Surveillance of adverse events following immunisation, NSW, 2018

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Abstract: Aim: This report summarises spontaneous surveillance data for adverse events following immunisation (AEFI) in NSW from 1 January 2018 to 31 December 2018. **Methods:** Analysis of de-identified data on all AEFI reported to the Therapeutic Goods Administration (TGA) for persons from NSW. **Results:** There were 831 AEFI reported for vaccines administered from 1 January to 31 December 2018. Of all AEFI, 2% were reported in Aboriginal and Torres Strait Islander people. There was an increase in overall AEFI reporting rate (10.4 per 100 000 population) in 2018, compared with 2017 (8.4 per 100 000 population); however, the vast majority of reported events were of a non-serious nature, similar to previous years. The increase was mainly attributable to: the meningococcal ACWY school-based vaccination program; the annual seasonal influenza vaccination program for all children aged 6 months to <5 years; enhanced immunogenicity trivalent influenza vaccines for adults aged ≥65 years; and the meningococcal ACWY conjugate vaccination program for all children at 12 months of age. Overall, the most commonly reported adverse events were associated with the following vaccines: seasonal influenza (33.7%); DTPa-IPV (11.7%); 13vPCV (9.3%); dTpa (8.8%); DTPa-IPV-HepB-Hib (8.5%); meningococcal ACWY (7.6%); HPV (7.3%); and rotavirus (7.3%). The most frequently reported adverse events were: injection site reaction (256); rash (146); pyrexia (128); vomiting (45); headache (44); nausea (37); and pain (36). There was one death reported in this period. **Conclusion:** The majority of AEFI reported to the TGA were mild transient events, although there was a small increase in adverse events observed in 2018 compared with 2017.

Abbreviations of vaccine types

BCG	Bacille Calmette-Guérin
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
MenACWY	quadrivalent meningococcal (serogroups A, C, W-135, Y) conjugate vaccine
MenB-MC	recombinant multicomponent meningococcal B 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 10th in a series of annual reports of adverse events following immunisation (AEFI) in New South Wales (NSW). This report summarises spontaneous surveillance

data reported from NSW for 2018 and describes reporting trends over the 19-year period 2000–2018.

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 surveillance of AEFI after Therapeutic Goods Administration (TGA) approval of a vaccine 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 the schedule of vaccines provided through the National Immunisation Program (NIP). Changes to the NIP in previous years have been reported elsewhere.[2–12] Recent NIP and NSW schedule changes that impact on AEFI surveillance data in NSW presented in this report are:

- July 2018 (NIP):
  - meningococcal ACWY conjugate vaccine funded for all children at 12 months of age, replacing combined Hib and meningococcal C-containing vaccine;
  - Hib dose moved to 18 months and given as monovalent Hib vaccine;
  - schedule for routine childhood vaccination with 13vPCV changed from 2, 4 and 6 months of age to 2, 4 and 12 months of age.
- April 2018:
  - enhanced immunogenicity trivalent influenza vaccines (high dose and adjuvanted) funded nationally for all adults aged ≥65 years (NIP);
  - annual seasonal influenza vaccination funded by NSW for all children aged 6 months to <5 years (NSW).
- February 2018: a two-dose schedule of 9-valent HPV funded for adolescents aged 12–14 years, delivered through a school-based program; 4-valent HPV ceased to be used in the program (NIP).
- January 2018: meningococcal ACWY school-based vaccination program funded for all NSW secondary school students in Years 10 and 11, as well as adolescents aged 15–19 years who have not received the vaccine at school (NSW).

Methods

AEFI are notifiable to NSW public health units by medical practitioners and hospital CEOs under the NSW *Public Health Act 2010*. Cases with any missing information and all serious AEFI are followed up by public health units and Health Protection NSW. All notifications are forwarded to the TGA. The TGA also receives reports directly from vaccine manufacturers, members of the public and other sources. The TGA sends these reports to NSW Health, and they are included in this report.[13,14]

Adverse events following immunisation data

Notifications from all sources across Australia are received by the TGA, coded using internationally consistent criteria[15] and entered into the TGA's Adverse Events Management System (AEMS). The term 'AEFI record' is used throughout this report to signify the occurrence of an AEFI because a single adverse event can result in more than one notification and generate more than one record in the AEMS. Duplication of adverse event reports/cases is more likely to occur in situations where there are sequential adverse events in a single patient or if multiple vaccines are involved. Records identified as duplicates are linked and not included as separate reports.

Typically, each AEFI record lists several symptoms, signs and diagnoses that have been coded 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 categories that were broadly analogous to the adverse events listed in previous editions of the *Australian Immunisation Handbook*.[13,14] However, the methodological framework for analysing and reporting on adverse events was revised in the 2012 report, after which AEFI analysis has been conducted using MedDRA preferred terms (PTs).[17] Grouping of adverse events 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.

Study definitions of AEFI outcomes

Australian sponsors are required to apply seriousness coding to vaccine AEFI reports to ensure legislated requirements are met. Reports are coded by TGA as 'serious' or 'non-serious' based on 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 adverse event 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.

A limitation of our report is interpretation of the serious code for all reported adverse events that, while included for

completeness, is primarily used as a guide for sponsor reporting. As it is not necessarily applied based on review of detailed and verified clinical data, and may not capture all medically important events, reporting rates of serious adverse events are unlikely to be robust.

Data analysis

De-identified information on AEFI reports from the TGA's AEMS database was released to NCIRS for analysis and reporting. AEFI records contained in the AEMS 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 2018 and 31 December 2018; and the residential address of the individual was recorded as within NSW. Vaccines are classified as 'suspected' if the notification/report contains sufficient information to be valid and a causal relationship between reported adverse events and the vaccine is deemed at least possible.

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 reliably available from the Australian Immunisation Register (AIR) 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 adolescent doses 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 2018, because of reporting delays and the late onset of some reported AEFI. Numbers are updated for previous years. The information collated in the AEMS 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, stimulated reporting and the variable quality and completeness of information provided in individual notifications.[12]

It is important to note that this report is based on vaccine and adverse event information collated in the AEMS database and not on comprehensive clinical notes. Also, Indigenous status is not routinely recorded in all AEFI reports received by the TGA, so is likely to be underestimated.

Results

There was a total of 831 AEFI records in the AEMS database with a date of vaccination of 2018 and the vaccinated person was resident in NSW. Of these, 58% (482) were females, 40% (331) males and 2% (18) had their gender missing in the database. Also, 2% (20) were reported as Aboriginal and Torres Strait Islander people.

Of all 831 reports, 39% (328) were for children aged less than 7 years and 57% (470) were for people aged 7 years and over. Approximately 4% (33) had age missing in the database.

Forty-five per cent (372) of AEFI were reported to the TGA via NSW Health and the remainder were reported directly to the TGA: 18% (152) by general practitioners, 16% (137) by nurses, 9% (71) by pharmaceutical companies, 7% (61) by members of the public, and 4% (37) by hospitals.

Reporting trends

The overall AEFI reporting rate for 2018 was 10.4 per 100 000 population, compared with 8.4 per 100 000 in 2017.

Figure 1 shows an increase in the reported events and annual reporting rate per 100 000 population during 2018 compared with 2017. However, the vast majority of reported events were of a non-serious nature, similar to previous years.[8,12,26,27]

Figures 2a, 2b and 3 demonstrate marked variations in reporting levels in association with previous changes to the NIP from 2000 onwards. The increase in reports in 2018 was possibly associated with the introduction of the adolescent meningococcal ACWY conjugate vaccine funded in NSW; enhanced immunogenicity trivalent influenza vaccines for adults aged ≥65 years and NSW funded seasonal influenza vaccination programs for children aged 6 months to <5 years.

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

Age group and vaccine

Figure 4a shows that the estimated AEFI reporting rates were highest in 2–6 year olds during 2018 (48.2 per 100 000 doses, 95% CI 40.5–57.0) and appeared to have increased compared with 2017 (43.9 per 100 000 doses,

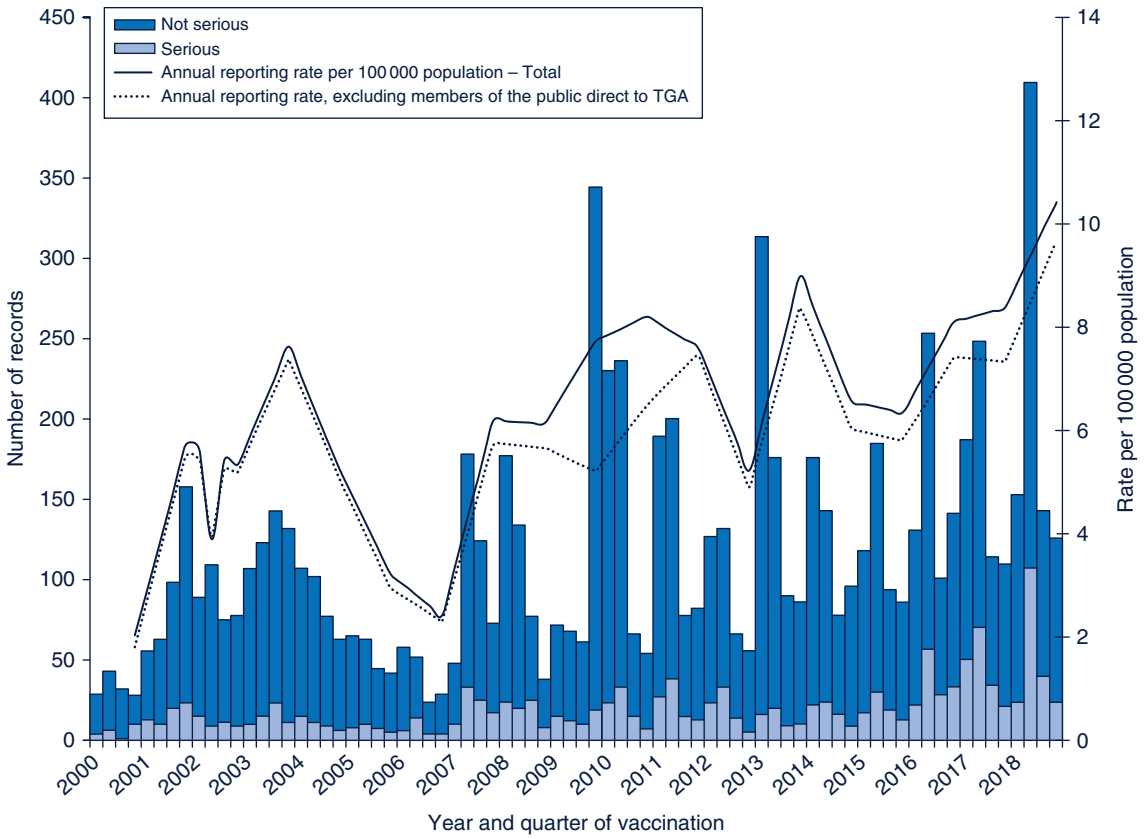

Figure 1. Reports of adverse events following immunisation, NSW, 2000–2018, by quarter of vaccination.

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 Events Management System database, Therapeutic Goods Administration.

95% CI 34.0–55.7), although this increase was not statistically significant. Also, no statistically significant changes were observed in children less than or equal to 1 year in 2018 compared with 2017, although rates appeared to decrease in those aged between 1 and less than 2 years.

Although vaccine dose information was available from the AIR for people aged 7 years and older from 30 September 2016 onwards, the data completeness was variable across age groups and underestimated overall, hence we only estimated population-based AEFI reporting rates as shown in Figure 4b. There was a 1.3 percentage point increase in estimated AEFI reporting rates in the 20–64 years age group during 2018 (3.9 per 100 000 population) compared with 2017 (2.6 per 100 000 population). In contrast, there was a 0.6 percentage point decrease in estimated rates in the ≥65 years age group during 2018 (11.5 per 100 000 population) compared with 2017 (12.2 per 100 000 population). There were no significant changes in estimated AEFI reporting rates for those aged between 7 and <20 years.

The estimated reporting rates per 100 000 doses in children aged less than 7 years did not change significantly for the majority of vaccines when compared with 2017 (Table 1). However, DTPa-IPV was recorded in 94 reports and 15 of these were coded as serious (Tables 1 and 2). For those aged between 12 and 17 years, there were 45 HPV vaccine-related reports, and of these three were coded as serious. In those aged 65 years and over, seasonal influenza vaccines were recorded in 92 reports, and of these 20 were reported as serious (Tables 1 and 2). Overall, as shown in Table 2, the most commonly reported adverse events were associated with seasonal influenza (33.7%), followed by DTPa-IPV (11.7%), 13vPCV (9.3%), dTpa (8.8%), DTPa-IPV-HepB-Hib (8.5%), meningococcal ACWY (7.6%), HPV vaccine (7.3%), rotavirus (7.3%), 23vPPV (5.4%) and MMR (5.2%). Twenty-three per cent of all reported adverse events were categorised as serious.

Adverse events

The distribution and frequency of adverse events listed in AEFI records for 2018 are shown in Table 3. The most frequently reported adverse events were injection site reaction (ISR) (256), rash (146), pyrexia (128), vomiting (45), headache (44), nausea (37) and pain (36).

Of the total 256 cases with ISR, 54% (137) were in those aged ≥7 years. Also, more than half of the cases with rash (81) and pyrexia (70) were reported in those aged <7 years.

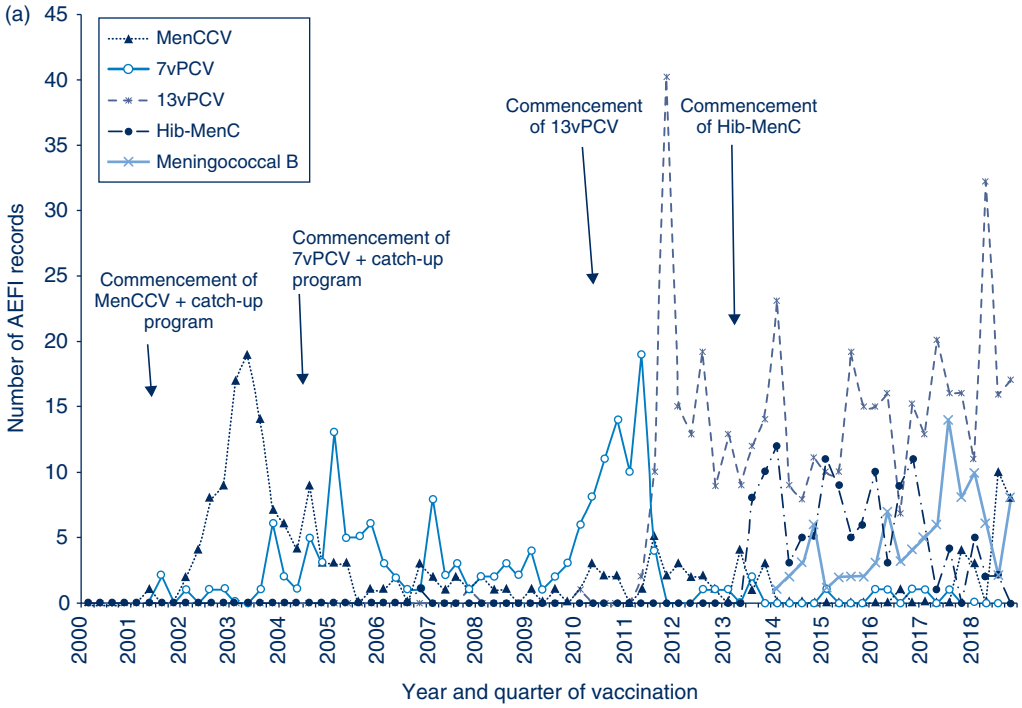

Figure 2a. Adverse events following immunisation in children aged less than 7 years for selected vaccines, NSW, 2018, by quarter of vaccination.

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 Hib–MenC on 1 July 2013.

Source: Adverse Events Management System database, Therapeutic Goods Administration.

Anaphylaxis was reported in 12 people, eight of whom were aged ≥7 years.

Also, there were 18 reported cases of syncope and 10 cases of presyncope during 2018. Eighty-three per cent (15) of cases of syncope and 70% (7) of cases of presyncope were reported in persons aged 7 years and older.

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

There were five cases of Guillain–Barre syndrome (GBS) and three cases of intussusception during this reporting period.

Serious adverse events

Approximately 23% (195) of reported events were defined as 'serious' (i.e. recovery with sequelae, requiring hospitalisation, experiencing a life-threatening event or death) in 2018. As shown in Figure 1, the overall percentage of 'serious' events in this reporting period slightly decreased compared with the previous reporting period, although a slight increase was observed in the second quarter of 2018.

Adverse events recorded as 'serious' included pyrexia (34), injection site reaction (32), vomiting (14), rash (14), headache (14), anaphylaxis (9), convulsions (8) and others, as shown in Table 3. Seventy-five per cent (8) of convulsions were febrile convulsions seen in children aged <7 years.

Of the 195 serious adverse events, 15% (29) were reported in children aged <1 year, 10% (20) in 1–<2 year olds, 12% (24) in 2–<7 year olds, 2% (4) in 7–<12 year olds, 7% (14) in 12–<18 year olds, 25% (48) in 18–<65 year olds and 17% (48) in ≥65 year olds. Approximately 12% of serious cases had missing age.

Indigenous status

Two per cent (20/831) of reported AEFI were in Aboriginal and Torres Strait Islander people. The majority (80%, $n = 16$) of these were recorded as 'non serious'.

Death

One death was reported to the TGA but no clear causal relationship with vaccination was found.

- A 22-month-old female died in late March 2018, approximately 5 months after receiving a dose of DTPa-containing vaccine and the MMRV vaccine in early November 2017. The child had >3 months history of a refractory seizure disorder, likely mitochondrial based on genetic testing.

There were no miscarriages (spontaneous abortion) reported in this period.

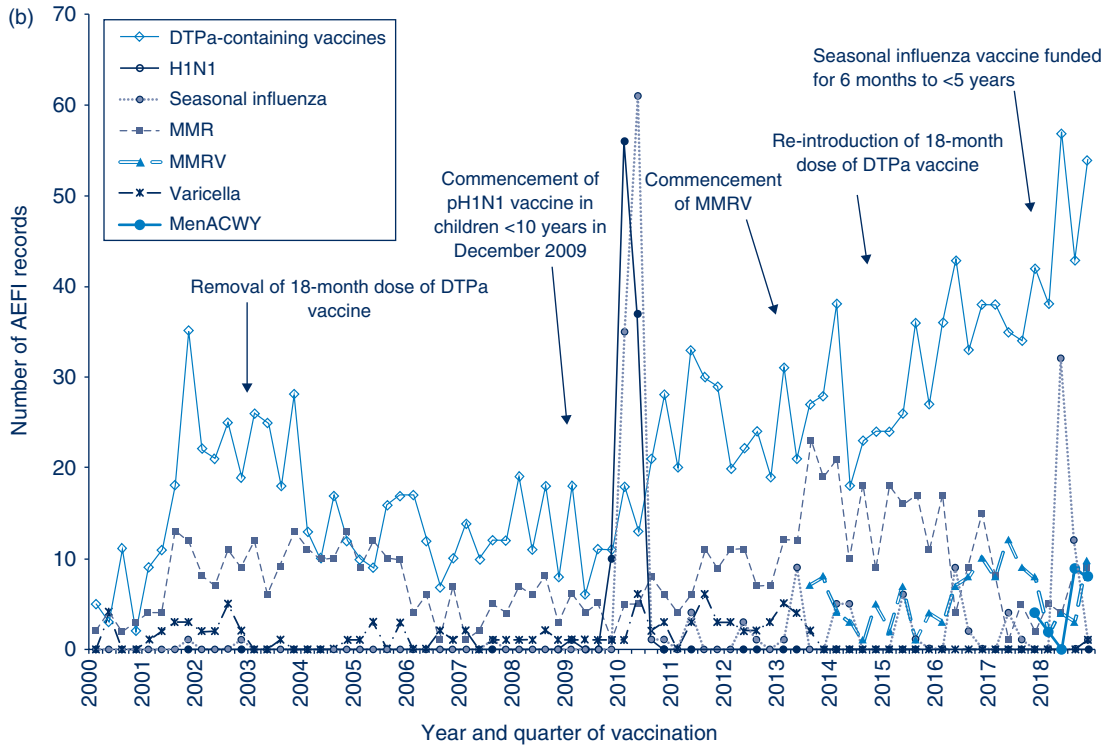

Figure 2b. Adverse events following immunisation in children aged less than 7 years for selected vaccines, NSW, 2000–2018, by quarter of vaccination.

NB: DTPa-IPV was introduced into the NIP schedule in November 2005 replacing DTPa and oral polio vaccine (OPV); commencement of the pH1N1 (pandemic influenza vaccine) in children aged less than 10 years in December 2009; seasonal trivalent influenza vaccine was extended to medically at risk children in 2010; MMRV vaccine was introduced on 1 July 2013; re-introduction of 18-month booster dose of DTPa vaccine in April 2016.

Source: Adverse Events Management System database, Therapeutic Goods Administration.

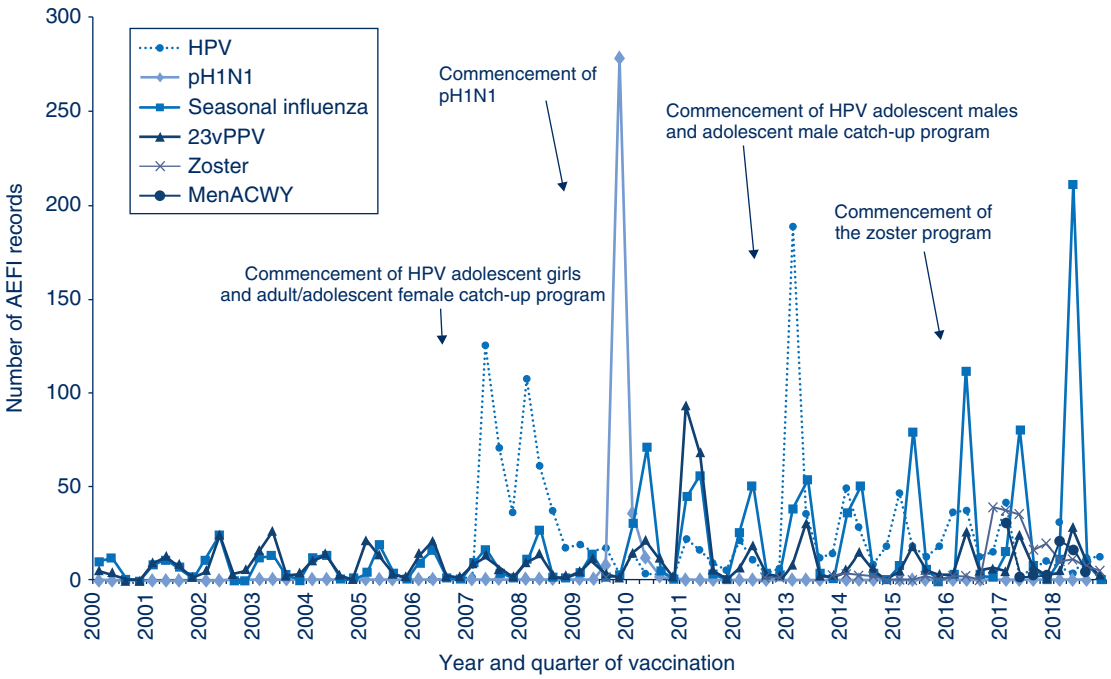

Figure 3. Adverse events following immunisation for people aged ≥7 years in frequently reported vaccines, NSW, 2000–2018, by quarter of vaccination.

Source: Adverse Events Management System database, Therapeutic Goods Administration.

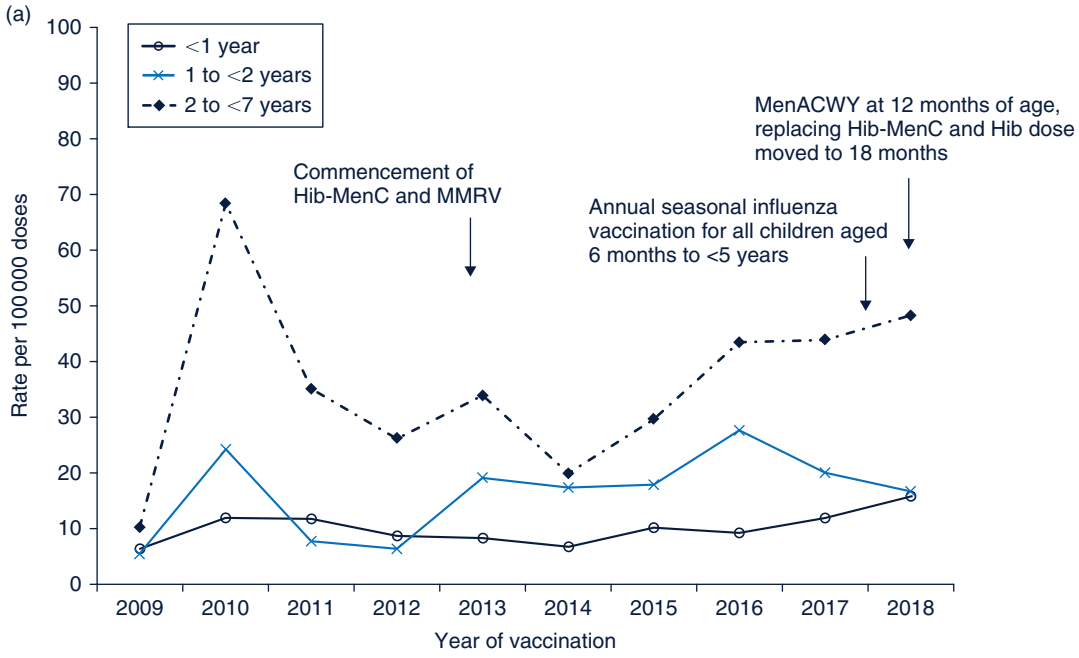

Figure 4a. Reporting rates of adverse events following immunisation for NSW per 100 000 doses, 2009–2018, for people aged less than 7 years, by year of vaccination.
Source: Adverse Events Management System database, Therapeutic Goods Administration.

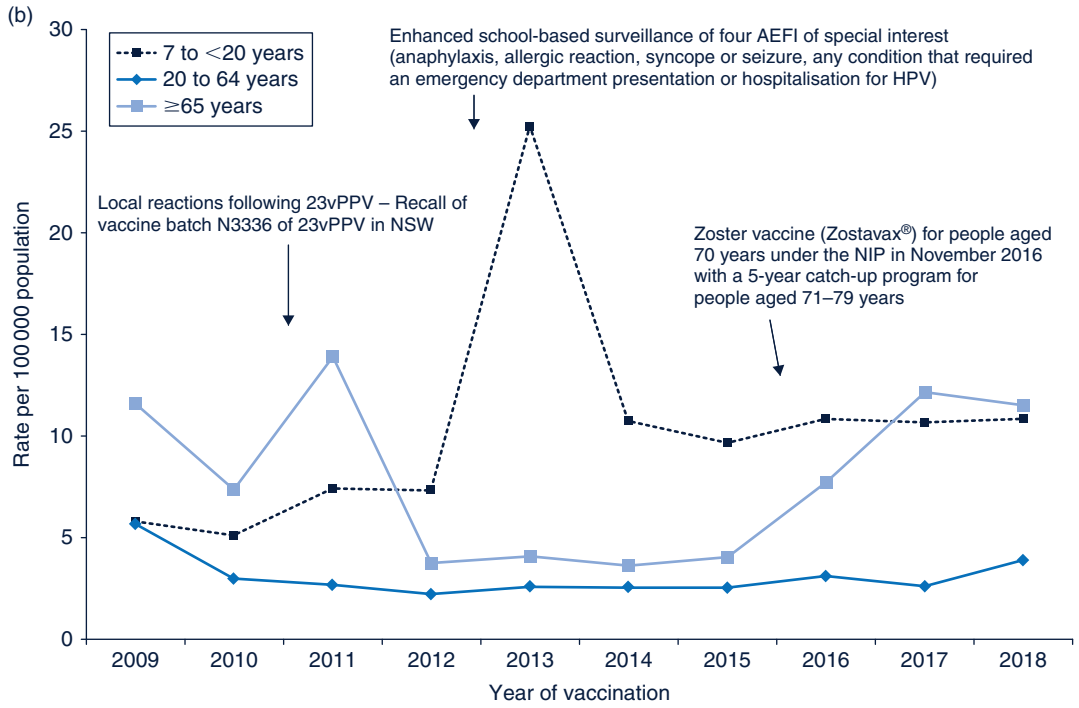

Figure 4b. Reporting rates of adverse events following immunisation for NSW per 100 000 population, 2009–2018, for people aged ≥7 years, by year of vaccination.
Source: Adverse Events Management System database, Therapeutic Goods Administration.

Discussion

There was an increase in estimated AEFI population-based rates in 2018 compared with 2017; however, this increase was not statistically significant. Adverse events reports have increased over the past decade. This is partially due to having more population-wide vaccination programs (increasing the number of vaccination episodes per person) and partially due to improved reporting to NSW Health and the TGA.

In 2018, the increase was mainly attributable to NIP funding for the meningococcal ACWY conjugate vaccine for all

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, 2018

Vaccine[a]	AEFI records[b] 2018	Serious[c] 2018	Reporting rate per 100 000 doses[d] 2018	
	N	*n*	Rate	(95% CI)
<7 years				
DTPa-IPV	94	15	96.8	(78.2–118.5)
13vPCV	76	22	29.6	(23.3–37.0)
Hexavalent (DTPa-IPV-HepB-Hib)	70	19	25.8	(20.1–32.6)
Rotavirus	60	18	34.2	(26.1–44.0)
Seasonal influenza	45	13	20.2	(14.7–27.0)
DTPa	28	7	29.1	(19.4–42.1)
MMR	27	5	27.3	(18.0–39.7)
Meningococcal B	26	3	61.3	(40.0–89.7)
MMRV	19	5	19.7	(11.9–30.8)
Hib-MenC	9	1	17.5	(8.0–33.2)
Hepatitis B	5	1	49.0	(15.9–114.3)
Hib	2	0	38.7	(4.7–139.6)
Varicella	1	1	35.2	(0.9–196.0)
12–17 years				
HPV	45	3	30.4	(22.2–40.7)
MenACWY	35	6	29.2	(20.3–40.6)
dTpa	32	1	40.3	(27.6–56.9)
Seasonal influenza	6	3	12.2	(4.5–26.6)
18–64 years				
Seasonal Influenza	120	32	22.2	(18.4–26.6)
dTpa	28	4	18.9	(12.6–27.3)
MMR	13	4	53.0	(28.2–90.6)
23vPPV	11	2	92.5	(46.2–165.5)
Hepatitis B	10	1	21.8	(10.5–40.2)
MenACWY	9	2	77.0	(35.2–146.2)
Hepatitis A	8	2	23.9	(10.3–47.1)
Hepatitis A-Typhoid	7	1	14.2	(5.7–29.3)
Hepatitis A-Hepatitis B	3	0	14.9	(3.1–43.5)
Yellow fever	1	0	9.2	(0.2–51.1)
≥65 years				
Seasonal influenza	92	20	14.6	(11.8–17.9)
23vPPV	33	5	39.7	(27.3–55.8)
Zoster	32	8	47.2	(32.3–66.6)
dTpa	5	1	17.6	(5.7–41.0)

[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 2018 and 31 December 2018. 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.
Source: Adverse Events Management System database, Therapeutic Goods Administration.

children at 12 months of age. Furthermore, from January 2018, the meningococcal ACWY school-based vaccination program was funded for all NSW secondary school students in Years 10 and 11, as well as adolescents aged 15–19 years who had not received the vaccine at school. NSW also funded annual seasonal influenza vaccination for all children aged 6 months to <5 years the same year. In addition, enhanced immunogenicity trivalent influenza vaccines (high dose and adjuvanted) for all adults aged ≥65 years were NIP funded from 2018. A slight increase in AEFI was observed in the second quarter of 2018 that was associated with the influenza vaccination programs.

Table 2. Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI), NSW, 2018

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	280	(33.7)	250	(89)	71	(25)	45	(16)	228	(81)
DTPa-IPV	97	(11.7)	93	(96)	15	(15)	94	(97)	3	(3)
PCV13	77	(9.3)	8	(10)	22	(29)	76	(99)	0	(0)
dTpa	73	(8.8)	29	(40)	6	(8)	0	(0)	73	(100)
DTPa-IPV-HepB-Hib	71	(8.5)	7	(10)	19	(27)	70	(99)	0	(0)
Meningococcal-ACWY	63	(7.6)	42	(67)	11	(17)	19	(30)	44	(70)
HPV	61	(7.3)	31	(51)	5	(8)	0	(0)	58	(95)
Rotavirus	61	(7.3)	12	(20)	18	(30)	60	(98)	0	(0)
23vPPV	45	(5.4)	27	(60)	7	(16)	1	(2)	44	(98)
MMR+MMRII	43	(5.2)	13	(30)	7	(16)	27	(63)	15	(35)
Zoster	40	(4.8)	35	(88)	9	(23)	1	(3)	33	(83)
DTPa	28	(3.4)	12	(43)	7	(25)	28	(100)	0	(0)
Meningococcal B	28	(3.4)	24	(86)	4	(14)	26	(93)	2	(7)
Hepatitis B	22	(2.6)	16	(73)	3	(14)	5	(23)	12	(55)
MMRV	21	(2.5)	5	(24)	6	(29)	19	(90)	1	(5)
Typhoid	12	(1.4)	2	(17)	1	(8)	2	(17)	10	(83)
Hepatitis A-Typhoid	12	(1.4)	6	(50)	2	(17)	2	(17)	11	(92)
Hepatitis A	11	(1.3)	1	(9)	2	(18)	1	(9)	10	(91)
Hib-MenC	9	(1.1)	2	(22)	1	(11)	9	(100)	0	(0)
dT	6	(0.7)	5	(83)	0	(0)	0	(0)	6	(100)
Hepatitis A and B	6	(0.7)	2	(33)	1	(17)	0	(0)	6	(100)
Varicella	3	(0.4)	1	(33)	1	(33)	1	(33)	2	(67)
Yellow fever	3	(0.4)	1	(33)	0	(0)	0	(0)	2	(67)
Rabies	3	(0.4)	2	(67)	1	(33)	0	(0)	3	(100)
BCG	3	(0.4)	3	(100)	0	(0)	2	(67)	0	(0)
MenCCV	2	(0.2)	0	(0)	2	(100)	2	(100)	0	(0)
Hib	2	(0.2)	0	(0)	0	(0)	2	(100)	0	(0)
Q fever	1	(0.1)	1	(100)	1	(100)	0	(0)	1	(100)
Total[d]	831	(100.0)	633	(74)	195	(23)	328	(39)	470	(57)

[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 280 AEFI records; this was the only suspected vaccine in 89% of the 280 AEFI records, 25% were defined as 'serious' and 81% 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 Events Management System database, Therapeutic Goods Administration.

AusVaxSafety (an active sentinel vaccine safety surveillance system, http://www.ausvaxsafety.org.au/) also monitored the safety of vaccines and found no safety signal during 2018.[28] Both surveillance systems (TGA and AusVaxSafety) reported similar milder adverse events during 2018.

There was no safety signal related to the use of influenza or diphtheria, tetanus, and acellular pertussis-containing (dTpa) vaccines in pregnancy. This is consistent with a number of large studies that have shown no increased risk of adverse pregnancy outcomes attributable to pertussis and influenza vaccination.[29,30] Miscarriages affect approximately 1 in 5 pregnancies that are less than 20 weeks gestation.[31] The TGA encourages all reporters to provide sufficient information to allow the TGA to assess any potential causal relationship between the administration of a vaccine and the adverse event reported.

Injection site reaction, rash and pyrexia were the most commonly reported adverse events in 2018. Vaccines such as DTPa-IPV, meningococcal B, hepatitis B, rotavirus,

Table 3. Selected reported adverse events[a] as classified predominantly by MedDRA Preferred Terms in records of adverse events following immunisation (AEFI), NSW, 2018[b]

MedDRA Preferred Terms (adverse events)	AEFI records	Only adverse event 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]	256	142	(55)	32	(13)	115	(45)	137	(54)
Rash[g]	146	63	(43)	14	(10)	81	(55)	63	(43)
Pyrexia	128	11	(9)	34	(27)	70	(55)	56	(44)
Vomiting	45	6	(13)	14	(31)	21	(47)	24	(53)
Headache	44	0	(0)	14	(32)	3	(7)	41	(93)
Nausea	37	0	(0)	12	(32)	2	(5)	33	(89)
Pain	36	7	(19)	3	(8)	6	(17)	30	(83)
Urticaria	35	17	(49)	11	(31)	15	(43)	20	(57)
Malaise	35	0	(0)	10	(29)	4	(11)	30	(86)
Dizziness	34	2	(6)	5	(15)	1	(3)	32	(94)
Myalgia	25	2	(8)	4	(16)	0	(0)	25	(100)
Angioedema	25	1	(4)	7	(28)	7	(28)	18	(72)
Diarrhoea	23	1	(4)	10	(43)	9	(39)	12	(52)
Pruritus	23	2	(9)	3	(13)	5	(22)	18	(78)
Paraesthesia	23	0	(0)	7	(30)	0	(0)	22	(96)
Lethargy	20	0	(0)	9	(45)	6	(30)	11	(55)
Erythema	19	3	(16)	1	(5)	8	(42)	11	(58)
Syncope	18	3	(17)	2	(11)	3	(17)	15	(83)
Dyspnoea	17	1	(6)	5	(29)	3	(18)	14	(82)
Decreased appetite	15	0	(0)	5	(33)	9	(60)	5	(33)
Chest discomfort	15	0	(0)	4	(27)	0	(0)	15	(100)
Cough	14	0	(0)	4	(29)	5	(36)	9	(64)
Chills	12	1	(8)	3	(25)	1	(8)	11	(92)
Anaphylaxis	12	5	(42)	9	(75)	1	(8)	8	(67)
Pallor	12	0	(0)	2	(17)	5	(42)	7	(58)
Swelling	12	1	(8)	2	(17)	3	(25)	9	(75)
Fatigue	11	0	(0)	2	(18)	3	(27)	8	(73)
Abdominal pain	11	3	(27)	3	(27)	7	(64)	4	(36)
Apnoea	11	2	(18)	5	(45)	9	(82)	0	(0)
Flushing	11	0	(0)	1	(9)	0	(0)	10	(91)
Arthralgia	10	2	(20)	1	(10)	0	(0)	10	(100)
Presyncope	10	7	(70)	1	(10)	3	(30)	7	(70)
Oropharyngeal pain	10	0	(0)	2	(20)	0	(0)	10	(100)
Asthenia	9	0	(0)	1	(11)	0	(0)	9	(100)
Bradycardia	9	0	(0)	3	(33)	9	(100)	0	(0)
Extensive limb swelling	8	6	(75)	3	(38)	6	(75)	2	(25)
Irritability	8	0	(0)	1	(13)	7	(88)	0	(0)
Injected limb mobility decreased	8	0	(0)	0	(0)	0	(0)	8	(100)
Convulsions[h]	10	2	(13)	8	(75)	8	(75)	2	(25)
Somnolence	8	0	(0)	2	(25)	6	(75)	2	(25)
Lymphadenitis	8	3	(38)	1	(13)	1	(13)	7	(88)
Rhinorrhoea	7	0	(0)	0	(0)	4	(57)	3	(43)
Tachycardia	7	1	(14)	4	(57)	3	(43)	4	(57)
Hypotonic-hyporesponsive episodes	6	1	(17)	4	(67)	5	(83)	0	(0)
Hypoaesthesia	5	1	(20)	3	(60)	0	(0)	5	(100)

Guillain–Barré syndrome	5	5	(100)	5	(100)	0	(0)	3	(60)
Intussusception	3	3	(100)	2	(67)	3	(100)	0	(0)
Haematochezia	2	1	(50)	1	(50)	2	(100)	0	(0)

[a]A complete list of adverse events as classified by individual Preferred Terms is available on request.
[b]Selected reported adverse events reported during January 2018 to December 2018. Note: for injection site reaction, rash and convulsions, PTs were grouped as described below.
[c]AEFI records where only one adverse event 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 adverse event 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, partial seizures and febrile convulsion.
Source: Adverse Events Management System database, Therapeutic Goods Administration.

13vPCV and DTPa had higher reporting rates than other vaccines for children aged less than 7 years in the current reporting period. However, the majority of these rates were not significantly higher than the previous reporting period.[32]

Conclusion

Overall, the total number of reported AEFI slightly increased during 2018 compared with 2017. The majority of AEFI 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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