Surveillance of adverse events following immunisation, NSW, 2017

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Abstract: Aim: This report summarises passive surveillance data for adverse events following immunisation (AEFI) in NSW from 1 January 2017 to 31 December 2017. **Methods:** Analysis of de-identified data on all AEFI reported to the Therapeutic Goods Administration (TGA) for persons from NSW. **Results:** There were 683 AEFI reported for vaccines administered from 1 January to 31 December 2017. Of all AEFI, 2% were reported in Aboriginal and Torres Strait Islander people. There was an increase in the overall AEFI reporting rate (8.7 per 100 000 population) in 2017, compared with 2016 (8.5 per 100 000 population); however, the vast majority of reported events were of a non-serious nature, similar to previous years. This overall increase is likely due to the introduction in November 2016 of the zoster vaccine (Zostavax®) provided free for people aged 70–79 years under the National Immunisation Program (NIP), and also the meningococcal ACWY conjugate vaccine funded in NSW schools for grade 11–12 students and those aged 15–19 years who no longer attend school. Overall, the most commonly reported reactions were associated with seasonal influenza (17.7%), followed by zoster (16.5%), HPV vaccine (9.5%), 13vPCV (9.2%), DTPa-IPV-HepB-Hib (9.1%), dTpa (8.5%), rotavirus (8.3%), DTPa-IPV (6.7%) and DTPa (6.6%). Approximately 15% of the reported adverse events were categorised as serious in 2017 compared with 13% in the previous reporting period (2016). 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 reports observed in 2017 compared with 2016.

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 ninth 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 2017 and describes reporting trends over the 18-year period 2000–2017.

An adverse event following immunisation 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 to the NIP in previous years have been reported elsewhere.[2–12] Recent changes that impact on AEFI surveillance data in NSW presented in this report are:

- May 2017: Meningococcal ACWY conjugate vaccine funded in NSW for grade 11–12 students and persons aged 15–19 years who no longer attend school.
- February 2017: Two-dose human papillomavirus (HPV) vaccine schedule adopted in NSW for Year 7 students.
- November 2016: Zoster vaccine (Zostavax®) provided free for people aged 70 years under the NIP with a 5-year catch-up program for people aged 71–79 years.
- March 2016: NIP-funded booster dose of the diphtheria, tetanus, and acellular pertussis-containing vaccine (DTPa) at 18 months of age.
- 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 is no longer 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 pregnant women during the third trimester under the NSW maternal pertussis strategy from March 2015.

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 Therapeutic Goods Administration (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 assessed by the TGA 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 reactions 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 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 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 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 adverse events following immunisation outcomes and reactions

This report includes only AEFI records that are classified as 'suspected' (certain, possible or probable) to be causally related to immunisation. All adverse events reports (containing sufficient information) are accepted by TGA and analysed in this annual report. Inclusion of data from reports does not imply a causal relationship to vaccination merely that the event/s reported had a temporal relationship to vaccination. Further information on causality is available from the TGA website.

An AEFI record is classified as 'unlikely or unclassifiable/assessable' and excluded from the public Database of Adverse Event Notification (DAEN) and TGA reports to NCIRS, sponsors, states and territories or WHO (but remains in the AEMS database) if: (1) there is no reasonable temporal association between the use of a drug/vaccine and the clinical event; (2) the record does not contain enough information for an adequate assessment or the information is contradictory; or (3) uncommonly, that a clinical event is explained as more likely to have arisen from other causes. AEFI were defined as 'serious' or 'non-serious' based on information in the notification 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 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.

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 2017 and 31 December 2017; and the residential address of the individual was recorded as within 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 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 2017, 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, 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 reaction term information collated in the AEMS database and not on comprehensive clinical notes.

Results

In 2017, there was a total of 683 AEFI records in the AEMS database with a date of vaccination from NSW. Of these, 57% were females (388), 41% (280) males and 2% (15) had their gender missing in the database. Also, 2% (16) were reported as Aboriginal and Torres Strait Islander people.

Of all 683 reports, 35% (240) were for children aged less than 7 years and 61% (419) were for people aged 7 years and over. Approximately 4% (24) had age missing in the database.

Forty-five per cent (308) of AEFI were reported to the TGA via NSW Health and the remainder were reported directly to the TGA; 31% (213) by doctors/other health care providers, 16% (110) by members of the public, 8% (52) by drug companies and 3% (23) by hospitals.

Reporting trends

The overall AEFI reporting rate for 2017 was 8.7 per 100 000 population, compared with 8.5 per 100 000 in 2016.

Figure 1 shows a slight increase in the reported events and annual reporting rate per 100 000 population during 2017 compared with 2016. 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 slight increase in reports in 2017 was possibly associated with the introduction of the meningococcal ACWY conjugate vaccine funded in NSW schools for grade 11–12 students and also an increase in reports of adverse events following immunisation with zoster vaccine in the elderly (Figure 3).

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.

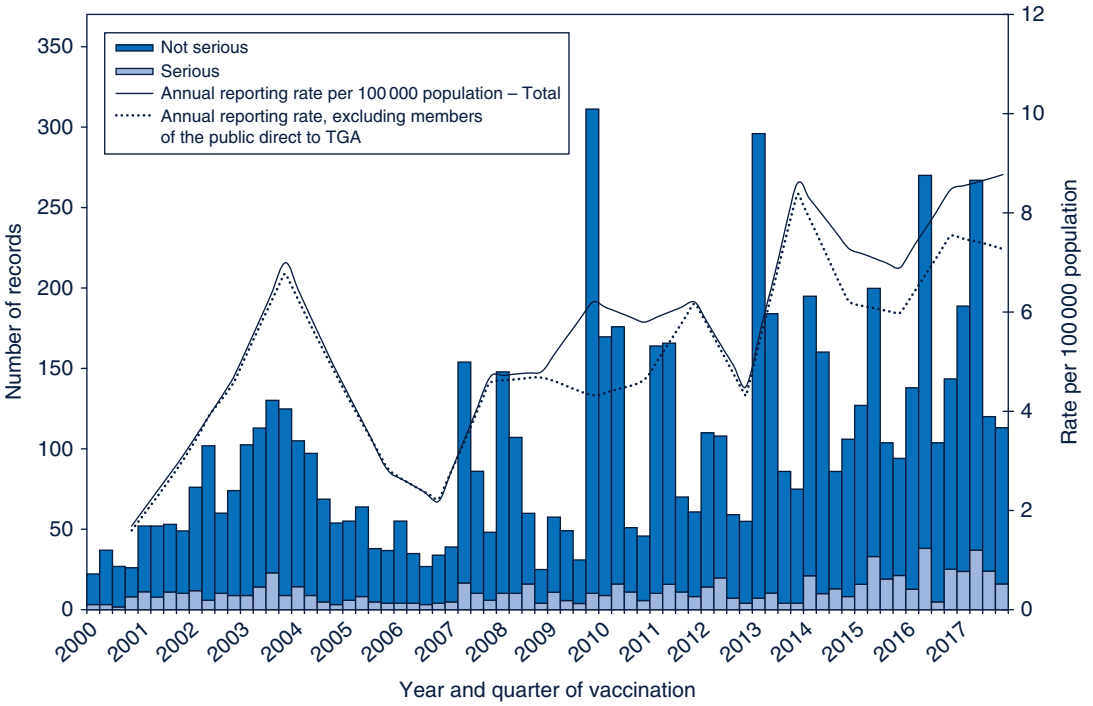

Figure 1. Reports of adverse events following immunisation, NSW, 2000–2017, by quarter of vaccination.

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.

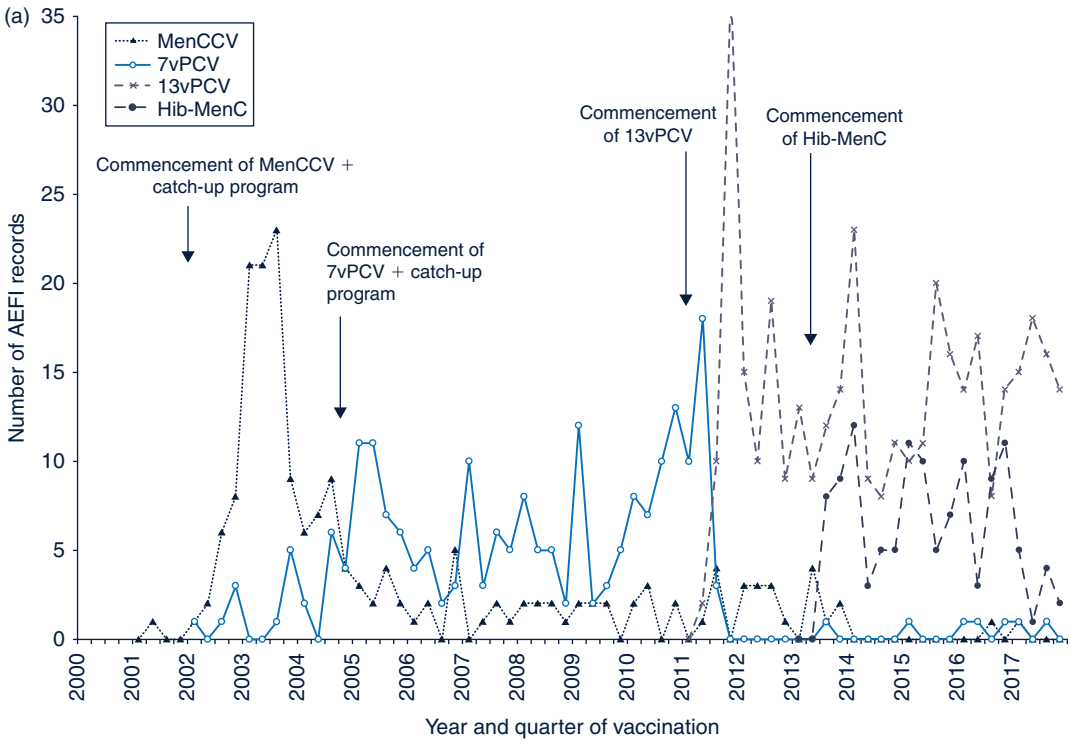

Figure 2a. Adverse events following immunisation in children aged less than 7 years for selected vaccines, NSW, 2017, by quarter of vaccination.

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.

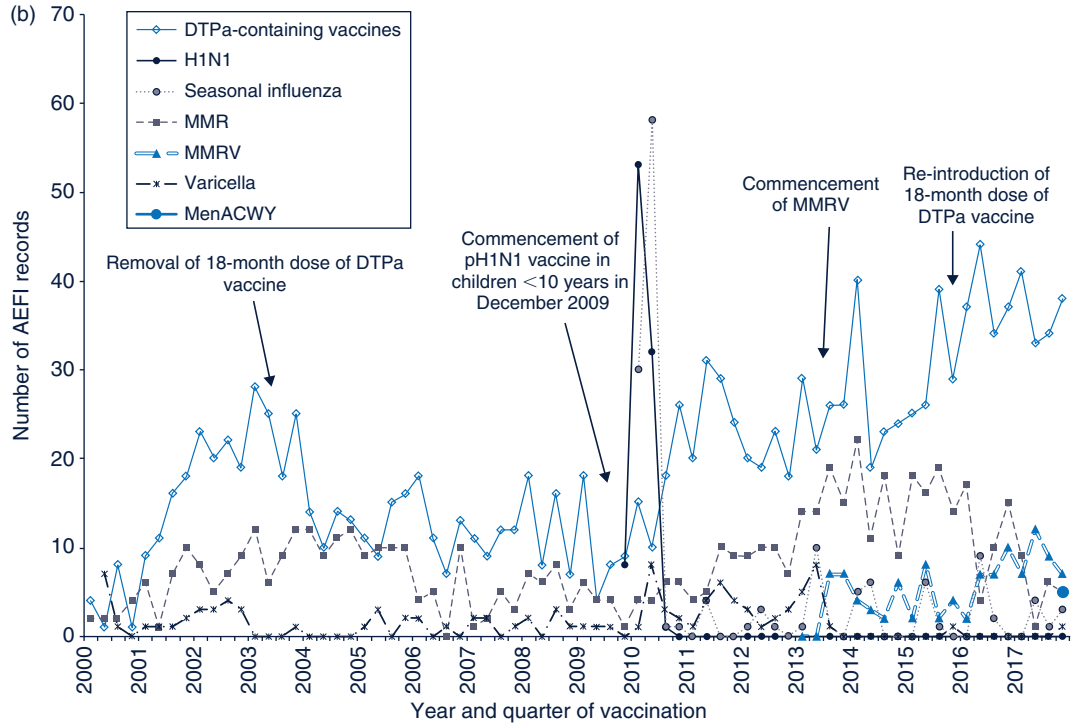

Figure 2b. Adverse events following immunisation in children aged less than 7 years for selected vaccines, NSW, 2000–2017, by quarter of vaccination.

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.

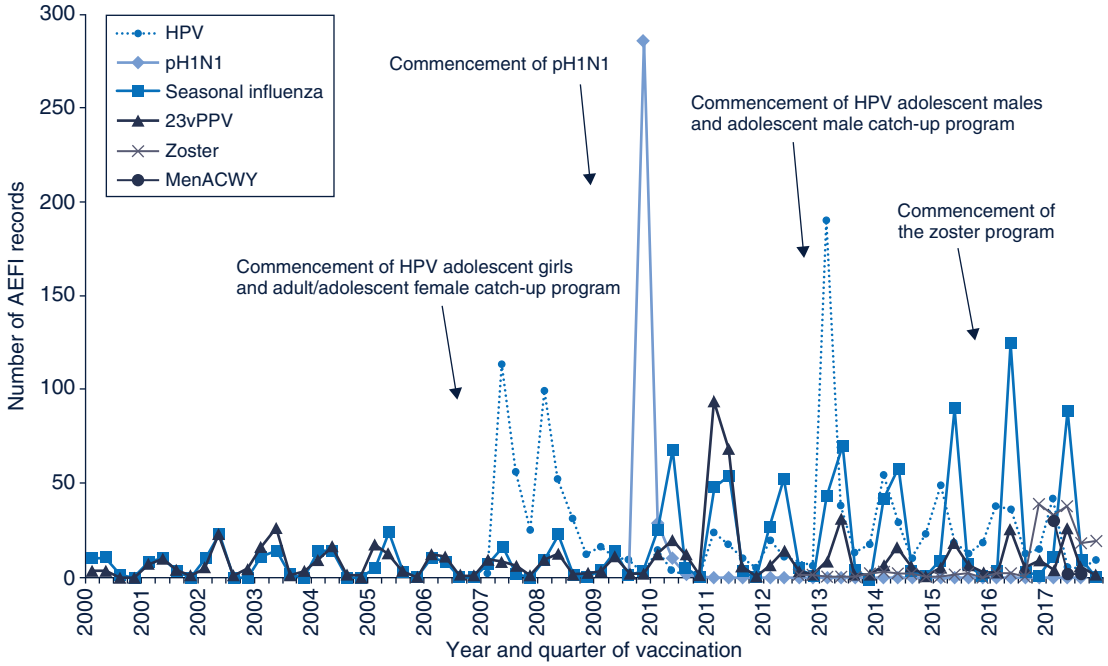

Figure 3. Adverse events following immunisation for people aged ≥7 years in frequently reported vaccines, NSW, 2000–2017, by quarter of vaccination.

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

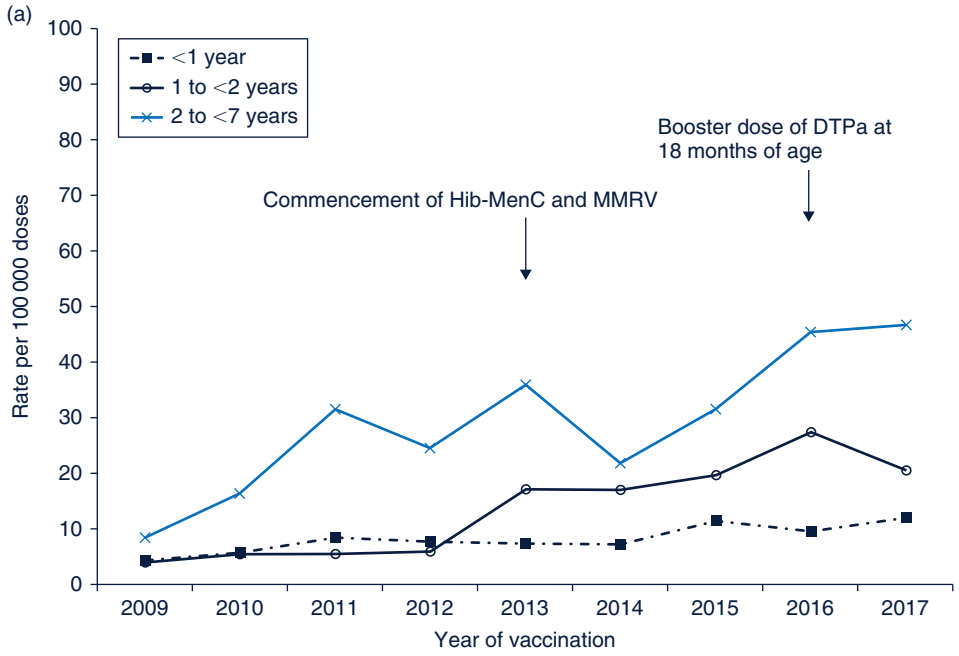

Figure 4a. Reporting rates of adverse events following immunisation for NSW per 100 000 doses, 2009–2017, for people aged less than 7 years, by year of vaccination.

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

Age group and vaccine

Figure 4a shows that the reporting rates were highest in 2–6 year olds during 2017 (46.5 per 100 000 doses, 95% CI 36.3–58.6) and appeared to have increased compared with 2016 (44.7 per 100 000 doses, 95% CI 34.7–56.6), although this increase was not statistically significant. Also, no statistically significant changes were observed in children less than or equal to 1 year in 2017 compared with 2016, 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 a gross underestimate overall, hence we only estimated population-based AEFI reporting rates as shown in Figure 4b. There was a 55% increase in reports in the 65 years and older age group during 2017 (12.5 per 100 000 population) compared with 2016 (8.1 per 100 000 population). This increase in those aged 65 years and older was mainly associated with zoster vaccine. There were no significant changes in reporting rates for those aged between 7 and 64 years.

Reporting rates per 100 000 doses in children aged less than 7 years did not change significantly for any existing vaccine (Table 1). However, 13vPCV was recorded in 63 reports and 16 of these were coded as serious (Tables 1 and 2). For those aged between 12 and 17 years, there were 54 HPV vaccine-related reports, and of these seven were coded as serious. In those aged 65 years and over, zoster vaccine was recorded in 104 reports, and of these four were reported as serious (Tables 1 and 2). Overall, as shown in Table 2, the most commonly reported reactions were associated with seasonal influenza (17.7%), followed by zoster (16.5%), HPV vaccine (9.5%), 13vPCV (9.2%), DTPa-IPV-HepB-Hib (9.1%), dTpa (8.5%), rotavirus (8.3%), DTPa-IPV (6.7%) and DTPa (6.6%). Fifteen per cent of all reported adverse events were categorised as serious.

In 2017, of the 113 zoster vaccine-related AEFI, 89% (101) were reported in adults aged 70 years and over.

Reactions

The distribution and frequency of reactions listed in AEFI records for 2017 are shown in Table 3. The most frequently reported adverse events were injection site reaction (ISR) (215), rash (107), pyrexia (99), pain (58), headache (48) and vomiting (43).

Of the total 215 cases with ISR, 54% (117) were in those aged ≥7 years. Also, more than half of the cases with rash (60) were reported in those aged ≥7 years, while 54% (53) of cases with pyrexia were observed in children aged <7 years.

Anaphylaxis was reported in 10 people, nine of whom were aged ≥7 years. All recovered rapidly following adrenaline administration.

There were 19 reported cases of syncope and eight cases of presyncope during 2017. Eighty-nine per cent (17) of cases

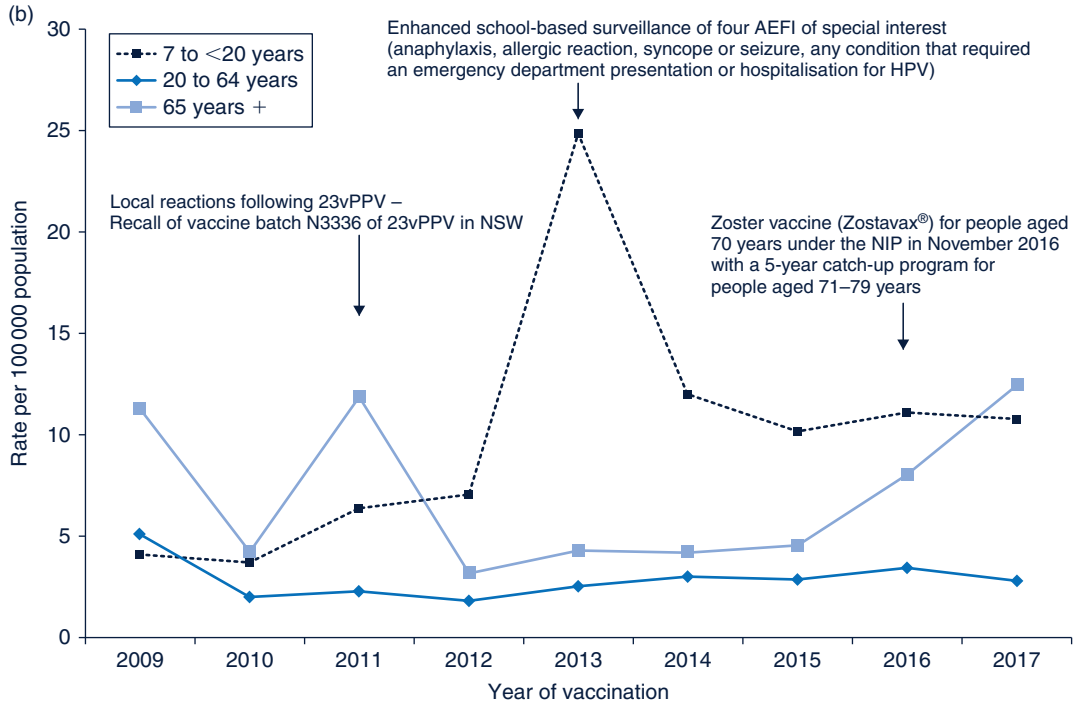

Figure 4b. Reporting rates of adverse events following immunisation for NSW per 100 000 population, 2009–2017, for people aged ≥7 years, by year of vaccination.

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

of syncope and 75% (6) of cases of presyncope were reported in persons aged 7 years and older.

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

There were no cases of Guillain–Barre syndrome (GBS) or intussusception during this reporting period.

Severity

Approximately 15% (101) of reported events were defined as 'serious' (i.e. recovery with sequelae, requiring hospitalisation, experiencing a life-threatening event or death) in 2017. As shown in Figure 1, the overall percentage (15%) of 'serious' events in this reporting period slightly increased (13%, $n = 81$) compared with the previous reporting period.

Reactions recorded as 'serious' included pyrexia (21), injection site reaction (18), vomiting (11), rash (10), syncope (10), anaphylactic reaction (10), convulsions (6) and others as shown in Table 3. Eighty-three per cent (5) of convulsions were febrile convulsions seen in children aged <7 years.

Fifteen serious adverse events were reported following DTPa-IPV-HepB-Hib vaccination in children aged <1 year, and all were administered with 13vPCV and rotavirus vaccine at the same visit. Reactions included hypotonic hyporesponsive episode (4), pyrexia (2), rash (2), acute disseminated encephalomyelitis (1), erythema (1), peripheral neuropathy (1), malaise (1), crying (1), seizure (1) and pallor (1).

In children aged 12–17 years there were 11 serious adverse events following meningococcal ACWY vaccination. Reactions included anaphylactic reaction (3), injection site reaction (3), syncope (2), pyrexia (1), diarrhoea (1) and nasopharyngitis (1).

Indigenous status

Two per cent (16/683) of reported AEFI were in Aboriginal and Torres Strait Islander people. The majority (69%, $n = 11$) of these were recorded as 'non serious'.

Deaths

One death was reported as temporally associated with receipt of vaccines in NSW in this reporting period.

- A 71-year-old man died in early January 2017, a month after receiving one dose of the zoster vaccine. The man had chronic lymphocytic leukaemia, a contraindication to the live zoster vaccine. The cause of death was disseminated varicella-zoster virus infection with meningoencephalitis and aspiration pneumonia resulting in death. This death was investigated by the TGA and a clear causal relationship with vaccination was found.[28]

Table 1. Vaccine types listed as 'suspected' in records of adverse events following immunisation for four age groups (<7, 12–17, 18–64 and ≥65 years), NSW, 2017

Vaccine[a]	AEFI records[b] 2017	Serious[c] 2017	Reporting rate per 100 000 doses[d] 2017	
	n	*n*	Rate	(95% CI)
<7 years				
13vPCV	63	16	22.8	(17.5–29.2)
Hexavalent (DTPa-IPV-HepB-Hib)	61	15	22.4	(17.1–28.7)
Rotavirus	57	14	32.1	(24.3–41.6)
DTPa-IPV	46	3	47.1	(34.5–62.9)
DTPa	42	5	43.6	(31.4–59.0)
MenB-MC	36	9	–	–
MMRV	35	5	36.3	(25.3–50.5)
Measles-mumps-rubella	21	2	20.4	(12.6–31.2)
Hib-MenC	12	2	12.1	(6.2–21.1)
Seasonal influenza	8	2	29.6	(12.8–58.3)
12–17 years				
HPV	54	7	36.6	(27.5–47.7)
dTpa	35	3	45.7	(31.9–63.6)
MenACWY	30	11	26.3	(17.7–37.5)
Varicella	12	3	20.1	(10.4–35.1)
Seasonal influenza	6	1	28.0	(10.3–60.9)
Hepatitis B	1	0	–	–
18–64 years				
Seasonal Influenza	69	8	–	–
dTpa	16	0	–	–
23vPPV	7	1	–	–
MMR	6	1	–	–
Hepatitis B	6	1	–	–
Yellow fever	3	0	–	–
MenC	1	0	–	–
≥65 years				
Zoster	104	4	–	–
Seasonal influenza	33	5	–	–
23vPPV	30	3	–	–
dTpa	1	0	–	–

AEFI: adverse events following immunisation.
[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 2017 and 31 December 2017. 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.

In addition to the above death, two miscarriages (spontaneous abortion) were reported in this period:

- A 36-year-old woman had an anembryonic pregnancy (blighted ovum) and a subsequent miscarriage. She had conceived a few days before having the influenza vaccine. This miscarriage was reported by a member of the public. No further details were available for this case; however, miscarriages in the early weeks of pregnancy affect 1 in 5 pregnancies in Australia.[29]
- A 44-year-old woman at 6 weeks gestation was given the Fluarix Tetra vaccine. She was undergoing fertility treatment with a donor egg and had embryo transfer on 5 March 2017. She was vaccinated on 29 March and developed vaginal spotting later on the day of vaccination. Ultrasound on 31 March confirmed a fetal heart beat, but she miscarried in the evening. The patient is aware that early miscarriage is common, but felt that it may be significant that it coincided with administration

Table 2. Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI), NSW, 2017

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	121	(17.7)	104	(86)	17	(14)	8	(7)	108	(89)
Zoster	113	(16.5)	105	(93)	4	(4)	0	(0)	108	(96)
HPV	65	(9.5)	24	(37)	10	(15)	2	(3)	59	(91)
13vPCV	63	(9.2)	2	(3)	16	(25)	63	(100)	0	(0)
DTPa-IPV-HepB-Hib	62	(9.1)	4	(6)	6	(10)	61	(98)	1	(2)
dTpa	58	(8.5)	22	(38)	7	(12)	2	(3)	55	(95)
Rotavirus	57	(8.3)	5	(9)	14	(25)	57	(100)	0	(0)
DTPa-IPV	46	(6.7)	43	(93)	3	(7)	45	(98)	1	(2)
DTPa	45	(6.6)	20	(44)	6	(13)	40	(89)	5	(11)
MenB-MC	42	(6.1)	37	(88)	12	(29)	36	(86)	6	(14)
Meningococcal-ACWY	40	(5.9)	37	(93)	16	(40)	5	(13)	34	(85)
23vPPV	38	(5.6)	28	(74)	4	(11)	0	(0)	36	(95)
MMRV	36	(5.3)	14	(39)	5	(14)	35	(97)	1	(3)
MMR	31	(4.5)	14	(45)	4	(13)	21	(68)	9	(29)
Varicella	15	(2.2)	4	(27)	4	(27)	1	(7)	14	(93)
Hib-MenC	14	(2.0)	3	(21)	3	(21)	12	(86)	2	(14)
Hepatitis B	12	(1.8)	4	(33)	4	(33)	2	(17)	10	(83)
Yellow fever	10	(1.5)	6	(60)	0	(0)	1	(10)	5	(50)
Hepatitis A	8	(1.2)	3	(38)	2	(25)	1	(13)	7	(88)
Typhoid	8	(1.2)	2	(25)	2	(25)	1	(13)	6	(75)
Q fever	4	(0.6)	4	(100)	0	(0)	0	(0)	4	(100)
Rabies	4	(0.6)	3	(75)	0	(0)	0	(0)	4	(100)
Hepatitis A-Typhoid	4	(0.6)	3	(75)	0	(0)	0	(0)	4	(100)
MenC	4	(0.6)	2	(50)	0	(0)	0	(0)	4	(100)
Hib	1	(0.1)	0	(0)	0	(0)	1	(100)	0	(0)
Total[d]	683	(100.0)	507	(74)	101	(15)	264	(39)	419	(61)

[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 121 AEFI records; this was the only suspected vaccine in 86% of the 121 AEFI records,14% were defined as 'serious' and 89% 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.

of the influenza vaccine. This miscarriage was reported by a member of the public.

Discussion

There was a slight increase in AEFI population-based rates in 2017 compared with 2016; however, this increase was not statistically significant. This increase appeared to be associated with the zoster vaccine for people aged 70–79 years being funded from 1 November 2016, and the meningococcal ACWY vaccinations in adolescents. AEFI reports have increased over the past decade. This is partially associated with 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.

From May 2017, a meningococcal ACWY conjugate vaccine was funded in NSW for Year 11–12 students and persons aged 15–19 years who no longer attend school. NSW Health distributed 120 381 doses of meningococcal ACWY vaccine between 1 May 2017 and 31 December 2017, and 114 253 vaccines were administered in the School Vaccination Program. During this first year of implementation of the program in NSW, there were 39 AEFI reports associated with meningococcal ACWY vaccine, and of these 30 (76.9%) were in children aged 12–17 years, 5 (12.8%) in children aged <7 years and 4 (10.3%)

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, 2017[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]	215	109	(51)	18	(8)	95	(44)	117	(54)
Rash[g]	107	40	(37)	10	(9)	41	(38)	64	(60)
Pyrexia	99	10	(10)	21	(21)	53	(54)	46	(46)
Pain	58	5	(9)	7	(12)	11	(19)	45	(78)
Headache	48	2	(4)	5	(10)	1	(2)	45	(94)
Vomiting	43	3	(7)	11	(26)	23	(53)	19	(44)
Nausea	29	0	(0)	4	(14)	1	(3)	27	(93)
Urticaria	27	16	(59)	4	(15)	12	(44)	15	(56)
Malaise	21	1	(5)	3	(14)	3	(14)	17	(81)
Diarrhoea	19	0	(0)	3	(16)	10	(53)	9	(47)
Syncope	19	12	(63)	10	(53)	1	(5)	17	(89)
Dizziness	18	0	(0)	1	(6)	2	(11)	16	(89)
Myalgia	18	1	(6)	3	(17)	1	(6)	17	(94)
Erythema	17	4	(24)	2	(12)	10	(59)	7	(41)
Pruritus	17	2	(12)	4	(24)	2	(12)	15	(88)
Paraesthesia	16	1	(6)	3	(19)	0	(0)	15	(94)
Fatigue	15	0	(0)	2	(13)	2	(13)	13	(87)
Chills	14	0	(0)	2	(14)	0	(0)	14	(100)
Cough	14	0	(0)	6	(43)	7	(50)	7	(50)
Extensive limb swelling	13	9	(69)	1	(8)	6	(46)	7	(54)
Lethargy	13	0	(0)	4	(31)	5	(38)	8	(62)
Irritability	13	0	(0)	2	(15)	12	(92)	1	(8)
Dyspnoea	13	0	(0)	4	(31)	0	(0)	13	(100)
Abdominal pain	12	0	(0)	2	(17)	4	(33)	8	(67)
Injected limb mobility decreased	12	1	(8)	0	(0)	1	(8)	11	(92)
Arthralgia	10	0	(0)	2	(20)	0	(0)	10	(100)
Anaphylactic reaction	10	8	(80)	10	(100)	1	(10)	9	(90)
Rhinorrhoea	9	0	(0)	3	(33)	5	(56)	4	(44)
Hypotonic-hyporesponsive episodes	9	8	(89)	4	(44)	9	(100)	0	(0)
Presyncope	8	4	(50)	1	(13)	2	(25)	6	(75)
Pallor	7	0	(0)	1	(14)	3	(43)	3	(43)
Oropharyngeal pain	6	0	(0)	1	(17)	3	(50)	3	(50)
Convulsions[h]	6	3	(50)	6	(100)	5	(83)	1	(17)
Decreased appetite	5	0	(0)	0	(0)	1	(20)	4	(80)
Hyperhidrosis	4	0	(0)	0	(0)	0	(0)	4	(100)
Chest discomfort	4	0	(0)	0	(0)	0	(0)	4	(100)
Crying	4	1	(25)	1	(25)	4	(100)	0	(0)
Tachycardia	3	0	(0)	2	(67)	0	(0)	3	(100)
Somnolence	3	0	(0)	1	(33)	3	(100)	0	(0)
Hypoaesthesia	3	0	(0)	1	(33)	0	(0)	3	(100)
Swelling face	1	0	(0)	1	(100)	0	(0)	1	(100)
Haematochezia	1	1	(100)	0	(0)	1	(100)	0	(0)
Lymphadenitis	1	1	(100)	0	(0)	0	(0)	1	(100)

[a]A complete list of adverse reactions as classified by individual Preferred Terms (PTs) is available on request.
[b]Selected reported adverse events reported during January 2017–December 2017. Note: for injection site reaction, rash and convulsions, PTs were grouped as described below.
[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, partial seizures and febrile convulsion.
Source: Adverse Events Management System database, Therapeutic Goods Administration.

in adults aged older than 17 years. The majority of the reactions were mild.

During 2017, 108 AEFI were associated with the zoster vaccine and 104 (96.3%) of these were reported in adults aged 65 years and older. AusVaxSafety (an active sentinel vaccine safety surveillance system, http://www.ausvaxsafety.org.au/) also monitored the safety of zoster vaccine and found no safety signal during the program.[30] Both surveillance systems (TGA and AusVaxSafety) reported similar milder reactions, e.g. injection site reactions and rash. In addition, more serious reactions such as herpes zoster and vaccination errors, particularly vaccination of immunocompromised persons, were also reported to both systems as previously published.[28,31] The death due to disseminated infection following vaccination reported during this period followed a vaccination error (vaccine given to an immunocompromised person).[28] This live vaccine (Zostavax®) is contraindicated for immunocompromised people. This case highlights the importance of ensuring that immunisation providers are aware of vaccine contraindications. Following this event, NSW Health and other jurisdictions across Australia undertook a range of activities to raise awareness of the contraindications of this vaccine with providers.

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.[32,33] Miscarriages affect approximately 1 in 5 pregnancies that are less than 20 weeks gestation.[29] It is likely that the two miscarriages (spontaneous abortions) reported in 2017 were coincidental to vaccination; however, there was not sufficient information available to conduct a causality assessment. 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 reactions in 2017. Vaccines such as DTPa-IPV, DTPa, MMRV, rotavirus, seasonal influenza, 13vPCV and Infanrix hexa 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.[34]

Conclusion

Overall, the total number of reported AEFI increased slightly during 2017 compared with 2016. 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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