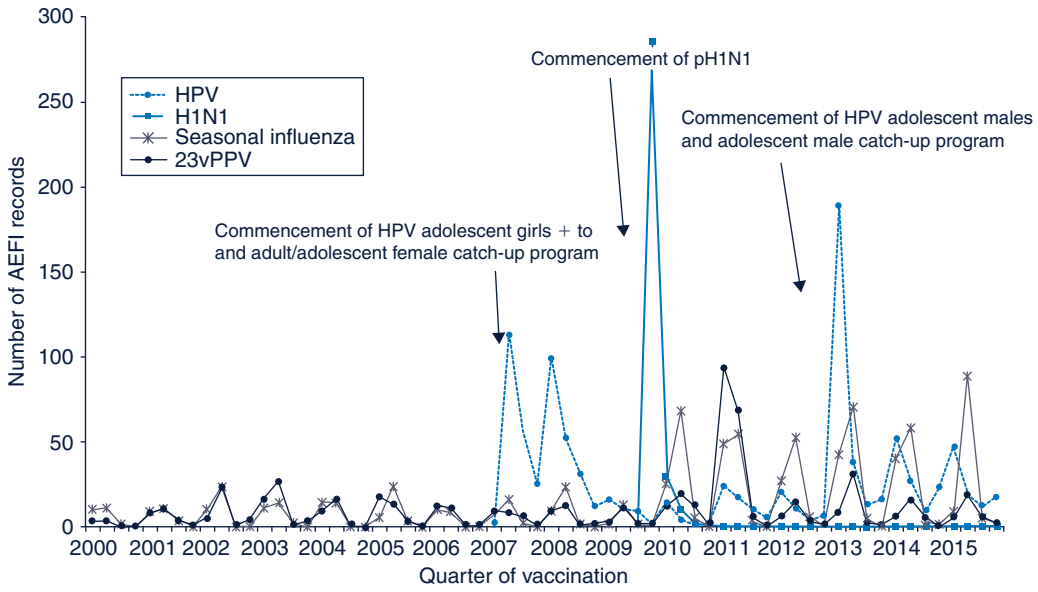


**Figure 3. Adverse events following immunisation for people aged ≥7 years in frequently reported vaccines, NSW, 2000–2015, by quarter of vaccination.**

**Source: Adverse Drug Reactions Reporting System database, TGA.**

Reporting rates per 100 000 doses in under 7 year olds did not change significantly for any vaccine (Table 1).

MMRV vaccine was recorded in 15 reports and five of these were coded as serious (Tables 1 and 2). The MMRV reporting rate for under 7 year olds was 15.5 per 100 000 doses in 2015 compared with 13.3 in 2014, although this increase in rate was not statistically significant.

Overall, as shown in Table 2, the most frequently reported individual vaccines during 2015 were seasonal influenza ($n = 114$; 22%) followed by HPV vaccine ($n = 98$; 19%),

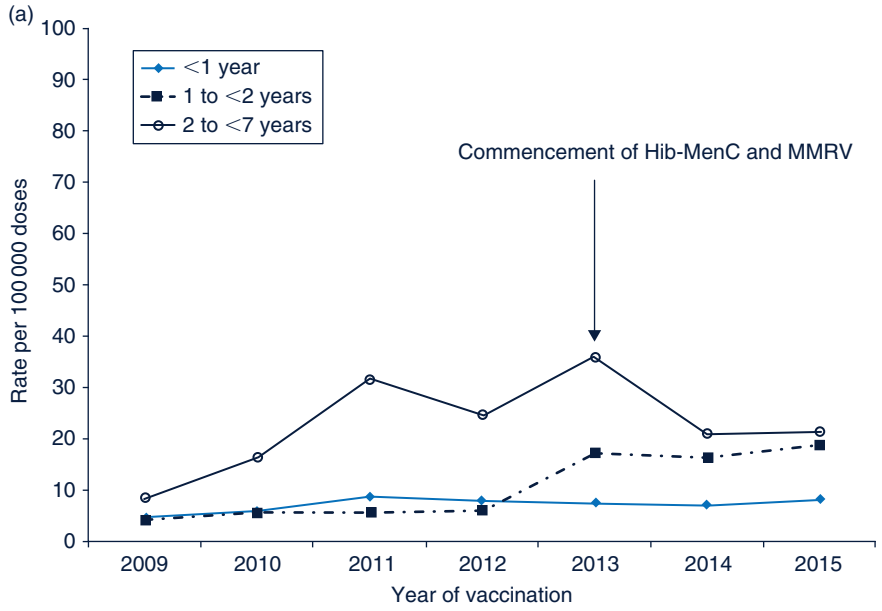


**Figure 4a. Reporting rates of adverse events following immunisation for NSW per 100 000 doses, 2009–2015, for people aged less than7 years, by year of vaccination.**

**Source: Adverse Drug Reactions Reporting System database, TGA.**

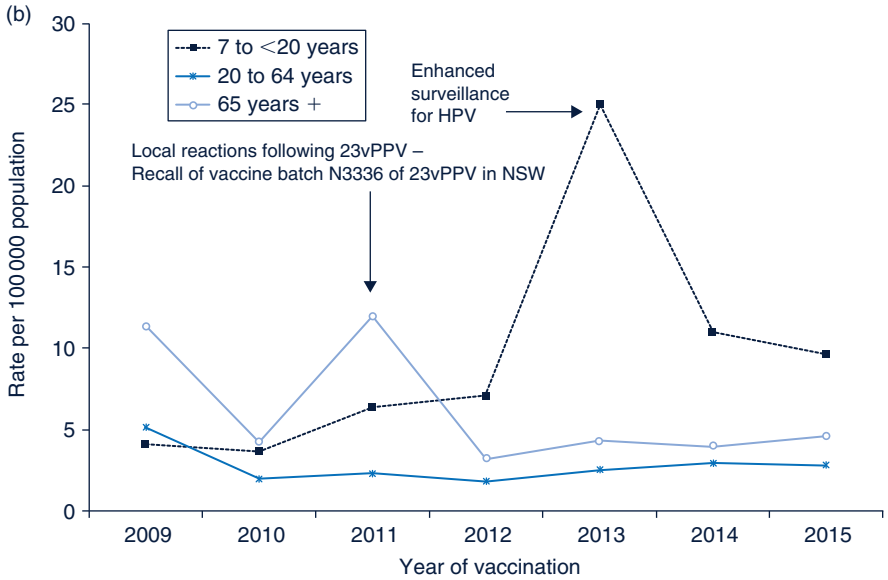


**Figure 4b. Reporting rates of adverse events following immunisation for NSW per 100 000 population, 2009–2015, for people aged ≥7 years, by year of vaccination.**

**Source: Adverse Drug Reactions Reporting System database, TGA.**

dTpa ($n = 76$; 15%), MMR ($n = 75$; 15%), DTPa-IPV-HepB-Hib ($n = 63$; 12%) and PCV13 ($n = 55$; 11%).

### *Reactions*

The distribution and frequency of reactions listed in AEFI records for 2015 are shown in Table 3. The most frequently reported adverse events were injection site reaction (ISR) ($n = 99$; 19%), rash ($n = 92$; 18%), pyrexia ($n = 88$; 17%) and headache ($n = 45$; 9%).

Of the total 99 cases of ISR, the majority ($n = 64$; 65%) were in those aged 7 years and over. Also, more than half of the rash ($n = 57$) and pyrexia ($n = 53$) cases were reported in children aged less than 7 years while 93% ($n = 42$) of headache was observed in those aged 7 years and over.

There were 19 reported cases of syncope and six cases of presyncope during 2015. Seventy-nine per cent ($n = 15$) of cases of syncope and 100% ($n = 6$) of presyncope were reported in persons aged 7 years and older.

**Table 1. Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI) for four age groups (<7, 12–17, 18–64 and ≥65 years), NSW, 2015**

| Vaccines[a] | AEFI records[b] 2015 | Serious[c] 2015 | Reporting rate per 100 000 doses[d] 2015 | |
|---|---|---|---|---|
| | *n* | *n* | Rate | (95% CI) |
| **<7 years** | | | | |
| Measles-mumps-rubella | 67 | 11 | 35.9 | (27.8–45.6) |
| Hexavalent (DTPa-IPV-HepB-Hib) | 62 | 20 | 22.7 | (17.4–29.1) |
| DTPa-IPV | 53 | 12 | 52.1 | (39.0–68.1) |
| 13vPCV | 55 | 18 | 20.0 | (15.0–26.0) |
| Rotavirus | 52 | 18 | 29.5 | (22.0–38.7) |
| Hib-MenC | 33 | 6 | 33.5 | (23.1–47.1) |
| MMRV | 15 | 5 | 15.5 | (8.7–25.6) |
| Varicella | 18 | 4 | – | – |
| MenB | 7 | 3 | – | – |
| Seasonal influenza[e] | 7 | 1 | – | – |
| **12–17 years** | | | | |
| HPV | 86 | 14 | 39.2 | (31.3–48.4) |
| dTpa | 47 | 5 | 62.1 | (45.7–82.6) |
| Varicella | 18 | 4 | 30.7 | (18.2–48.5) |
| Hepatitis B | 1 | 0 | – | – |
| Seasonal influenza[e] | 1 | 0 | – | – |
| **18–64 years** | | | | |
| Seasonal influenza[e] | 68 | 8 | – | – |
| dTpa | 26 | 4 | – | – |
| 23vPPV | 10 | 0 | – | – |
| MMRV | 7 | 0 | – | – |
| Hepatitis B | 4 | 0 | – | – |
| Q fever | 4 | 0 | – | – |
| Yellow fever | 1 | 0 | – | – |
| **≥65 years** | | | | |
| Seasonal Influenza[e] | 31 | 14 | – | – |
| 23vPPV | 20 | 0 | – | – |
| dTpa | 0 | 0 | – | – |

[a]Records where at least one of the vaccines shown in the table was suspected of involvement in the reported adverse event.
[b]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 2015 and 31 December 2015. More than one vaccine may be coded as 'suspected' if several were administered at the same time.
[c]'Serious' is defined in the Methods section.
[d]The estimated AEFI reporting rate per 100 000 vaccine doses recorded.
[e]Rates for seasonal influenza are not provided as dose data not reliable.
Source: Adverse Drug Reactions Reporting System database, TGA.

There were only 10 reports of hypotonic-hyporesponsive episode (HHE) and all were reported from children aged under 7 years.

Furthermore, there were four reported cases of Guillain-Barré syndrome (GBS) during this period. Of the four cases, three cases were reported in adults. The suspected vaccine was seasonal influenza in two of these cases who were aged 65 years and older, and no clear causal relationship with vaccination was found.

Anaphylaxis was reported only in one child, aged less than 7 years during 2015. The child had received Infanrix hexa, Rotarix and 13vPCV. The child recovered rapidly following adrenaline administration.

### *Severity*

Only 17% ($n = 85$) of reported events were defined as 'serious' (i.e. recovery with sequelae, requiring hospitalisation, experiencing a life-threatening event or death).

There is a slight increase in percentage of 'serious' events in this reporting period compared with the previous reporting period (Figure 1). This could be due to active surveillance using AusVaxSafety being rolled out

Table 2. Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI), NSW, 2015

| Suspected vaccine type | AEFI records | | One suspected vaccine only[a] | | 'Serious' | | Age group[b] <7 years | | Age group[b] ≥7 years | |
|---|---|---|---|---|---|---|---|---|---|---|
| | *n* | (%) | *n* | (%)[c] | *n* | (%)[c] | *n* | (%)[c] | *n* | (%)[c] |
| Influenza | 114 | (22.4) | 105 | (92) | 15 | (13) | 7 | (6) | 103 | (90) |
| HPV | 98 | (19.2) | 43 | (44) | 15 | (15) | 3 | (3) | 94 | (96) |
| dTpa | 76 | (14.9) | 31 | (41) | 9 | (12) | 3 | (4) | 73 | (96) |
| MMR | 75 | (14.7) | 21 | (28) | 11 | (15) | 67 | (89) | 8 | (11) |
| DTPa-IPV-HepB-Hib | 63 | (12.4) | 7 | (11) | 20 | (32) | 62 | (98) | 1 | (2) |
| PCV13 | 55 | (10.8) | 0 | (0) | 18 | (33) | 55 | (100) | 0 | (0) |
| DTPa-IPV | 53 | (10.4) | 28 | (53) | 12 | (23) | 53 | (100) | 0 | (0) |
| Rotavirus | 53 | (10.4) | 10 | (19) | 18 | (34) | 52 | (98) | 1 | (2) |
| 23vPPV | 34 | (6.7) | 25 | (74) | 0 | (0) | 3 | (9) | 31 | (91) |
| Hib-MenC | 34 | (6.7) | 4 | (12) | 6 | (18) | 33 | (97) | 1 | (3) |
| Varicella | 22 | (4.3) | 3 | (14) | 5 | (23) | 1 | (5) | 20 | (91) |
| MMRV | 15 | (2.9) | 13 | (87) | 5 | (33) | 15 | (100) | 0 | (0) |
| Meningococcal B | 11 | (2.2) | 8 | (73) | 3 | (27) | 7 | (64) | 4 | (36) |
| Hepatitis B | 8 | (1.6) | 6 | (75) | 1 | (13) | 1 | (13) | 6 | (75) |
| dT | 6 | (1.2) | 4 | (67) | 0 | (0) | 0 | (0) | 6 | (100) |
| Q fever | 5 | (1) | 5 | (100) | 0 | (0) | 0 | (0) | 5 | (100) |
| Hepatitis A | 4 | (0.8) | 2 | (50) | 0 | (0) | 0 | (0) | 4 | (100) |
| Typhoid | 3 | (0.6) | 2 | (67) | 0 | (0) | 0 | (0) | 3 | (100) |
| Hepatitis A + B | 2 | (0.4) | 2 | (100) | 0 | (0) | 0 | (0) | 2 | (100) |
| Rabies | 1 | (0.2) | 1 | (1) | 1 | (100) | 0 | (0) | 1 | (100) |
| Hepatitis A-Typhoid | 1 | (0.2) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (100) |
| Zoster | 1 | (0.2) | 1 | (100) | 1 | (100) | 0 | (0) | 1 | (100) |
| Yellow fever | 1 | (0.2) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (100) |
| Hib | 1 | (0.2) | 0 | (0) | 0 | (0) | 0 | (0) | 1 | (100) |
| BCG | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Cholera | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Tetanus | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Japanese encephalitis | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) |
| Total[d] | 510 | (100) | 322 | (63) | 85 | (17) | 203 | (40) | 298 | (58) |

[a]AEFI records where only one vaccine was suspected of involvement in a reported adverse event.
[b]AEFI records are not shown if both age and date of birth were not reported.
[c]Percentages are calculated for the number of AEFI records where the vaccine was suspected of involvement in the AEFI, e.g. Influenza was 'suspected' in 114 AEFI records; this was the only suspected vaccine in 92% of the 114 AEFI records, 13% were defined as 'serious' and 90% were for those aged ≥7 years.
[d]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.
Source: Adverse Drug Reactions Reporting System database, TGA.

more widely resulting in detection and reporting of events.[27,28]

Reactions recorded as 'serious' were pyrexia ($n = 11$), syncope ($n = 9$), rash ($n = 9$), vomiting ($n = 8$), headache ($n = 7$), hypotonic-hyporesponsive episodes ($n = 6$), intussusception ($n = 3$), Guillain-Barré syndrome ($n = 4$), febrile convulsion ($n = 2$), anaphylactic reaction ($n = 1$) and others as shown in Table 3.

The three reported cases of intussusception that were 'serious' had received the second dose of Infanrix hexa, 13vPCV and Rotarix. Of these three cases, one case resolved spontaneously requiring no surgery while the other two recovered following surgical intervention.

### *Indigenous status*

There were 3% (17/510) of AEFI reported in Aboriginal and Torres Strait Islander people. Most of these had either received Gardasil (35%, $n = 6$) or had Infanrix-IPV (24%, $n = 4$). Other reports included vaccines such as Infanrix hexa, M-M-R II, Boostrix, Fluvax, Menitorix, Varivax and H-B-VAX II. The majority of these were recorded as 'not serious'.

**Table 3. Selected reported adverse events and reactions of interest[a] as classified predominantly by MedDRA Preferred Terms in records of adverse events following immunisation (AEFI), NSW, 2015[b]**

| MedDRA Preferred Terms (Adverse events) | AEFI records | Only reaction reported[c] | | 'Serious' | | Age group[d] <7 years | | Age group[d] ≥7 years | |
|---|---|---|---|---|---|---|---|---|---|
| | *n* | *n* | (%)[e] | *n* | (%)[e] | *n* | (%)[e] | *n* | (%)[e] |
| Injection site reaction[f] | 99 | 44 | (44) | 7 | (7) | 35 | (35) | 64 | (65) |
| Rash[g] | 92 | 37 | (40) | 9 | (10) | 57 | (62) | 35 | (38) |
| Pyrexia | 88 | 4 | (5) | 11 | (13) | 53 | (60) | 34 | (39) |
| Headache | 45 | 2 | (4) | 7 | (16) | 2 | (4) | 42 | (93) |
| Extensive limb swelling | 37 | 21 | (57) | 3 | (8) | 17 | (46) | 20 | (54) |
| Vomiting | 35 | 3 | (9) | 8 | (23) | 18 | (51) | 17 | (49) |
| Nausea | 30 | 0 | (0) | 2 | (7) | 2 | (7) | 27 | (90) |
| Pain | 27 | 3 | (11) | 1 | (4) | 2 | (7) | 25 | (93) |
| Lethargy | 22 | 0 | (0) | 3 | (14) | 7 | (32) | 12 | (55) |
| Urticaria | 21 | 10 | (48) | 0 | (0) | 10 | (48) | 11 | (52) |
| Dizziness | 21 | 0 | (0) | 3 | (14) | 1 | (5) | 18 | (86) |
| Syncope | 19 | 12 | (63) | 9 | (47) | 4 | (21) | 15 | (79) |
| Diarrhoea | 18 | 3 | (17) | 2 | (11) | 11 | (61) | 7 | (39) |
| Arthralgia | 18 | 1 | (6) | 0 | (0) | 1 | (6) | 15 | (83) |
| Pruritus | 18 | 0 | (0) | 1 | (6) | 4 | (22) | 14 | (78) |
| Malaise | 15 | 1 | (7) | 2 | (13) | 1 | (7) | 14 | (93) |
| Myalgia | 15 | 1 | (7) | 0 | (0) | 1 | (7) | 14 | (93) |
| Erythema | 14 | 1 | (7) | 2 | (14) | 5 | (36) | 9 | (64) |
| Dyspnoea | 13 | 0 | (0) | 1 | (8) | 1 | (8) | 12 | (92) |
| Chills | 12 | 0 | (0) | 1 | (8) | 1 | (8) | 11 | (92) |
| Irritability | 11 | 0 | (0) | 4 | (36) | 11 | (100) | 0 | (0) |
| Abdominal pain | 11 | 0 | (0) | 2 | (18) | 2 | (18) | 8 | (73) |
| Injected limb mobility decreased | 11 | 0 | (0) | 0 | (0) | 2 | (18) | 9 | (82) |
| Hypotonic-hyporesponsive episodes | 10 | 9 | (90) | 6 | (60) | 10 | (100) | 0 | (0) |
| Paraesthesia | 9 | 0 | (0) | 1 | (11) | 0 | (0) | 9 | (100) |
| Cough | 8 | 1 | (13) | 1 | (13) | 0 | (0) | 8 | (100) |
| Decreased appetite | 8 | 0 | (0) | 1 | (13) | 4 | (50) | 4 | (50) |
| Fatigue | 7 | 0 | (0) | 0 | (0) | 1 | (14) | 6 | (86) |
| Somnolence | 7 | 1 | (14) | 0 | (0) | 5 | (71) | 2 | (29) |
| Presyncope | 6 | 5 | (83) | 0 | (0) | 0 | (0) | 6 | (100) |
| Hyperhidrosis | 6 | 0 | (0) | 0 | (0) | 1 | (17) | 5 | (83) |
| Hypoaesthesia | 6 | 1 | (17) | 1 | (17) | 0 | (0) | 6 | (100) |
| Intussusception | 5 | 5 | (100) | 3 | (60) | 4 | (80) | 0 | (0) |
| Pallor | 4 | 0 | (0) | 0 | (0) | 1 | (25) | 3 | (75) |
| Oropharyngeal pain | 4 | 0 | (0) | 2 | (50) | 0 | (0) | 4 | (100) |
| Tachycardia | 4 | 0 | (0) | 1 | (25) | 1 | (25) | 3 | (75) |
| Swelling face | 4 | 0 | (0) | 1 | (25) | 0 | (0) | 4 | (100) |
| Guillain–Barré syndrome | 4 | 1 | (25) | 3 | (75) | 1 | (25) | 3 | (75) |
| Rhinorrhoea | 3 | 0 | (0) | 2 | (67) | 2 | (67) | 1 | (33) |
| Chest discomfort | 3 | 0 | (0) | 0 | (0) | 0 | (0) | 3 | (100) |
| Convulsions[h] | 2 | 1 | (50) | 2 | (100) | 2 | (100) | 0 | (0) |
| Febrile convulsion | 2 | 1 | (50) | 2 | (100) | 2 | (100) | 0 | (0) |
| Crying | 2 | 0 | (0) | 1 | (50) | 2 | (100) | 0 | (0) |
| Lymphadenitis | 2 | 0 | (0) | 0 | (0) | 0 | (0) | 2 | (100) |
| Anaphylactic reaction | 1 | 1 | (100) | 1 | (100) | 1 | (100) | 0 | (0) |

[a]Selected reported adverse events reported during January 2015–December 2015. Note: for injection site reaction, rash and convulsions, Preferred Terms were grouped as described below.
[b]A complete list of adverse reactions as classified by individual Preferred Terms is available on request.
[c]AEFI records where only one reaction was reported.
[d]Not shown if neither age nor date of birth were recorded or missing data.
[e]Percentages relate to the number of AEFI records in which the specific reaction term was listed.
[f]Injection site reaction MedDRA codes include 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.
[g]Rash MedDRA codes include rash, rash generalised, rash maculo-papular, rash macular, rash vesicular, rash papular, rash morbilliform, and rash pustular.
[h]Convulsion MedDRA codes include convulsion, grand mal convulsion, and partial seizures.
Source: Adverse Drug Reactions Reporting System database, TGA.

### *Deaths*

There were no deaths reported that were temporally associated with receipt of vaccines in NSW in this reporting period.

## Discussion

There was a slight drop in the number of AEFI reports and population-based rates in 2015 compared with the previous reporting period, although this drop was not statistically significant. This slight drop was likely due to the cessation of the secondary school HPV vaccine catch-up program for Year 9 male students, resulting in a decline in HPV doses for this reporting period compared with the previous report (although no statistically significant declines in HPV AEFI reporting rates).[26] Also, there were no reports of AEFI of individual pathogen vaccines such as meningococcal C (MenC) and *Haemophilus influenza type* B (Hib) in children aged less than 7 years since the combined Hib–MenC vaccine replaced the respective monovalent MenC and Hib vaccines in July 2013.[29]

From 2015, the seasonal influenza vaccine was provided free for all Aboriginal and Torres Strait Islander children aged 6 months to 5 years.[30] During this first year of implementation of the program in NSW, no adverse events following seasonal influenza vaccine were reported in Aboriginal and Torres Strait Islander children aged 6 months to 5 years.

Although the dTpa vaccine was recommended and funded for women during the third trimester of pregnancy and for new mothers in maternity units of public hospitals (if not vaccinated in the third trimester) and also a booster dose of DTPa was recommended at 18 months of age, there has been no impact on AEFIs for these vaccines for this reporting period.

Injection site reaction, pyrexia and rash were the most commonly reported reactions in 2015. Vaccines such as MMR, DTPa-containing vaccines, 13vPCV and rotavirus had higher reporting rates than other vaccines for children aged less than 7 years in the current reporting period. However, these rates were not significantly higher than the previous reporting period.[26]

## Conclusion

Overall, the total number of reported AEFIs decreased during 2015 compared with the previous reporting period. 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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