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Surveillance of adverse events following immunisation in Australia annual report, 2019

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Surveillance of adverse events following immunisation in Australia annual report, 2019

Aditi Dey, Han Wang, Helen Quinn, Alexis Pillsbury, Catherine Glover, Megan Hickie, Nicholas Wood, Frank Beard, Kristine Macartney

Abstract

This report summarises Australian spontaneous surveillance data for adverse events following immunisation (AEFI) for 2019 reported to the Therapeutic Goods Administration (TGA) and describes reporting trends over the 20-year period from 1 January 2000 to 31 December 2019. There were 3,782 AEFI records for vaccines administered in 2019, an annual AEFI reporting rate of 14.9 per 100,000 population. There was an 11.8% decrease in the overall AEFI reporting rate in 2019 compared to 2018 (16.9 per 100,000 population). This decrease in the AEFI reporting rate in 2019 was mainly attributable to a decline in reported adverse events related to the human papillomavirus (HPV), dTpa, meningococcal ACWY and seasonal influenza vaccines. AEFI reporting rates for most individual vaccines in 2019 were similar to 2018. The most commonly-reported adverse events were injection site reaction (35.8%), rash (16.6%), pyrexia (15.3%), vomiting (8.1%), urticaria (5.8%), pain (5.8%) and headache (5.7%). There were five deaths reported to the TGA. In one report, the timing and clinical findings were consistent with a causal association with vaccination. In the remaining four reports, no clear causal relationship with vaccination was found.

Key words: AEFI, adverse events, vaccines, surveillance, immunisation, vaccine

Introduction

This report summarises national spontaneous surveillance data for adverse events following immunisation (AEFI) reported to the Therapeutic Goods Administration (TGA). The report focuses on AEFI reported for vaccines administered during 2019 and trends in AEFI reporting over the 20-year period 1 January 2000 – 31 December 2019.

An adverse event following immunisation is defined as any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine.¹ The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.¹ Thus, AEFI may be caused by a vaccine(s) or may be coincidental. Adverse events may also include conditions that occur following the incorrect handling and/or administration of a

vaccine(s). The post-marketing surveillance of AEFI is particularly important to detect signals of rare, late onset or unexpected events, which are difficult to detect in pre-registration vaccine trials.

Reports summarising national AEFI surveillance data have been published regularly since 2003.^{2–15} Trends in reported AEFI are influenced by changes to vaccine funding and availability through the National Immunisation Program (NIP), and impact of these changes on the interpretation of trend data has been described in previous reports published since 2003.^{2–15} Changes to the NIP since 2005 are summarised in the Appendix, in Table A.1.

To assist readers, the Appendix also contains a glossary of the abbreviations of the vaccines referred to in this report.

Recent changes that impact on AEFI surveillance data presented in this 2019 report are:ⁱ

December 2019:

- In SA, multicomponent recombinant meningococcal B vaccine catch-up for children from 12 months to < 4 years of age ceased on 31 December 2019.

April 2019:

- Meningococcal ACWY conjugate vaccine funded under the NIP for adolescents aged 14–16 years delivered through a school-based program and adolescents aged 15 to 19 years delivered through primary care providers as part of an ongoing catch-up program.

March 2019:

- NT: annual seasonal influenza vaccination program funded for all children aged 6 months to < 5 years.

February 2019:

- Annual seasonal influenza vaccination funded on the national childhood vaccination schedule for all Australian children aged 6 months to < 5 years.
- Aboriginal and Torres Strait Islander children and adolescents aged 5–14 years funded for influenza vaccine under NIP.

October 2018:

- Multicomponent recombinant meningococcal B vaccine funded by SA for children 6 weeks to 12 months of age, with catch-up for children from 12 months to < 4 years of age.

July 2018:

- 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 trivalent influenza vaccines (high-dose and adjuvanted) funded nationally for all adults aged ≥ 65 years.
- Annual seasonal influenza vaccination funded by ACT, NSW, Qld, SA, Tas and Vic for all children aged 6 months to < 5 years.
- Meningococcal ACWY conjugate vaccine funded by SA for Aboriginal and Torres Strait Islander children and adolescents aged 12 months to 19 years living in the Eyre and Far North, and Flinders and Upper North regions.

February 2018:

- Meningococcal ACWY conjugate vaccine funded by ACT for grade 10 students and persons aged 16–19 years who no longer attend school.
- A 2-dose schedule of 9vHPV funded for adolescents aged 12–14 years, delivered through a school-based program; 4vHPV ceased to be used in the program.

January 2018:

- Meningococcal ACWY conjugate vaccine funded by WA for children aged 12 months to < 5 years.
- Meningococcal ACWY school-based vaccination program funded for all NSW secondary school students in Years 10 and 11, as well as adolescents aged 15 to 19 years who have not received the vaccine at school.

i Jurisdictional abbreviations: ACT (Australian Capital Territory), NSW (New South Wales), NT (Northern Territory), Qld (Queensland), SA (South Australia), Tas. (Tasmania), Vic. (Victoria), WA (Western Australia).

Methods

AEFI are reported to the TGA by state and territory health departments, health professionals, vaccine companies and members of the public.¹⁶ All reported AEFI are assessed using internationally-consistent criteria¹⁷ and entered into the Australian Adverse Event Management System (AEMS) database. Where there is insufficient information to determine causality for select serious adverse events, the TGA will attempt to contact the reporter on up to three occasions to elicit further information. Data mining and signal detection activities are also conducted by the TGA.

AEFI data

De-identified information on all AEFI reported to the TGA from 1 January 2000 to 31 December 2019 and stored in the AEMS database were released to the National Centre for Immunisation Research and Surveillance (NCIRS) in March 2020. Readers are referred to previous AEFI surveillance reports for a description of the surveillance system.^{3,6}

Recordsⁱⁱ contained in the AEMS database were eligible for inclusion in the analysis if a vaccine was recorded as ‘suspected’ⁱⁱⁱ of causal involvement in the reported adverse event and *either*

- a. the vaccination occurred between 1 January 2000 and 31 December 2019, or
- b. for records where the vaccination date was not recorded, the date of onset of symptoms or signs occurred between 1 January 2000 and 31 December 2019.

ii The term ‘AEFI record’ is used throughout this report because a single AEFI notification/report to the TGA can generate more than one record in the AEMS database. This may occur if there is a time sequence of separate adverse events in a single patient, such as local and systemic adverse events.

iii 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.

Study definitions of AEFI outcomes

Australian sponsors (vaccine companies) are required to apply seriousness coding to vaccine AEFI reports to ensure legislated requirements are met. Reports are coded as ‘serious’ or ‘non-serious’ based on criteria similar to those used by the World Health Organization¹⁷ and the United States of America’s Vaccine Adverse Events Reporting System.¹⁸ An adverse event report is defined as ‘serious’ if it meets one or more of the following criteria: (1) results in death; (2) is life-threatening; (3) requires inpatient hospitalisation or prolongation of existing hospitalisation; (4) results in persistent or significant disability/incapacity; (5) is a congenital anomaly/birth defect; or (6) is a medically important event or reaction.

Typically, each AEFI record lists several reaction terms that are symptoms, signs and/or diagnoses that have been coded by TGA staff from the reporter’s description into standardised terms using the Medical Dictionary for Regulatory Activities (MedDRA).^{19,20}

A limitation of our report was interpretation of the ‘serious’ code for reported adverse events which, 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.

In reports published previously, in order to analyse the data, MedDRA coding terms were grouped to create a set of reaction categories that were broadly analogous to the adverse events listed in previous editions of the *Australian Immunisation Handbook*.^{16,21} However, the methodological framework of reporting of adverse events was revised in 2014 and an amended format for AEFI analyses using MedDRA preferred terms (PTs) was adopted.²² Since 2014, MedDRA PTs have been used for analysis in our reports. Grouping of adverse events using PTs is more comparable with data from other

countries and internationally accepted.^{23–25} In conjunction with the currently used national vaccine-specific reporting form,²⁶ the use of PTs allows better reflection of post-marketing surveillance data on vaccines in Australia.

Data analysis

All data analyses were performed using SAS software version 9.4.²⁷ Average annual population-based AEFI reporting rates were calculated for each state and territory and by age group, using 2019 population estimates obtained from the Australian Bureau of Statistics.²⁸ All rates are presented as average annual rates per 100,000 population. AEFI reporting rates per 100,000 administered doses were estimated where information was available on the number of doses administered. The number of administered doses of each of the vaccines given was obtained from the Australian Immunisation Register (AIR), a national population-based register.²⁹ From 30 September 2016, the Australian Childhood Immunisation Register (ACIR) became a whole-of-life register (AIR), with the ability to record all vaccinations for people of all ages given by a registered vaccination provider.³⁰ As part of the transition to a whole-of-life register, from late 2018, all vaccinations given through school-based programs should be recorded on the AIR.

Notes on interpretation

Caution is required when interpreting the data presented in this report. Due to reporting delays and late onset of some AEFI, the data are considered preliminary, particularly for the fourth quarter of 2019. Data published in previous reports may differ from those presented in this report for the same period because this report has been updated to include delayed notifications to the TGA that were not included in prior publications. Data can also differ because records may be updated and recoded when follow-up information is received or when vaccine-specific analyses are conducted.

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

It is important to note that this report is based on vaccine information and MedDRA PTs collated in the AEMS database and not on comprehensive clinical notes or case reviews. The reported symptoms, signs and diagnoses in each AEFI record in the AEMS database are temporally associated with vaccination but are not necessarily causally associated with a vaccine or vaccines.

For children aged 7 years to < 17 years, AEFI reporting rates for HPV, dTpa booster and meningococcal ACWY vaccines should be interpreted with caution due to possible under-reporting/transitioning issues of school-based vaccinations to the AIR.

Comparison with online Database of Adverse Events Notifications (DAEN)

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

Results

The AEMS database included a total of 3,782 records where the date of vaccination (or onset of adverse event, if vaccination date was not reported) was between 1 January and 31 December 2019. Of these, 54.6% (2,066) were in females; 43.6% (1,649) in males; and 1.8% (67) did not mention their sex (missing/unspecified/indeterminate). Also, 1.5 % (58) were reported in Aboriginal and Torres Strait Islander people.

In 2019, analysis of AEFI reported by 'organisation type' showed that 70.2% (2,655) of AEFI were reported to the TGA via states and territories; 9.3% (353) by clinic/practice; 2.1% (81) by hospitals; 0.9% (34) by community pharmacy; 0.5% (18) by community centre; 0.1% (3) by aged care facility; 0.8% (30) by other organisation type; and 16.1% (608) did not mention their organisation type (missing data/unknown). Analysis of AEFI reporting was also undertaken by 'sender type' that showed 75.3% (2,847) of AEFI were reported by state and territory health departments; 13.9% (524) were by health professionals; 7% (264) by patient/consumer; and 3.9% (147) by pharmaceutical company.

Reporting trends

The overall AEFI reporting rate for 2019 was 14.9 per 100,000 population compared with 16.9 per 100,000 in 2018. The highest rate over the 2000–2019 period was observed in 2010 (17.4 per 100,000), predominantly due to reported AEFI in children following vaccination with the pandemic and 2010 seasonal trivalent influenza vaccines.¹²

Most reported events in 2019 were recorded as non-serious, similar to previous years (Figure 1).^{10,11} Figures 2, 3 and 4 demonstrate marked variations in reporting levels in all age groups associated with changes to the NIP. The decrease in reports in 2019 could be associated with NIP schedule changes in 2018–2019 (as shown in Table A.1), particularly for schedule changes to HPV immunisation (3-dose 4vHPV to 2-dose 9vHPV) in July 2018.

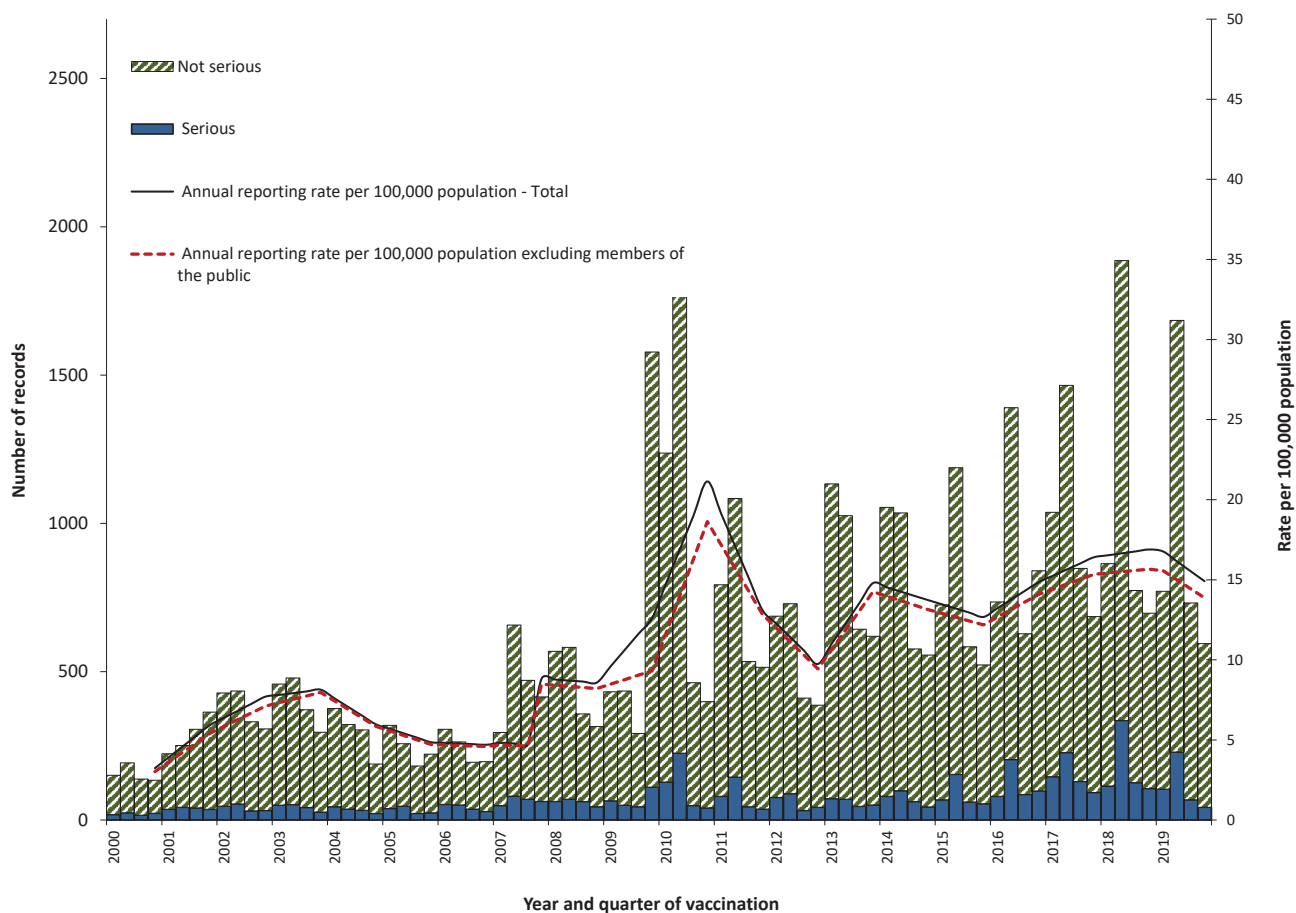
A seasonal pattern of AEFI reporting was apparent in 2019 as in previous years, with the highest number of AEFI notifications for vaccinations administered in the first half of the year (Figure 1). This corresponds to the months when influenza vaccine is given and older Australians may be more likely to be given 23vPPV in conjunction with the influenza vaccine (April to June). Considerably more AEFI reports following influenza vaccination were received in each year from 2010 onwards compared to previous (pre-pandemic) years (Figure 4).

Age distribution

The highest age-specific AEFI reporting rate per 100,000 population occurred in children aged 1 to < 2 years, the age group scheduled to receive meningococcal ACWY vaccination at 12 month of age; the booster dose of DTPa at 18 months of age; and the change in schedule for 13vPCV from 2, 4 and 6 months of age to 2, 4 and 12 months of age (Figure 5). Compared with 2018, AEFI reporting rates in 2019 declined across most age groups; however, there was a slight increase observed in children aged 2 to < 7 years (Figure 5).

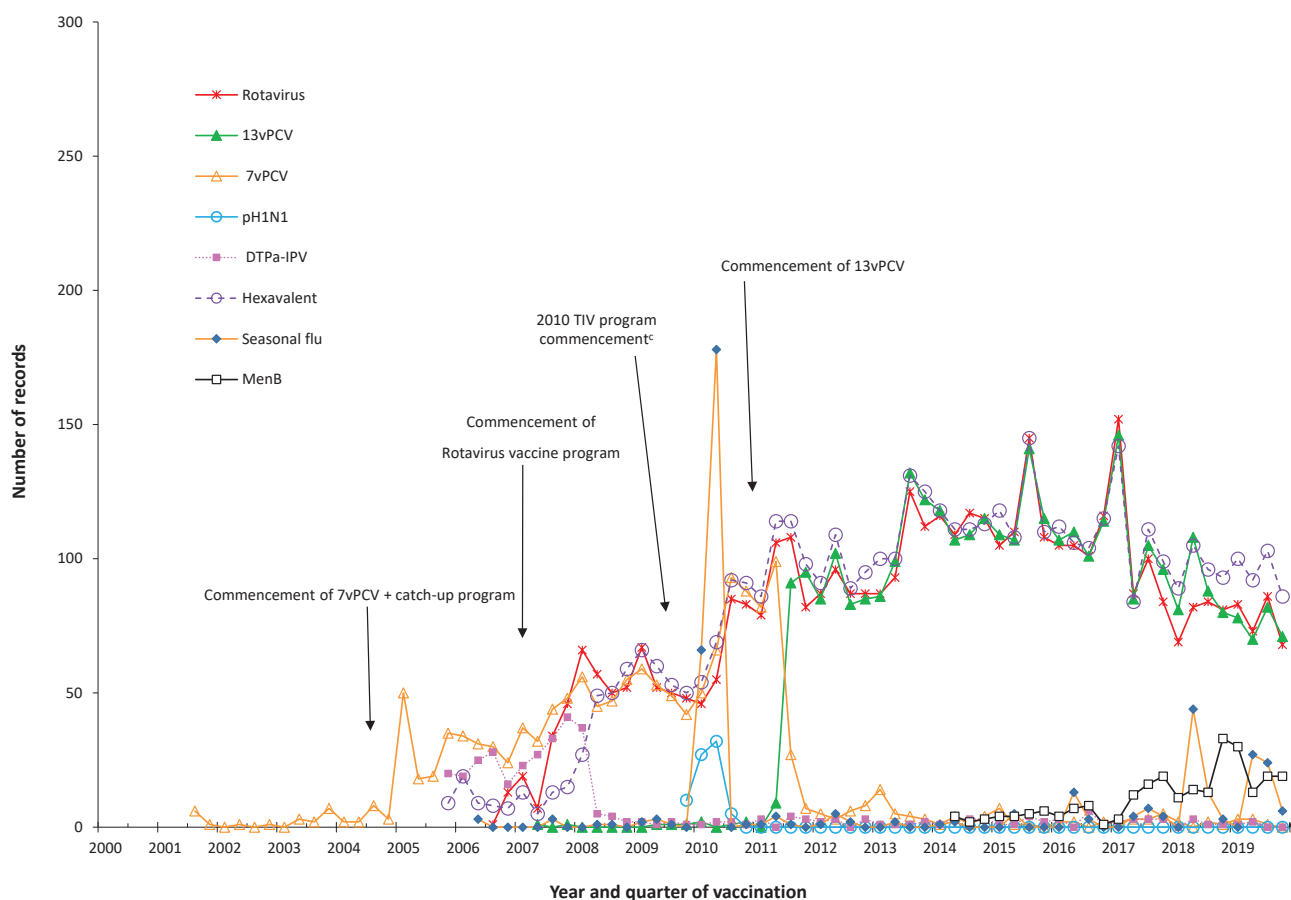
There were overlapping confidence intervals for reporting rates per 100,000 doses for most individual vaccines in 2019 compared to 2018, noting the new additions to the NIP schedule: namely, meningococcal ACWY vaccination in adolescents aged 14–16 years delivered through a school-based program, and in adolescents aged 15 to 19 years delivered through primary care providers as part of an ongoing catch-up program; and annual seasonal influenza vaccination funded on the national childhood vaccination schedule for all Australian children aged 6 months to < 5 years and Aboriginal and Torres Strait Islander children and adolescents aged 5–14 years of age funded for seasonal influenza vaccine (Table 1).

Figure 1: Adverse events following immunisation, AEMS database, 2000 to 2019, by year and quarter of vaccination^a



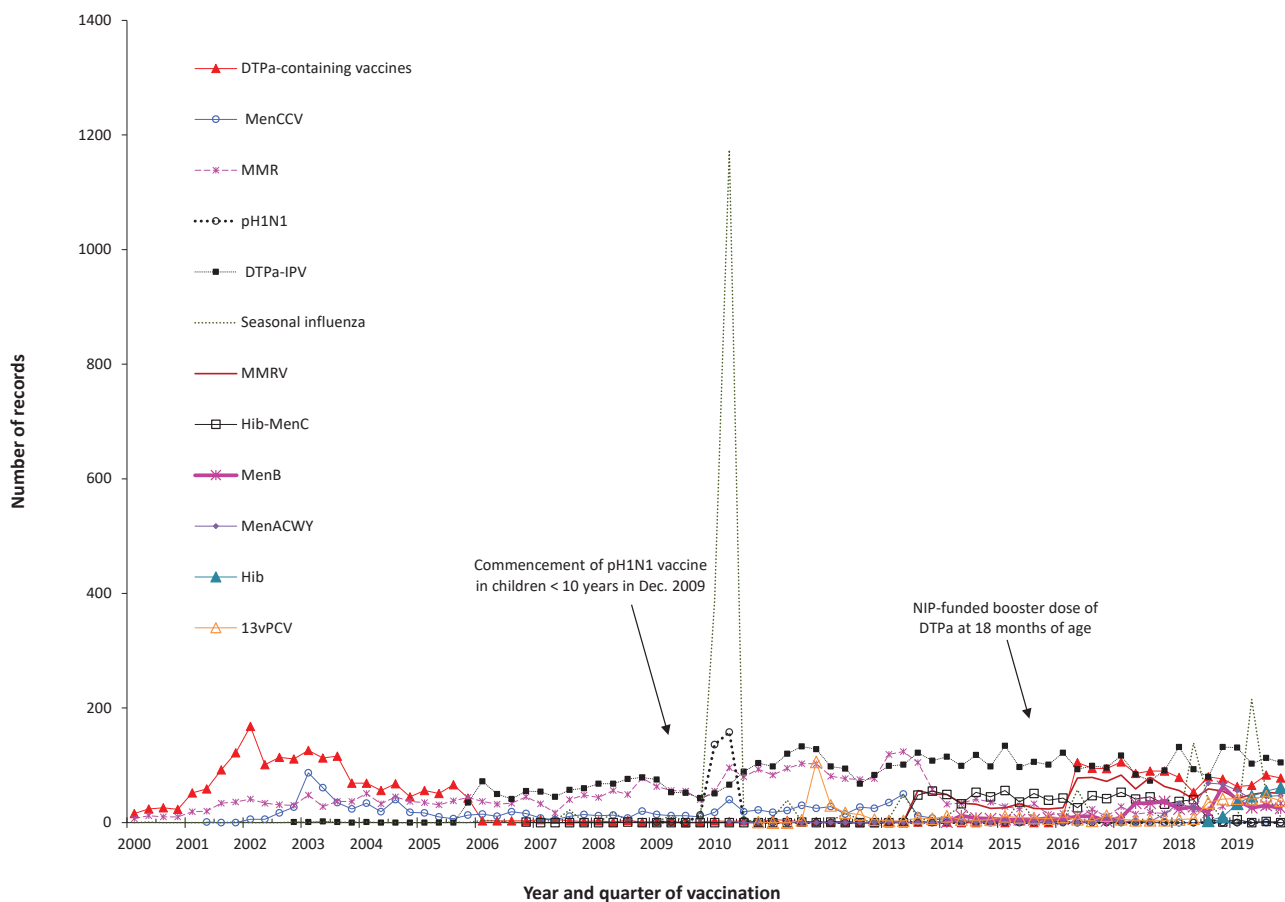
a For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA was used as a proxy for vaccination date.

Figure 2: Adverse events following immunisation for children aged < 1 year, AEMS database, 2000 to 2019, by year and quarter of vaccination^{a,b}



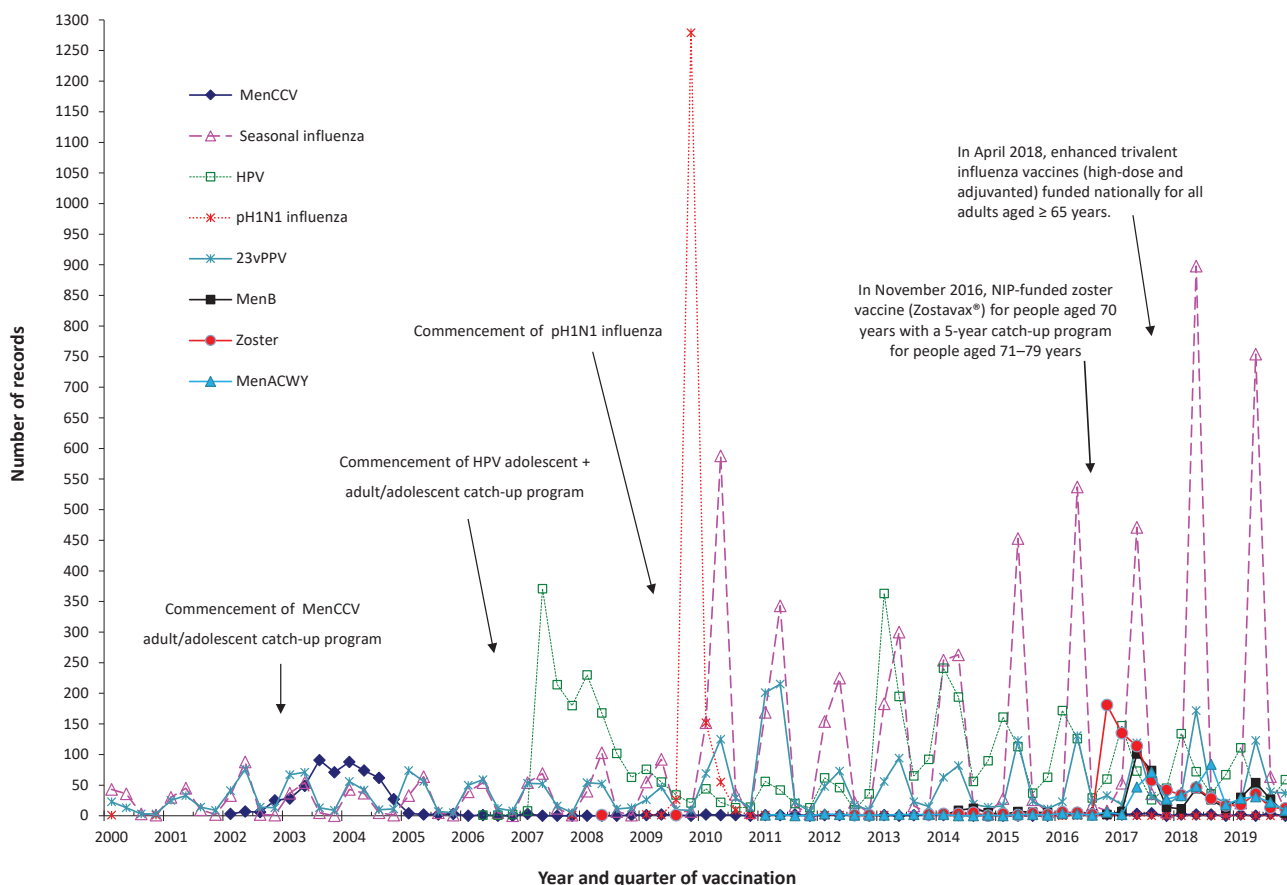
- a For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA was used as a proxy for vaccination date.
- b DTPa-IPV and DTPa-IPV-HepB-Hib (hexavalent) vaccines were introduced into the NIP schedule in November 2005; rotavirus (RotaTeq and Rotarix) vaccines on 1 July 2007; pH1N1 influenza vaccine for children 6 months to 10 years on December 2009; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Indigenous programs to at risk populations; and the 13-valent pneumococcal conjugate vaccine (13vPCV) on 1 July 2011. In July 2018, the schedule for routine childhood vaccination with 13vPCV changed from 2, 4 and 6 months of age to 2, 4 and 12 months of age. Also, MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under the NIP. In October 2018, a multicomponent recombinant meningococcal B vaccine was funded by SA for children 6 weeks to 12 months of age, with catch-up for children from 12 months to < 4 years of age.
- c Safety signal for fever and febrile convulsion found to be due to Seqirus (formerly bioCSL) Fluvax 2010 TIV in children.

Figure 3: Adverse events following immunisation for children aged 1 to < 7 years in frequently-reported vaccines, AEMS database, 2000 to 2019, by year and quarter of vaccination^{a,b}



- a For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA was used as a proxy for vaccination date.
- b DTPa-IPV vaccine was introduced into the NIP schedule in November 2005 replacing DTPa and OPV vaccines; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Indigenous programs to at risk populations; MMRV and Hib–MenC vaccines on July 2013, and HPV vaccine program extended to boys in February 2013. In April 2016, NIP-funded booster dose of DTPa vaccine was introduced at 18 months of age. MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under the NIP. In October 2018, a multicomponent recombinant meningococcal B vaccine was funded by SA for children 6 weeks to 12 months of age, with catch-up for children from 12 months to < 4 years of age. In July 2018, a meningococcal ACWY conjugate vaccine was funded for all children at 12 months of age, replacing combined Hib and meningococcal C-containing vaccine. The Hib dose was moved to 18 months and given as a monovalent Hib vaccine.

Figure 4. Adverse events following immunisation for people aged ≥ 7 years in frequently-reported vaccines, AEMS database, 2000–2019, by year and quarter of vaccination.



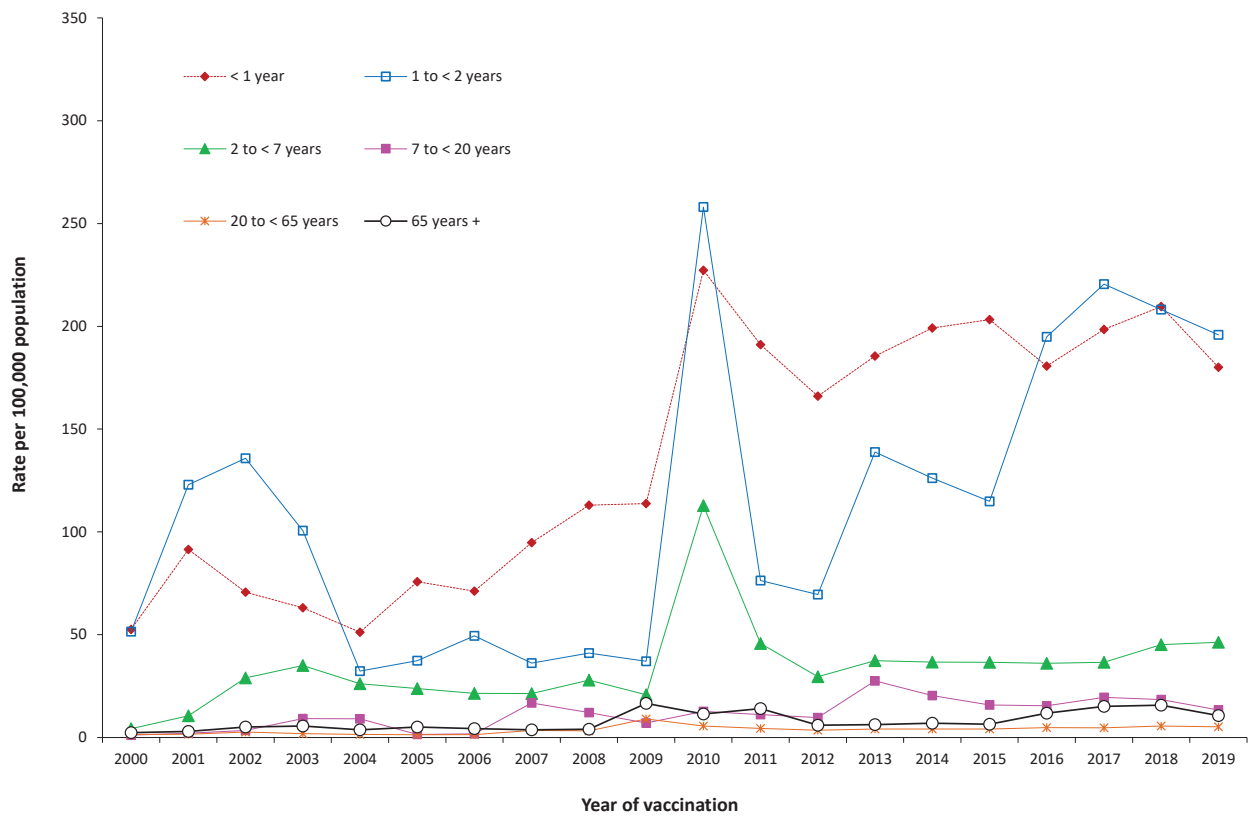
a For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA was used as a proxy for vaccination date.

b MenCCV was introduced into the NIP schedule on 1 January 2003; pH1N1 influenza vaccine for children 6 months to 10 years on December 2009; pH1N1 vaccination for those ≥ 10 years commenced on 30 Sep 2009; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Indigenous programs to at-risk populations; and HPV vaccine program extended to boys in February 2013. MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under the NIP.

In November 2016, zoster vaccine (Zostavax) was NIP-funded for people aged 70 years with a 5-year catch-up program for people aged 71–79 years.

In April 2018, enhanced trivalent influenza vaccines (high-dose and adjuvanted) was funded nationally for all adults aged ≥ 65 years.

Figure 5: Reporting rates of adverse events following immunisation per 100,000 population, AEMS database, 2000 to 2019, by age group and year of vaccination^a



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

Table 1: Vaccine types listed as ‘suspected’ in records of adverse events following immunisation by age groups (< 7, 7–17, 18–64 and ≥ 65 years), AEMS database, 2019

Vaccines ^a	AEFI records ^b (n)	Vaccine doses ^c 2019	Reporting rate ^d per 100,000 doses (95% CI)	
			2019	2018
< 7 years				
DTPa-containing vaccines	1,168	1,468,590	79.5 (75.1–84.3)	77.6 (73.2–82.3)
Hexavalent (DTPa-IPV-HepB-Hib)	417	860,185	48.5 (43.9–53.4)	48.3 (43.8–53.2)
DTPa-IPV	296	298,253	99.2 (88.3–111.2)	94.5 (83.8–106.1)
DTPa	455	310,152	146.7 (133.5–160.8)	143.4 (130.2–157.6)
Pneumococcal conjugate-13vPCV	468	873,935	53.6 (48.8–58.6)	53.4 (48.6–58.7)
Seasonal influenza	331	998,073	33.2 (29.7–36.9)	34.6 (30.3–39.2)
Rotavirus vaccine	316	551,178	57.3 (51.2–64.0)	58.3 (52.0–65.0)
Measles-mumps-rubella	247	315,741	78.2 (68.8–88.6)	73.8 (64.5–84.0)
Meningococcal ACWY	205	368,051	55.7 (48.3–63.9)	67.9 (59.0–77.7)
<i>Haemophilus influenzae</i> type b	199	269,166	73.9 (64.0–84.9)	80.3 (42.8–137.3)
Measles-mumps-rubella-varicella	197	300,161	65.6 (56.8–75.5)	68.1 (59.1–78.0)
Meningococcal B	196	278,673	70.3 (60.8–80.9)	103.6 (90.0–118.7)
Varicella	16	12,478	128.2 (73.3–208.2)	124.7 (76.2–192.6)
Hepatitis B	11	28,211	39.0 (19.5–69.8)	32.2 (15.4–59.2)
Hib-MenC	7	17,037	41.1 (16.5–84.7)	58.4 (47.0–71.7)
Meningococcal C conjugate	1	1,398	71.5 (1.8–398.5)	39.0 (4.7–140.9)
7–17 years				
HPV	211	604,913	34.9 (30.3–39.9)	57.5 (51.1–64.6)
dTpa	148	331,851	44.6 (37.7–52.4)	135.7 (118.3–154.8)

Vaccines ^a	AEFI records ^b (n)	Vaccine doses ^c 2019	Reporting rate ^d per 100,000 doses (95% CI)	
			2019	2018
Seasonal influenza	118	737,619	16.0 (13.2–19.2)	24.4 (19.7–29.8)
Meningococcal B	72	89,090	80.8 (63.2–101.8)	131.0 (102.5–164.9)
Meningococcal ACWY	65	261,898	24.8 (19.2–31.6)	63.2 (53.4–74.2)
Measles-mumps-rubella	8	22,093	36.2 (15.6–71.3)	42.3 (21.1–75.8)
Measles-mumps-rubella-varicella	7	6,861	102.0 (41.0–210.2)	26.8 (3.2–96.7)
23vPPV	7	2,303	304.0 (122.2–626.3)	501.8 (250.8–896.1)
Varicella	7	14,115	49.6 (19.9–102.2)	48.7 (21.1–75.8)
Hepatitis B	6	29,424	20.4 (7.5–44.4)	15.6 (5.1–36.4)
Meningococcal C conjugate	5	3,452	144.8 (47.0–338.0)	38.9 (10.6–99.5)
18–64 years				
Seasonal influenza	519	2,944,531	17.6 (16.2–19.2)	28.5 (26.1–31.0)
dTpa	107	534,387	20.0 (16.4–24.2)	26.4 (21.9–31.6)
23vPPV	45	48,222	93.3 (68.1–124.9)	113.0 (83.0–150.2)
Meningococcal B	38	20,990	181.0 (128.1–248.5)	78.4 (46.5–123.9)
Hepatitis B	31	190,773	16.2 (11.0–23.1)	25.7 (17.9–35.7)
MMR	30	168,536	17.8 (12.0–25.4)	53.7 (39.0–72.1)
Hepatitis A	23	350,820	6.6 (4.2–9.8)	12.5 (9.0–16.8)
Meningococcal ACWY	21	57,525	36.5 (22.6–55.8)	47.4 (32.8–66.3)
Varicella	21	30,725	68.3 (42.3–104.5)	49.2 (26.2–84.2)
Q fever	8	N/A ^e	–	–
≥ 65 years				
Seasonal influenza	210	2,484,182	8.5 (7.3–9.7)	16.4 (14.7–18.3)
23vPPV	164	306,222	53.6 (45.7–62.4)	74.3 (64.3–85.4)

Vaccines ^a	AEFI records ^b (n)	Vaccine doses ^c 2019	Reporting rate ^d per 100,000 doses (95% CI)	
			2019	2018
Zoster	72	173,477	41.5 (32.5–52.3)	49.3 (40.6–59.3)
dTpa	23	98,181	23.4 (14.9–35.2)	22.5 (13.3–35.6)

a Records where at least one of the vaccines shown in the table was suspected of causal involvement in the reported adverse event.

b Number of AEFI records in which the vaccine was coded as 'suspected' of causal involvement in the reported adverse event and the vaccination was administered between 1 January and 31 December 2019. More than one vaccine may be coded as 'suspected' if several were administered at the same time.

c Number of vaccine doses recorded on the AIR and administered between 1 January and 31 December 2019.

d The estimated reporting rate per 100,000 vaccine doses recorded.

e N/A: not applicable.

Table 2: Adverse events following immunisation (AEFI) records, AEMS database, January to December 2019, by jurisdiction

State or territory	AEFI records		Annual reporting rate per 100,000 population ^a			
	n	(%)	'Serious' ^b	Aged < 7 years	Overall rate	(95% CI)
Australian Capital Territory	64	(1.7)	1.2	55.5	15.0	(11.6–19.2)
New South Wales	666	(17.6)	1.1	41.1	8.2	(7.6–8.9)
Northern Territory	57	(1.5)	1.2	71.4	23.2	(17.6–30.0)
Queensland	587	(15.5)	1.0	57.2	11.5	(10.6–12.5)
South Australia	247	(6.5)	1.3	67.7	14.1	(12.4–16.0)
Tasmania	56	(1.5)	0.6	45.4	10.5	(7.9–13.6)
Victoria	1,634	(43.2)	1.8	180.3	24.8	(23.6–26.0)
Western Australia	326	(8.6)	1.2	58.3	12.4	(11.1–13.9)
Other ^c	145	(3.8)	N/A ^d	N/A ^d	N/A ^d	–
Total	3,782	(100.0)	1.8	85.2	14.9	(14.4–15.4)

a Average annual rates per 100,000 population calculated using mid-2019 population estimates (Australian Bureau of Statistics).

b AEFI records defined as 'serious' (i.e. recovery with sequelae, hospitalisation, life-threatening or death).

c Records where the jurisdiction in which the adverse event occurred was not reported or was unclear.

d N/A: not applicable.

For children < 7 years of age, AEFI reporting rates for varicella and MenCCV vaccines should be interpreted with caution since monovalent versions of these vaccines were replaced by combination vaccines in July 2013, and hence very few doses of monovalent vaccine were recorded in 2019. Also, note that Hib-MenC vaccine was replaced by meningococcal ACWY at 12 months and Hib vaccine at 18 months in July 2018.

Geographical distribution

Population-based AEFI reporting patterns varied between states and territories during 2019 (Table 2).

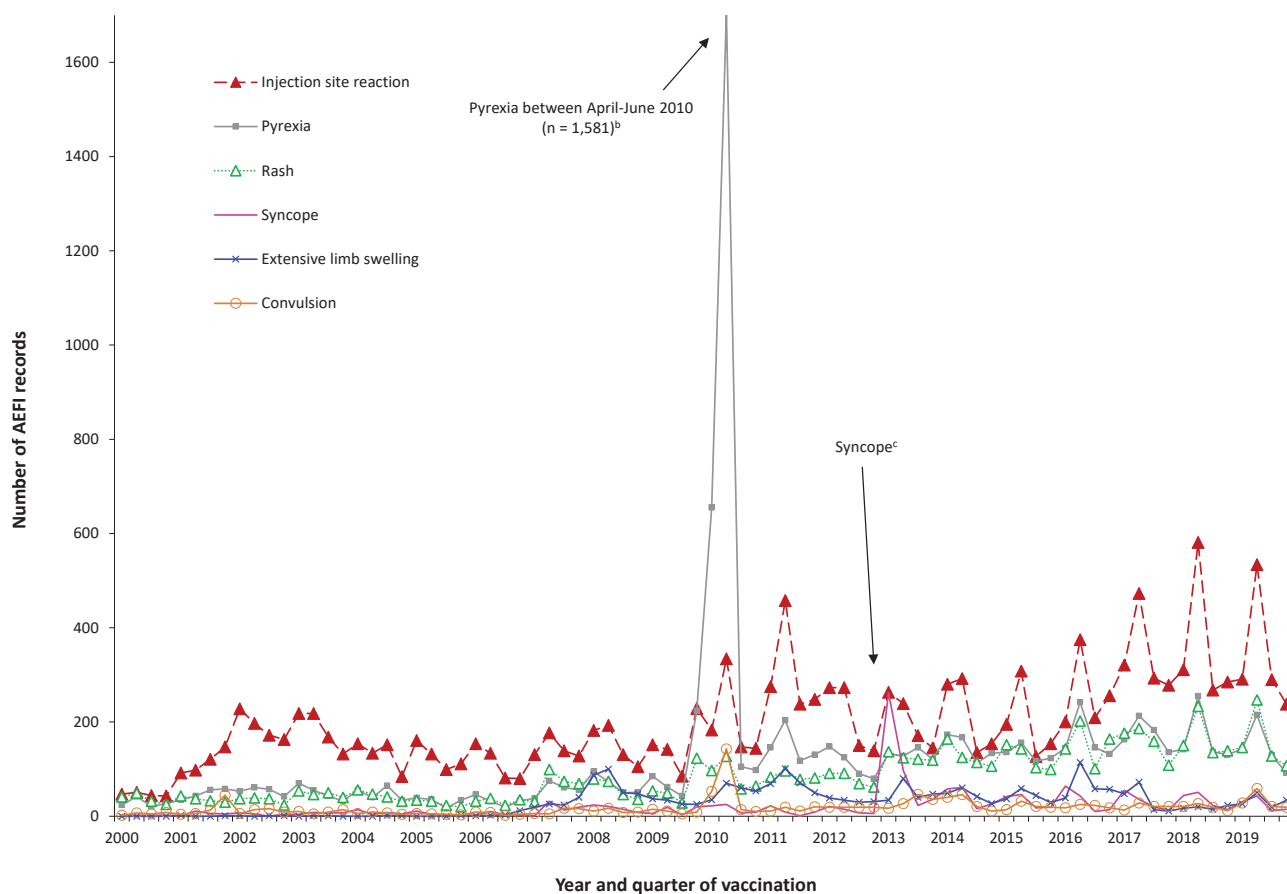
Vaccines

The vaccine most frequently reported as associated with AEFI was seasonal influenza vaccine (1,234 records; 32.6% of total 2019 records), followed by 13vPCV (n = 487, 12.9%), DTPa-IPV (n = 474; n = 12.5%), hexavalent DTPa-IPV-HepB-Hib (n = 442; 11.7%), rotavirus (n

= 337; 8.9%), meningococcal B (n = 314; 8.3%), meningococcal ACWY (n = 299; 7.9%), DTPa (n = 296; n = 7.8%), MMR (n = 295; n = 7.8%), dTpa (n = 278; n = 7.4%) and HPV (n = 242; 6.4%) (Table 3).

Of the 1,234 adverse events following seasonal influenza vaccination, 331 (26.8%) were reported in children aged < 7 years. There were 314 reported adverse events following meningococcal B vaccination, with 62.4% of these (196) in children < 7 years of age (Table 3).

Figure 6: Selected frequently reported adverse events following immunisation, AEMS database, 2000 to 2019, by year and quarter of vaccination^a



- a For reports where the date of vaccination was not recorded, the date of onset or date event was reported to TGA was used as a proxy for vaccination date.
- b Associated with administration of Seqirus (formerly bioCSL) Fluvax 2010 TIV and associated stimulated reporting.
- c The peak in syncope coincided with the enhanced HPV surveillance program in which there was stimulated reporting of syncope for the first 6 months of 2013.

Adverse events

The most frequently reported adverse events in 2019 were injection site reactions (ISRs) (n = 1,353; 35.8% of total), rash (n = 628; 16.6%), pyrexia (n = 579; 15.3%), vomiting (n = 305; 8.1%), urticaria (n = 220; 5.8%), pain (n = 218; 5.8%) and headache (n = 217; 5.7%) (Table 4, Figure 6). Adverse events of particular concern included convulsions (n = 127; 3.4%), anaphylaxis (n = 57; 1.5%), hypotonic-hyporesponsive episode (n = 44; 1.2%), intussusception (n = 15; 0.4%) and Guillain-Barré syndrome (GBS) (n = 6; 0.2%) (Table 4).

The number of reports of particular adverse events has changed over time (Figure 6) and these relate to changes in the vaccination schedule (Table A.1).

Table 3: Vaccine types listed as ‘suspected’ in records of adverse events following immunisation (AEFI), AEMS database, 2019

Suspected vaccine type ^a	AEFI records		One suspected vaccine only ^b		‘Serious’ ^c		Age group ^d < 7 years		Age group ^d ≥ 7 years	
	n	(%)	n	(%) ^e	n	(%) ^e	n	(%) ^e	n	(%) ^e
	Influenza	1,234	(32.6)	1,008	(81.7)	140	(11.3)	331	(26.8)	847
13vPCV	487	(12.9)	10	(2.1)	74	(15.2)	468	(96.1)	5	(1.0)
DTPa-IPV	474	(12.5)	424	(89.5)	16	(3.4)	456	(96.2)	12	(2.5)
DTPa-IPV-HepB-Hib	442	(11.7)	77	(17.4)	71	(16.1)	417	(94.3)	4	(0.9)
Rotavirus	337	(8.9)	38	(11.3)	63	(18.7)	316	(93.8)	1	(0.3)
Meningococcal B	314	(8.3)	196	(62.4)	41	(13.1)	196	(62.4)	115	(36.6)
Men ACWY	299	(7.9)	69	(23.1)	32	(10.7)	205	(68.6)	90	(30.1)
DTPa	296	(7.8)	77	(26.0)	17	(5.7)	296	(100.0)	0	(0.0)
MMRV	295	(7.8)	72	(24.4)	38	(12.9)	247	(83.7)	40	(13.6)
dTpa	278	(7.4)	112	(40.3)	25	(9.0)	0	(0.0)	278	(100.0)
HPV	242	(6.4)	110	(45.5)	16	(6.6)	2	(0.8)	234	(96.7)
23vPPV	226	(6.0)	151	(62.7)	14	(6.2)	7	(3.8)	216	(96.2)
MMRV	209	(5.5)	23	(11.0)	12	(5.7)	197	(94.3)	9	(4.3)
Hib	203	(5.4)	4	(2.0)	13	(6.4)	199	(98.0)	2	(1.0)
Zoster	79	(2.1)	68	(86.1)	6	(7.6)	0	(0.0)	79	(100.0)
Hepatitis B	51	(1.3)	18	(35.3)	8	(15.7)	11	(21.6)	37	(72.5)
Varicella	44	(1.2)	25	(56.8)	7	(15.9)	16	(36.4)	28	(63.6)
BCG	22	(0.6)	18	(81.8)	1	(4.5)	21	(95.5)	0	(0.0)
dT	18	(0.5)	14	(77.8)	1	(5.6)	0	(0.0)	18	(100.0)

Suspected vaccine type ^a	AEFI records		One suspected vaccine only ^b		'Serious' ^c		Age group ^d < 7 years		Age group ^d ≥ 7 years	
	n	(%)	n	(%) ^e	n	(%) ^e	n	(%) ^e	n	(%) ^e
	Hepatitis A	16	(0.4)	3	(18.8)	0	(0.0)	3	(18.8)	13
Typhoid	13	(0.3)	1	(7.7)	0	(0.0)	1	(7.7)	12	(92.3)
Hepatitis A-Typhoid	13	(0.3)	7	(53.8)	2	(15.4)	0	(0.0)	12	(92.3)
Yellow fever	11	(0.3)	7	(63.6)	3	(27.3)	0	(0.0)	11	(100.0)
Hepatitis A + B	9	(0.2)	3	(33.3)	1	(11.1)	0	(0.0)	9	(100.0)
Q fever	9	(0.2)	9	(100.0)	4	(44.4)	0	(0.0)	8	(88.9)
Rabies	8	(0.2)	8	(100.0)	0	(0.0)	0	(0.0)	8	(100.0)
Hib-MenC	7	(0.2)	1	(14.3)	1	(14.3)	7	(100.0)	0	(0.0)
IPV	7	(0.2)	1	(14.3)	0	(0.0)	0	(0.0)	7	(100.0)
MenCCV	7	(0.2)	3	(42.9)	0	(0.0)	1	(14.3)	5	(71.4)
Japanese encephalitis	2	(0.1)	1	(50.0)	1	(50.0)	0	(0.0)	2	(100.0)
Tetanus	1	(0.0)	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)

a See appendix for abbreviations of vaccine names.

b AEFI records where only one vaccine was suspected of causal involvement in a reported adverse event.

c 'Serious' is defined in the Methods section.

d Includes only AEFI records where an age or date of birth has been reported.

e Percentages are calculated for the number of AEFI records where the vaccine was suspected of causal involvement in the event.

Table 4: Selected reported adverse events^a classified by MedDRA Preferred Terms in records of adverse events following immunisation (AEFI), AEMS database, 2019^b

MedDRA Preferred Terms (adverse events)	AEFI records		Only adverse event reported ^c		'Serious' ^d		Age group ^e < 7 years		Age group ^e ≥ 7 years	
	N	n	n	(%) ^f	n	(%) ^f	n	(%) ^f	n	(%) ^f
Injection site reaction ^g	1,353	766	35	(56.6)	35	(2.6)	745	(55.1)	581	(42.9)
Rash ^h	628	238	50	(37.9)	50	(8.0)	404	(64.3)	207	(33.0)
Pyrexia	579	23	62	(4.0)	62	(10.7)	362	(62.5)	207	(35.8)
Vomiting	305	33	37	(10.8)	37	(12.1)	192	(63.0)	106	(34.8)
Urticaria	220	99	29	(45.0)	29	(13.2)	129	(58.6)	81	(36.8)
Pain	218	19	11	(8.7)	11	(5.0)	28	(12.8)	183	(83.9)
Headache	217	2	17	(0.9)	17	(7.8)	16	(7.4)	192	(88.5)
Nausea	162	4	14	(2.5)	14	(8.6)	7	(4.3)	148	(91.4)
Malaise	152	1	18	(0.7)	18	(11.8)	26	(17.1)	120	(78.9)
Dizziness	150	11	11	(7.3)	11	(7.3)	1	(0.7)	141	(94.0)
Lethargy	131	2	16	(1.5)	16	(12.2)	57	(43.5)	69	(52.7)
Extensive limb swelling	129	61	8	(47.3)	8	(6.2)	91	(70.5)	38	(29.5)
Diarrhoea	127	19	21	(15.0)	21	(16.5)	80	(63.0)	38	(29.9)
Convulsions ⁱ	127	66	67	(52.0)	67	(52.8)	87	(68.5)	34	(26.8)
Syncope	101	42	9	(41.6)	9	(8.9)	13	(12.9)	86	(85.1)
Irritability	101	2	9	(2.0)	9	(8.9)	95	(94.1)	6	(5.9)
Pallor	98	3	17	(3.1)	17	(17.3)	55	(56.1)	37	(37.8)
Myalgia	95	2	3	(2.1)	3	(3.2)	5	(5.3)	89	(93.7)
Pruritus	90	5	9	(5.6)	9	(10.0)	29	(32.2)	56	(62.2)
Paraesthesia	81	7	10	(8.6)	10	(12.3)	1	(1.2)	76	(93.8)

MedDRA Preferred Terms (adverse events)	AEFI records		Only adverse event reported ^c		'Serious' ^d		Age group ^e		Age group ^e	
	N	n	n	(%) ^f	n	(%) ^f	< 7 years		≥ 7 years	
							n	(%) ^f	n	(%) ^f
Decreased appetite	81	0	0	(0.0)	6	(7.4)	52	(64.2)	29	(35.8)
Chills	76	1	1	(1.3)	4	(5.3)	9	(11.8)	67	(88.2)
Erythema	76	6	6	(7.9)	8	(10.5)	42	(55.3)	33	(43.4)
Injected limb mobility decreased	73	2	2	(2.7)	3	(4.1)	10	(13.7)	62	(84.9)
Dyspnoea	72	1	1	(1.4)	29	(40.3)	16	(22.2)	51	(70.8)
Fatigue	69	0	0	(0.0)	4	(5.8)	12	(17.4)	55	(79.7)
Cough	66	1	1	(1.5)	16	(24.2)	28	(42.4)	34	(51.5)
Abdominal pain	61	0	0	(0.0)	9	(14.8)	29	(47.5)	29	(47.5)
Anaphylactic reaction	57	34	34	(59.6)	41	(71.9)	17	(29.8)	25	(43.9)
Angioedema	55	9	9	(16.4)	9	(16.4)	35	(63.6)	16	(29.1)
Presyncope	48	27	27	(56.3)	2	(4.2)	19	(39.6)	29	(60.4)
Hypotonic-hyporesponsive episode	44	28	28	(63.6)	11	(25.0)	44	(100.0)	0	(0.0)
Throat irritation	43	4	4	(9.3)	9	(20.9)	1	(2.3)	40	(93.0)
Arthralgia	40	1	1	(2.5)	2	(5.0)	2	(5.0)	35	(87.5)
Flushing	37	0	0	(0.0)	2	(5.4)	10	(27.0)	27	(73.0)
Somnolence	34	1	1	(2.9)	4	(11.8)	17	(50.0)	15	(44.1)
Hyperhidrosis	33	0	0	(0.0)	2	(6.1)	6	(18.2)	27	(81.8)
Chest discomfort	31	0	0	(0.0)	4	(12.9)	0	(0.0)	31	(100.0)
Tachycardia	29	1	1	(3.4)	10	(34.5)	9	(31.0)	17	(58.6)
Rhinorrhoea	25	0	0	(0.0)	0	(0.0)	14	(56.0)	11	(44.0)
Oropharyngeal pain	25	1	1	(4.0)	3	(12.0)	4	(16.0)	20	(80.0)
Cold sweat	21	0	0	(0.0)	1	(4.8)	8	(38.1)	12	(57.1)

MedDRA Preferred Terms (adverse events)	AEFI records		Only adverse event reported ^c		'Serious' ^d		Age group ^e			
	N	n	n	n	n	n	< 7 years		≥ 7 years	
							(%) ^f	(%) ^f	(%) ^f	(%) ^f
Asthenia	19	0	0	4	4	4	21.1	21.1	11	57.9
Chest pain	18	0	0	2	2	2	11.1	0.0	18	100.0
Blister	17	0	0	1	1	1	5.9	35.3	11	64.7
Hypoaesthesia	16	3	3	2	2	2	12.5	6.3	13	81.3
Hypotonia	16	0	0	2	2	2	12.5	100.0	0	0.0
Apnoea	15	3	3	3	3	3	20.0	100.0	0	0.0
Hypotension	15	0	0	5	5	5	33.3	13.3	13	86.7
Intussusception	15	11	11	13	13	13	86.7	80.0	0	0.0
Haematochezia	15	5	5	4	4	4	26.7	73.3	0	0.0
Tremor	12	3	3	1	1	1	8.3	16.7	10	83.3
Guillain-Barré syndrome	6	5	5	6	6	6	100.0	16.7	5	83.3
Lymphadenitis	4	1	1	1	1	1	25.0	25.0	3	75.0
Hypersensitivity	2	1	1	1	1	1	50.0	0.0	2	100.0

a A complete list of adverse events as classified by individual Preferred Terms is available on request.

b Selected reported adverse events reported during Jan-Dec 2019. Note: for injection site reaction, rash and convulsions, PT's were grouped as described below.

c AEFI records where only one adverse event was reported.

d 'Serious' outcomes are defined in the Methods section.

e Includes only AEFI records where an age or date of birth has been reported

f Percentages relate to the number of AEFI records in which the specific adverse event was listed

g 'Injection site reaction' includes the following MedDRA PTs: injection site pain, injection site swelling, 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 inflammation, injection site bruising, injection site infection, and injection site warmth.

h 'Rash' includes the following MedDRA PTs: rash, rash generalised, rash erythematous, rash pruritic, rash macular, rash vesicular, rash papular, rash morbilliform, and rash pustular.

i 'Convulsion' includes the following MedDRA PTs: febrile convulsion, convulsion, grand mal convulsion, and partial seizures.

Serious adverse events

There were variations in the proportions of reports with outcomes defined as serious (Table 3), although these remained generally low as in previous years. The majority of reported adverse events in 2019 were coded as non-serious (n = 3,338, 88%). Twelve per cent of reported adverse events in 2019 were coded as serious, noting that not all reports included detailed or clinically verified data.

Five deaths were reported to the TGA and assessed by TGA as 'causality possible'. In one of these reports, the timing of vaccination and the clinical findings were consistent with a causal association. In the other four, no clear causal relationship with vaccination was found:

- A 79-year-old male died in April 2019, a few days after receiving a seasonal quadrivalent influenza vaccine. He presented to hospital with viral polyarthritides and acute kidney injury, on a background of past medical history of myelofibrosis, abdominal aortic aneurysm and a permanent cardiac pacemaker. He progressed to having bacterial sepsis, leading to fatal multi-organ failure. Batch record review of the vaccine showed no anomalies and the vaccine was produced according to specifications, including all quality control checks complied. The case has been referred to the Coroner.
- An 80-year-old female died in June 2019, a few weeks after receiving an enhanced immunogenicity seasonal trivalent influenza vaccine. She had comorbidities (dyslipidaemia, gastro-oesophageal reflux disease, chronic obstructive pulmonary disease (COPD), cholecystectomy, anaemia) and was diagnosed with Guillain-Barré syndrome, which subsequently progressed to ventilator-acquired pneumonia and respiratory failure. The case has been referred to the Coroner.
- A 77-year-old male died in July 2019, a few weeks after receiving a zoster vaccine. He had history of psoriatic arthritis and being

on immunosuppressive treatment along with several comorbidities including heart failure, renal impairment, COPD and valvular heart disease. The vaccine was given in line with existing recommendations. He developed disseminated varicella zoster virus infection (Oka strain) and subsequently died a few weeks after vaccination. This man's death was determined by an expert panel to be causally related to zoster vaccination.

- A 75-year-old male with comorbidities (syndrome of inappropriate antidiuretic hormone secretion and fluctuating blood pressure) died in September 2019, several months after receiving enhanced immunogenicity trivalent seasonal influenza vaccine and 23-valent pneumococcal polysaccharide vaccine a week apart in May 2019. In July 2019, a few weeks after vaccination, he went to a GP complaining of unsteady gait, slow walking and pain in lower back and hip. He was hospitalised for hypoxic respiratory failure and subsequently had deteriorating respiratory function. The principal diagnoses and causes of his death were aspiration pneumonitis, Guillain-Barré syndrome and emphysema.
- An eight-month-old male child died in October 2019, after receiving a second dose of influenza vaccine in mid October 2019. The patient had fever and experienced cardio-respiratory arrest. At the time of the event, the child had significant cardiac, respiratory and neurodevelopmental problems related to a genetic abnormality. No further details were available.

One miscarriage (spontaneous abortion) was reported in this period, noting spontaneous abortions are known to occur in 11–22% of all pregnancies:^{33,34}

- A 31-year-old female was vaccinated in early pregnancy with a varicella vaccine. She presented at the hospital with vaginal bleeding. At hospital, she was assessed as low risk of congenital varicella for this pregnancy. She subsequently had a miscarriage.

In summary, all deaths following immunisation reported to the TGA were reviewed by the TGA and, where relevant, by other relevant authorities, based on the information received from reporters. The TGA encourages all reporters to provide sufficient information to allow the TGA to assess any causal relationship between the administration of a vaccine and the adverse event reported. The majority of deaths were assessed as being most likely due to concomitant disease that was pre-existing at the time of vaccination. However, for one of the deaths, the timing of vaccination and the clinical findings were consistent with a causal association.

Discussion

This report uses similar methodology to the previous six annual reports.^{2,15,35–38} Analysis using MedDRA preferred terms allows for clearer reporting of adverse events, but needs to be taken into account when comparing the data in this report with data from annual reports prior to 2013.

In 2019, there was an 11.8% decrease in the AEFI reporting rate compared with the previous year and reporting rates were significantly lower (with no overlapping confidence intervals) in five jurisdictions in 2019 compared with 2018.³⁸ This decrease was mainly attributable to a decline in adverse events related to the HPV, dTpa, seasonal influenza and meningococcal ACWY vaccines.

Among people aged 7 to 17 years, there was a decrease in the AEFI reporting rate for meningococcal ACWY vaccine in 2019 (24.8 per 100,000 doses) compared to 2018 (63.2 per 100,000 doses). The observed decline may reflect the elapsed time since introduction of funded meningococcal ACWY vaccine; although the meningococcal ACWY vaccine was introduced to the NIP for adolescents and young adults aged 15–19 in 2019, there were jurisdiction-funded program for adolescents including catch-ups during the preceding couple of years (2017–2018).

There was also a significant decline in the AEFI reporting rate for dTpa from 2018 (135.7 per 100,000 doses) to 2019 (44.6 per 100,000 doses), in children and adolescent aged 7–17 years.

There is usually an increase in reporting of adverse events when a new program or scheduled dose is rolled out, as immunisation providers are more likely to report milder, less serious AEFI for vaccines they are not as familiar with, or that are being given to a new population group. A reduction and stabilisation of reporting rates over time often occurs thereafter.^{2,4,5,7,10,12–15,35–37,39} The variation in reporting of injection site reactions is related to changes in the immunisation schedule for vaccines that are known to have higher rates of ISR, including DTPa-containing, 23vPPV and HPV vaccines.^{3–14,40,41} Increases in reported AEFI are largely associated with time periods when new vaccines were added to the NIP, or when eligibility was extended. In 2019, meningococcal ACWY conjugate vaccine was funded under the NIP for adolescents aged 14–16 years delivered through a school-based program and adolescents aged 15 to 19 years delivered through primary care providers as part of an ongoing catch-up program. Also, Aboriginal and Torres Strait Islander children and adolescents aged 5–14 years of age were funded for influenza vaccine under NIP.

Overall, ISR; rash; pyrexia; vomiting; urticaria; pain; and headache were the most commonly-reported adverse events to the TGA in 2019. However, there was an increase in the number of reports for some PTs, including anaphylaxis, which increased from 40 reports in 2018 to 57 reports in 2019: this was likely due to a change in the way that reports of anaphylaxis were coded. The majority (52.4%) of these were reported in adults aged ≥ 18 years. In addition, during this third year (2019) of implementation of the zoster vaccination program, there were 79 AEFI reports in adults who received the zoster vaccine (compared to 135 reports in 2018), with the majority of these (92%) reported as not serious.

AEFI reporting rates for most individual vaccines in 2019 were similar to 2018. These findings are similar to nationally-representative vaccine safety data from AusVaxSafety,⁴² which actively monitors the safety of vaccines (e.g. pertussis, zoster, influenza, HPV) in vaccinated people from 375 sentinel surveillance sites nationwide. No safety signals were observed for pertussis, zoster, influenza and HPV vaccines in 2019 in AusVaxSafety.⁴²

Overall for data from the AEMS, the majority of AEFI reports detailed non-serious events and no new safety concerns arose during this period (2019). More than half (54.6%) of reported events were in females and 1.5% were reported in Aboriginal and Torres Strait Islander people. Five deaths were reported during 2019, four of which were assessed as being most likely due to concomitant disease that was pre-existing at the time of vaccination. Disseminated varicella-zoster virus (VZV) infection from Oka vaccine strain was causally associated with death in one of the cases. The use of live attenuated VZV-containing vaccines in people who are immunocompromised is contraindicated due to the risk of unchecked vaccine virus replication causing serious disease.¹⁶ The occurrence of this death resulted in a TGA alert⁴³ to healthcare providers on the risk of mild to serious complications (including death) from infection with VZV if Zostavax is administered to people with compromised immune function.

Conclusion

AEFI reporting rates decreased in 2019 compared with 2018 and the majority of adverse events reports were non-serious transient events. The data reported here are consistent with an overall high level of safety for vaccines used in Australia when administered according to the clinical recommendations contained within the Australian Immunisation Handbook.

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Appendix A

Abbreviations of vaccine types

Abbreviation	Definition
BCG	Bacille Calmette-Guérin (i.e. tuberculosis)
DTPa	diphtheria-tetanus-pertussis (acellular) – paediatric formulation
dTpa	diphtheria-tetanus-pertussis (acellular) – adolescent and adult formulation
DTPa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus (quadrivalent)
DTPa-IPV-HepB-Hib	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus, hepatitis B and <i>Haemophilus influenzae</i> type b vaccine (hexavalent)
HepB	hepatitis B
Hib	<i>Haemophilus influenzae</i> type b
Hib-HepB	combined <i>Haemophilus influenzae</i> type b and hepatitis B
Hib-MenC	combined <i>Haemophilus influenzae</i> type b and meningococcal C conjugate vaccine
HPV	human papillomavirus
MenACWY	quadrivalent meningococcal (serogroups A, C, W-135, Y) conjugate vaccine
MenB	meningococcal B vaccine
MenCCV	meningococcal C conjugate vaccine
MMR	measles-mumps-rubella
MMRV	measles-mumps-rubella-varicella
pH1N1	pandemic H1N1 influenza 2009
7vPCV	7-valent pneumococcal conjugate vaccine
13vPCV	13-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine

Table A.1: Changes in immunisation policy and the National Immunisation Program (2005–2019)^a

Year	Change
2019	<p>December 2019 In South Australia, multicomponent recombinant meningococcal B vaccine catch-up for children from 12 months to < 4 years of age ceased on 31 December 2019.</p> <p>April 2019 Meningococcal ACWY conjugate vaccine funded under the NIP for adolescents aged 14–16 years delivered through a school-based program and adolescents aged 15 to 19 years delivered through primary care providers as part of an ongoing catch-up program.</p> <p>March 2019 NT: annual seasonal influenza vaccination program funded for all children aged 6 months to < 5 years.</p> <p>February 2019</p> <ul style="list-style-type: none"> • Annual seasonal influenza vaccination funded on the national childhood vaccination schedule for all Australian children aged 6 months to < 5 years. • Aboriginal and Torres Strait Islander children and adolescents aged 5–14 years of age funded for influenza vaccine under NIP.
2018	<p>October 2018 Multicomponent recombinant meningococcal B vaccine funded by South Australia for children 6 weeks to 12 months of age, with catch-up for children from 12 months to < 4 years of age.</p> <p>July 2018</p> <ul style="list-style-type: none"> • 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. <p>April 2018</p> <ul style="list-style-type: none"> • Enhanced trivalent influenza vaccines (high-dose and adjuvanted) funded nationally for all adults aged ≥ 65 years. • Annual seasonal influenza vaccination funded by the Australia Capital Territory, New South Wales, Queensland, South Australia, Tasmania and Victoria for all children aged 6 months to < 5 years. • Meningococcal ACWY conjugate vaccine funded by South Australia for Aboriginal and Torres Strait Islander children and adolescents aged 12 months to 19 years living in the Eyre and Far North, and Flinders and Upper North regions. <p>February 2018</p> <ul style="list-style-type: none"> • Meningococcal ACWY conjugate vaccine funded by the Australian Capital Territory for grade 10 students and persons aged 16–19 years who no longer attend school. • A 2-dose schedule of 9vHPV funded for adolescents aged 12–14 years, delivered through a school-based program; 4vHPV ceased to be used in the program. <p>January 2018</p> <ul style="list-style-type: none"> • Meningococcal ACWY conjugate vaccine funded by Western Australia for children aged 12 months to < 5 years. • Meningococcal ACWY school-based vaccination program funded for all New South Wales secondary school students in Years 10 and 11, as well as adolescents aged 15 to 19 years who have not received the vaccine at school.
2017	<p>January–December 2017 Meningococcal ACWY conjugate vaccine funded in Western Australia, Victoria and Tasmania for grade 10–12 students; New South Wales for grade 11–12; Queensland grade 10 students and persons aged 15–19 years who no longer attend school. The Northern Territory introduced the vaccine for at-risk people aged 1–19 years living in specified remote regions and all children aged 12 months.^b</p> <p>April 2017 Meningococcal B vaccine study commenced in South Australia for grade 10–12 students at participating schools.</p>
2016	<p>November 2016 Zoster vaccine (Zostavax) provided free for people aged 70 years under the NIP with a five year catch-up program for people aged 71–79 years.</p> <p>March 2016 Free booster dose of the diphtheria, tetanus, and acellular pertussis-containing vaccine (DTPa) at 18 months of age.</p>

Year	Change
2015	<p>March–June 2015 the dTpa vaccine for women during the third trimester of pregnancy was funded by New South Wales, South Australia, Western Australia, the Australian Capital Territory, Victoria and Tasmania. The Northern Territory had funded it since September 2013 and Queensland since July 2014.</p> <p>April 2015 new immunisation requirements for family assistance payments were announced by the federal government (the ‘No Jab, No Pay’ policy), to come into effect on 1 January 2016. Only parents of children (aged less than 20 years) who are ‘fully immunised’ or on a recognised catch-up schedule remain eligible to receive the Child Care Benefit, Child Care Rebate, and/or the Family Tax Benefit Part A end-of-year supplement.</p> <p>March 2015</p> <ul style="list-style-type: none"> • Seasonal influenza vaccine funded for Aboriginal and Torres Strait Islander children aged 6 months to less than 5 years. • Booster dose of DTPa vaccine recommended at 18 months of age (funded in March 2016).
2014	<p>December 2014 4vHPV vaccine catch-up program for males aged 14–15 years ceased.</p> <p>July 2014 dTpa vaccine funded by Queensland for women during the third trimester of pregnancy.</p>
2013	<p>December 2013 Secondary school Year 7 hepatitis B vaccine catch-up program ceased, as all younger age cohorts were eligible for infant immunisation under the NIP (commenced 2000).</p> <p>September 2013 dTpa vaccine funded by the Northern Territory for women during the third trimester of pregnancy and for parents of infants aged < 7 months under cocoon strategy</p> <p>July 2013</p> <ul style="list-style-type: none"> • Second dose of MMR vaccine, previously given at 4 years, was brought forward to 18 months of age and delivered as MMRV vaccine. • Combined <i>Haemophilus influenzae</i> type b (Hib) and meningococcal serogroup C (MenC) vaccine, Menitorix, was funded for infants aged 12 months. This combination vaccine replaced the single dose of monovalent meningococcal C conjugate vaccine (MenCCV) and booster dose of monovalent Hib vaccine previously scheduled at 12 months of age. <p>February 2013 4vHPV vaccine was extended to males aged 12–13 years, delivered through a school-based program, with a catch-up program for males aged 14–15 years in 2013 and 2014.</p>
2012	<p>October 2012 Fourth dose of Prevenar13, (13vPCV, a 13-valent pneumococcal conjugate vaccine) was listed on the NIP for Indigenous children, aged 12–18 months, residing in Queensland, South Australia, Western Australia and the Northern Territory. This replaced the booster dose of Pneumovax23, (23vPPV, a 23-valent pneumococcal polysaccharide vaccine) administered between 18 and 24 months of age for Indigenous children from these jurisdictions.</p>
2011	<p>October 2011–September 2012 all children aged between 12 and 35 months who had completed a primary pneumococcal vaccination course with 7vPCV were eligible to receive a free supplementary dose of Prevenar13.</p> <p>July 2011 Prevenar13 replaced Prevenar on the NIP for children at 2, 4 and 6 months of age in all states and territories except the Northern Territory which adopted 13vPCV from 1 October 2011.</p> <p>25 March 2011 TGA issued a recall of Batch N3336 of the 23-valent pneumococcal polysaccharide vaccine 23vPPV, Pneumovax23.</p> <ul style="list-style-type: none"> • April 2011: health professionals were advised not to administer a second or subsequent dose of Pneumovax23 vaccine. • December 2011: Revised recommendations regarding which patients should be re-vaccinated under the NIP were provided.
2010	<p>Annual vaccination with seasonal trivalent influenza vaccine (TIV, containing 3 influenza strains: A/H1N1, A/H3N2 and B) was funded under the NIP for people aged ≥ 6 months with medical risk factors (previously subsidised through the Pharmaceutical Benefits Scheme) and all Indigenous people aged ≥ 15 years (previously all Indigenous adults ≥ 50 years and 15–49 years with medical risk factors).</p> <p>23 April 2010 Use of the 2010 seasonal TIV in children < 5 years of age was suspended by Australia’s Chief Medical Officer due to an increased number of reports of fever and febrile convulsions post vaccination. A subsequent investigation identified that Fluvax and Fluvax junior (CSL Biotherapies), but neither of the other two available brands registered for use in young children, were associated with an unacceptably high risk of febrile convulsions. The recommendation to resume the use of seasonal influenza vaccine in children aged 6 months to 5 years, using brands other than Fluvax and Fluvax junior, was made in August 2010.</p>

Year	Change
2009	<p>Late 2009 All states and territories are using the single hexavalent DTPa-IPV-Hib-HepB (Infanrix hexa) vaccine for all children at 2, 4 and 6 months of age, due to an international shortage of <i>Haemophilus influenzae</i> type b (Hib) (PedvaxHib [monovalent] and Comvax [Hib-HepB]) vaccines. Pandemic H1N1 2009 influenza vaccine (Panvax) was rolled out across Australia from 30 September 2009 for people aged ≥ 10 years. From December 2009, the pandemic vaccine was made available to children aged 6 months to 10 years.</p>
2008	<p>Western Australia commenced a seasonal influenza vaccination program for all children aged 6 months to < 5 years (born after 1 April 2003). March 2008 Queensland, South Australia and Victoria changed from using two combination vaccines (quadrivalent DTPa-IPV and Hib-HepB) to the single hexavalent DTPa-IPV-HepB-Hib vaccine.</p>
2007	<p>July 2007 Universal funded immunisation against rotavirus at 2 and 4 months of age (Rotarix) or at 2, 4 and 6 months of age (Rotateq). April 2007 Funded immunisation against human papillomavirus for all Australian girls aged 12–13 years delivered through a school-based program from April 2007, with a temporary catch-up program through schools or primary care providers for females aged 13–26 years until December 2009.</p>
2005	<p>Universal 23-valent pneumococcal polysaccharide vaccine (23vPPV) for adults aged ≥ 65 years replaced previous subsidy through the Pharmaceutical Benefits Scheme. November 2005</p> <ul style="list-style-type: none"> • Universal funded immunisation against varicella at 18 months of age with a school-based catch-up program for children at 10–13 years of age not previously vaccinated and without a history of varicella infection (no funded catch-up for children 2–10 years of age). • IPV was funded to replace OPV, in combination vaccines. <p>January 2005 Universal funded infant 7-valent pneumococcal conjugate vaccine (7vPCV) program replaced the previous targeted childhood program, with a catch-up program for children aged < 2 years.</p>

- a As detailed in references 2, 4, 5, 7, 10, 12, 14, 15, and 36–39.
- b For more details see the meningococcal vaccination history table at <http://ncirs.org.au/sites/default/files/2019-04/Meningococcal-history-April-2019.pdf>.