NCIRS
National Centre for Immunisation Research and Surveillance

Surveillance of adverse events following immunisation in NSW 2021

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Contents

Abbreviations

13vPCV	13-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine
7vPCV	7-valent pneumococcal conjugate vaccine
AEFI	adverse event following immunisation
AEMS	Adverse Event Management System
CI	confidence interval
DAEN	Database of Adverse Event Notifications
DTPa	diphtheria-tetanus-pertussis (acellular) – paediatric formulation
dTpa	diphtheria-tetanus-pertussis (acellular) – adolescent and adult formulation
DTPa-Hib	combined diphtheria-tetanus-pertussis (acellular) and Haemophilus influenzae type b vaccine
DTPa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus (quadrivalent) – paediatric formulation
DTPa-IPV-HepB-Hib	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus, hepatitis B and Haemophilus influenzae type b vaccine (hexavalent)
dTpa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus (quadrivalent) – adolescent and adult formulation
H1N1pdm09	pandemic H1N1 influenza 2009
HepB	hepatitis B
Hib	Haemophilus influenzae type b
Hib and MenC	combined Haemophilus influenzae type b and meningococcal C conjugate vaccine
Hib and MenCY	combined Haemophilus influenzae type b and meningococcal C and Y conjugate vaccine
Hib-HepB	combined Haemophilus influenzae type b and hepatitis B
HPV	human papillomavirus
MenACWY	quadrivalent meningococcal (serogroups A, C, W-135, Y) conjugate vaccine
MenB	meningococcal B vaccine
MenC	meningococcal C conjugate vaccine
MMR	measles-mumps-rubella
MMRV	measles-mumps-rubella-varicella
NCIRS	National Centre for Immunisation Research and Surveillance
NIP	National Immunisation Program
PT	preferred terms
SMQ	standardised MedDRA query
TGA	Therapeutic Goods Administration
WHO	World Health Organization
Zoster (RZV)	recombinant zoster vaccine
Zoster (ZVL)	live-attenuated zoster vaccine

Abstract

Aim: This report summarises Australia's spontaneous surveillance data for adverse events following immunisation (AEFI) with non-COVID-19 vaccines in New South Wales (NSW) for 2021.

Methods: Analysis of de-identified data on all AEFI reported to the Therapeutic Goods Administration (TGA) for NSW, where AEFI are defined as any untoward medical occurrence that follows immunisation. This report excludes AEFI reports including pandemic COVID-19 vaccines, which are reported separately.

Results: There were 618 AEFI reports for vaccines administered from 1 January to 31 December 2021. The overall AEFI reporting rate of 7.5 [95% CI 7.0–8.2] per 100,000 population in 2021 is lower compared with 9.6 [95% CI 9.0–10.3] per 100,000 population in 2020. Approximately 15% of AEFI were classified as serious in 2021. The majority of reported events were of a non-serious nature, similar to previous years. Overall, reported adverse events were most commonly associated with the following vaccines: standard-formulation seasonal influenza (29.6%), 13vPCV (19.3%), DTPa-IPV-HepB-Hib (13.3%), DTPa-IPV (9.9%), rotavirus (9.7%), and high-dose or adjuvanted seasonal influenza (9.5%). The most frequently reported adverse events were hypersensitivity (122), injection site reaction (104), pyrexia (104), gastrointestinal nonspecific symptoms and therapeutic procedures (77), and headache (46). Five deaths were reported in this period, and for all five cases, the TGA did not establish a causal link between vaccination and the condition that caused the death.

Conclusion: The reporting rate for AEFI from NSW in 2021 was lower than the AEFI reporting rate in 2020. The majority of AEFI reported to the TGA from NSW were non-serious and no deaths following vaccination had a causal relationship with vaccination. These data are useful to inform ongoing immunisation programs in NSW.

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Introduction

This report summarises spontaneous (passive) adverse event following immunisation (AEFI) surveillance data reported for non-COVID-19 vaccines administered in 2021 in New South Wales (NSW) and trends in AEFI reporting over the 22-year period 2000–2021.

An adverse event(s) following immunisation (AEFI) 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 AEFI may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. AEFI can be a coincidental event or caused by the vaccine(s) and can be classified into the following categories:(1)

1. Vaccine product-related reaction
2. Vaccine quality defect-related reaction
3. Immunisation error-related reaction
4. Immunisation anxiety-related reaction
5. Coincidental event.

Ongoing post-marketing AEFI surveillance through a national spontaneous surveillance system is important in detecting unexpected AEFI that may not have been detected in pre-registration vaccine trials.

AEFI are notifiable to NSW public health units by medical practitioners and hospital chief executive officers under the *Public Health Act 2010* (NSW). 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 Notification (TGA). The TGA also receives reports directly from vaccine manufacturers, members of the public and other sources.(2) All reported AEFI are entered into the Australian Adverse Event Management System (AEMS) database. Where the initial report contains insufficient information, depending on the origin of the report, the TGA may contact the reporter directly, Health Protection NSW to elicit further information from the reporter via local public health units depending on the source of the report. The TGA continually analyses AEFI data to detect new potential safety issues or changes to known safety issues that may require regulatory action. Select serious adverse events are assessed for causality using internationally consistent criteria to identify whether there may be a link between the medical condition(s) involved and vaccination that indicates potential new safety information.

Trends in reported AEFI are influenced by many factors, including changes to the National Immunisation Program (NIP), vaccine introduction and availability, media coverage, awareness campaigns, and efforts to facilitate reporting. Changes to the NIP since 2005 are summarised in Table S1, and their impacts on reported AEFI trends are described in previous reports.(3-13) There were no changes to the NIP or vaccine availability in 2021 to highlight.

This report summarises national spontaneous (passive) surveillance data for NSW non-COVID-19 vaccine AEFI reported to the TGA. The report focuses on AEFI reported for vaccines administered in 2021 and trends in AEFI reporting over the 22-year period 1 January 2000 – 31 December 2021.

Methods

AEFI data

De-identified data on all AEFI reported to the TGA from 1 January 2000 to 31 December 2021 and stored in the AEMS database were released to the National Centre for Immunisation Research and Surveillance (NCIRS) in May 2022. Please refer to previous reports for a detailed description of the surveillance system.(3, 14)

AEFI reports with a patient state of NSW were included in analysis. Where the patient state was missing, the sender (reporter) state was used; where sender state was missing, the sender postcode was used.

Vaccine data

Vaccines were identified by trade name (standardised term in the TGA reference dataset), and where the trade name was not specified, the generic name (active ingredients associated with a trade name) and reported product name (product name used by the reporter). Individual vaccines were grouped by antigen and, for seasonal influenza and zoster vaccines, by type (for influenza, standard-formulation vs high-dose or adjuvanted; for zoster, live virus vs recombinant adjuvanted). Only vaccines with a role in relation to the reported adverse event of 'suspect' were included in analysis. In addition, only accepted reports were included. To be accepted, the report must contain sufficient information to be valid, which includes four key elements: a reporter, a patient, one or more suspected vaccines, and one or more reaction terms. Valid reports are accepted by the TGA with a default decision type of 'causality possible'. Reports that included both non-COVID-19 and COVID-19 vaccines as 'suspect' are included in the COVID-19 vaccine AEFI report and were excluded from this analysis.

Adverse event data

AEFI reports include reaction terms that are symptoms, signs and/or diagnoses that have been coded by TGA staff from the reporter's description into lower level terms, which are mapped to associated preferred terms (PT) using the Medical Dictionary for Regulatory Activities (MedDRA®).(15, 16)

Standardised MedDRA queries (SMQ) are sets of MedDRA terms that have been grouped after extensive testing, analysis, and expert discussion to facilitate pharmacovigilance investigation(17). For this analysis, the MedDRA Browser SMQ Analysis tool was used to group related PT to their SMQ to reduce the number of unique PT under analysis while providing meaningful results. As individual PT may map to zero, one, or more than one SMQ, the term reported was chosen as described in Table S2.

The PT/SMQ were numerically ranked by frequency, and the 50 most frequent PT/SMQ were reported, with ties determined using the minimum method (i.e. PT/SMQ reported the same number of times received the same minimum ranking possible).

AEFI report data

AEFI reports were defined by unique identifiers provided by the TGA. Each report was assigned a date based on the earliest vaccine date associated with the report; where a vaccine date was missing, the earliest symptom onset date was used; and where dates for both vaccine and symptom

onset were missing, the received date (the date when the sender of the case first received the minimum valid information as described above from the primary source) was used. Where the date of birth was available, it was used to calculate age at time of vaccination, symptom onset, or received date; where it was missing, the age at symptom onset provided by the TGA was used. Reports were grouped by age into <7 years, 7-17 years, 18-64 years, and ≥65 years. Reports with a vaccination, symptom onset, or received date (as described above) prior to 2021 were excluded from the 2021 specific analysis.

Reported deaths

All AEFI reports where a fatal outcome is reported are reviewed by the TGA. This review is designed to assess whether the medical condition(s) that caused death represent an emerging safety concern with a vaccine. For each report the TGA receives, a team of staff, including doctors and nurses, consider the strength of the evidence for a link between vaccination and the condition that caused the death using a standardised process based on the World Health Organization (WHO) guidelines.(18) When another cause for the events that resulted in death is not medically obvious, not stated and cannot be determined from the initial report, the TGA may request further information, depending on the origin of the report, from the reporter directly or from Health Protection NSW. This may include the results of investigations relating to the diagnosed cause of death or past medical history, post-mortem examination findings, the death certificate, and/or results of a Coronial Office investigation. Even when the TGA does not have sufficient information to confirm a causal link between a cause of death and vaccination, each case is still recorded in the DAEN as "Causality Possible", The TGA continues to review new information about the case as it arises, including Coronial findings that may be released sometime after the initial report is received.

Serious and non-serious AEFI

AEFI reports are coded as ‘serious’ or ‘non-serious’ based on criteria used by the WHO(19) and the US Vaccine Adverse Events Reporting System,(20) where 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
6. Is a medically important event or reaction.

The seriousness classification is applied by Australian sponsors (vaccine companies) to vaccine AEFI reports to ensure they meet legislated requirements. For other AEFI reports submitted to the TGA, the seriousness classification either reflects the view of the reporter or may have been applied following review by the TGA.

Data analysis

All data cleaning and analyses were performed using R version 4.0.3. Average annual population-based AEFI reporting rates were calculated for NSW and by age group using June 2021 population estimates obtained from the Australian Bureau of Statistics.(21) 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.(22) Confidence intervals presented are 95% exact binomial confidence intervals for proportions.

AEFI reports following COVID-19 vaccination have been analysed and will be presented in a separate report.

Notes on interpretation

The data reported here are provisional, particularly for the fourth quarter of 2021 due to reporting delays and the late onset of some reported AEFI. In addition, AEFI may have been reported in 2021 for vaccinations occurring in previous years. Numbers have therefore been updated for previous years and may not match previous reports.

In previous reports, where patient or sender state was missing, the report was excluded from the analysis. This report includes AEFI reports where sender postcode is from NSW, which has resulted in higher number of AEFI reports included in the analysis and a change in AEFI reporting rates for previous years. AEFI reporting frequencies and rates in this report should therefore not be directly compared to previous reports.

As this report analyses data from the AEMS database, the numbers published in this report may be different to the numbers found the Database of Adverse Event Notifications (DAEN) – medicines, a public online database maintained by the TGA that contains reports of adverse events for all medicines and vaccines.(23) The AEMS database includes more detailed information on each AEFI report and incorporates amendments and updates to reports when additional information is made available to the TGA. As the data for this analysis was extracted from AEMS in May 2022, there may be discrepancies with the DAEN – medicines, which is a live database that reflects new information made available to the TGA.

Results

There were 618 reports in the AEMS database where the date of vaccination (or onset of adverse event or received date, if vaccination date was not reported) was between 1 January and 31 December 2021. Of reports with sex reported (N=595), 358 (60.2%) were in females and 237 (39.8%) were in males; 23 reports (3.7% of total) did not report sex. Of reports with Indigenous status reported (N=92), 39 AEFI reports (42.4%) were for people identified as Aboriginal and/or Torres Strait Islander; Indigenous status was not reported in 526 reports (85.1%).

Of reports with age or date of birth reported (N=598), 268 (44.8%) were for children aged <7 years and 330 (55.2%) were for people aged ≥7 years, while 20 AEFI reports (3.2% of total) did not report age information.

Approximately half (306, 49.5%) of AEFI reports were reported by the state health department (representing notifications reported to NSW Health via public health units), while 34.8% (215) were reported by health professionals, 12.0% (74) were reported by consumers and 3.4% (21) were reported by pharmaceutical companies. There was one report sent by a regulatory authority and one by a distributor or other organisation.

There were 70 reports excluded from this analysis where suspect non-COVID-19 vaccines were reported together with suspect COVID-19 vaccines; these are included in the separate COVID-19 vaccine AEFI report.

Reporting rate

The overall AEFI reporting rate for 2021 was 7.5 [95% CI 7.0–8.2] per 100,000 population compared with 9.6 [95% CI 9.0–10.3] per 100,000 in 2020 and 10.0 [95% CI 9.3–10.7] per 100,000 in 2019 (Figure 1). The majority of reported events (85.1%) in 2021 were coded as non-serious.

Figures 2-5 demonstrate variations in AEFI reporting for vaccines in people aged <7, 7-17, 18-64 and ≥65 years associated with changes to the NIP from 2000 onwards. The decrease in reports in 2021 compared with 2020 was mainly attributable to fewer AEFI reports following a >30% reduction in the number of AEFI reports following 23vPPV, HPV vaccine, MMRV, dTpa, and standard-formulation seasonal influenza vaccine. The highest numbers of AEFI reports in 2021 followed standard-formulation seasonal influenza vaccine in people aged 18-64 years (Table 1, Figure 4), and 13vPCV, DTPa-IPV-HepB-Hib, rotavirus vaccine and DTPa-IPV in children aged <7 years (Table 1, Figure 2).

Age distribution

The highest age-specific AEFI reporting rate per 100,000 population occurred in children aged <7 years (Figure 6). Compared with 2020, reporting rates of AEFI decreased in all age groups in 2021 (Figure 6).

Vaccines

The vaccine most frequently reported in 2021 AEFI reports was standard-formulation seasonal influenza vaccine (183 reports; 29.6% of total), followed by 13vPCV (119 reports; 19.3%), DTPa-IPV-HepB-Hib (82 reports; 13.3%), DTPa-IPV (61 reports; 9.9%) and rotavirus vaccine (60 reports; 9.7%) (Table 2). Of the 183 AEFI reports following standard-formulation seasonal influenza

vaccination, 24 (13.1%) were classified as serious and 37 (20.2%) were reported in children aged <7 years (Table 2).

Adverse events

The most frequently reported PT or SMQ in 2021 were hypersensitivity (122 reports; 19.7%), injection site reactions (104 reports; 16.8%), pyrexia (104 reports; 16.8%), gastrointestinal non-specific symptoms and therapeutic procedures (77 reports; 12.5%) and headache (46 reports; 7.4%) (Table 3).

Serious adverse events

The proportion of AEFI reports where the outcome was categorised as serious remained low in 2021 with 14.9% of all AEFI reports coded as serious. The proportion of serious AEFI reports for the vaccines with the highest numbers of serious reports were: 24/183 (13.1%) following standard-formulation seasonal influenza vaccine, 23/119 (19.3%) following 13vPCV, 18/60 (30.0%) following rotavirus vaccine, 18/82 (22.0%) following DTPa-IPV-HepB-Hib, 13/59 (22.0%) following high-dose or adjuvanted seasonal influenza vaccine, and 9/51 (17.6%) following MMR (Table 3).

Death following vaccination

Five adverse events with a fatal outcome were reported to the TGA from NSW where the reporter considered a causal link between vaccination and the event was possible. Following assessment, the TGA did not receive sufficient information to establish a causal link between vaccination and the condition that caused the death for any of the five cases, however the TGA still recorded these cases as “causality possible” and will continue to consider new information about these cases as it arises. There were three cases in adults aged >70 years who died following complications of their existing underlying medical conditions. There were two cases in children: one case who died of complications from COVID-19 infection and one who died from a congenital condition.

Discussion

In 2021, there was a decrease in both the number of AEFI reports and the overall AEFI reporting rate compared with the previous years, consistent with national AEFI reporting rate trends (24, 25). While 70 AEFI reports with both non-COVID-19 and COVID-19 vaccines were excluded from this analysis, the number of AEFI reports and overall AEFI reporting rate with the inclusion of these reports (688 reports; 8.4 per 100,000 population) is still lower than for 2020 (788 reports; 9.6 per 100,000 population, Figure 1). This decrease in the AEFI reporting rate in 2021 could be related to the focus on COVID-19 vaccines and therefore AEFI reporting for COVID-19 vaccines in 2021.

In children aged <7 years, there was a decrease in the number of AEFI reports for all vaccines except MenB and MMR. The increased number of AEFI reports following MenB reflects increased AEFI reporting that typically occurs after a vaccine is introduced to the NIP.(4-6, 8, 11, 12, 24, 26-32) MenB was funded for Aboriginal and Torres Strait Islander children aged <12 months and individuals of any age with specified high-risk medical conditions from 2020 (Table S1). While the number of AEFI reports following MMR increased in 2021 compared to 2020, it remains within the range of AEFI reports following MMR over the past 20 years.

Among people aged 7 to 17 years, there was also a decrease in the number of AEFI reports for all vaccines. The decrease in AEFI reports may be a reflection of modestly lower vaccine uptake(33), possibly as a result of ongoing impacts of COVID-19 restrictions and/or infection delaying vaccinations or access to vaccinations via school-based programs.(34) The AEFI reporting rate for MenACWY in this age group (13.8 per 100,000 doses [95%CI 6.3–26.3]) has decreased and stabilised following vaccine program introduction and comparatively high AEFI reporting rates (29.2 per 100,000 doses [95%CI 20.3–40.6]) in 2018.(35)

In people aged 18 to 64 years, the majority of AEFI reports followed standard-formulation seasonal influenza vaccine while in people aged ≥65 years, high-dose or adjuvanted seasonal influenza vaccine had the highest number of AEFI reports, reflecting the vaccination recommendations for both age groups. Increased AEFI reports following high-dose or adjuvanted seasonal influenza vaccine in people aged ≥65 years may be a result of higher vaccine coverage in this age group in 2021 compared to 2020.(33)

Overall, the three most commonly reported AEFI in NSW were hypersensitivity (19.7%), injection site reactions (16.8%) and pyrexia (16.8%), consistent with previous years and with national AEFI reporting. While the proportion of serious AEFI reports in NSW was higher compared to Australia as a whole (14.9% vs 6.5%), the difference is likely a result of fewer reports of non-serious AEFI in NSW rather than a higher-than-expected number of serious AEFI, as the serious AEFI reporting rate in NSW is similar compared to the national rate (1.1 vs 0.9 per 100,000 population). Finally, of the five deaths following vaccination, none were considered to be causally related to vaccination following detailed review of individual reports by TGA staff.

These national spontaneous surveillance data are complemented by AusVaxSafety, an active sentinel vaccine safety surveillance system, that also monitors the safety of vaccines used in the NIP.(36) While the data from both systems cannot be directly compared due to differences in methodology, they provide complementary data on the safety of vaccines used in Australia.

There are some limitations to this analysis. AEFI reports can vary significantly in the amount of detail, completeness, and quality of information, and are not always verified against clinical notes. AEFI reports can include multiple vaccines, vaccination dates, AEFI, and AEFI onset dates. Based on the information provided, it not always possible to associate specific vaccines to specific AEFI

and AEFI onset dates. The seriousness criteria for AEFI reports can be applied differently based on the report source and is not always based on verified clinical data, so it may not capture all medically important events, and in addition may capture non-serious events; therefore, the seriousness classification of an AEFI report cannot be directly interpreted as an indicator of safety. While AEFI reporting rates can be estimated, they cannot be interpreted as incidence rates due to potential under-reporting, biased reporting, stimulated reporting (from increased awareness of potential adverse events of vaccines newly introduced to the NIP or covered in the media), and the variable quality and completeness of information provided in individual notifications.(3-8, 11-14, 26, 37-39) Indigenous status is not always reported in all AEFI reports and therefore AEFI rates in Aboriginal and Torres Strait Islander people are likely to be biased. Finally, the AEFI reported here are not necessarily causally related to vaccination. The TGA strongly encourages consumers and health professionals to report suspected adverse events, even if there is only a very small chance a vaccine was the cause. With large scale vaccination programs, it is inevitable by chance that some people will experience a new illness or die within a few days or weeks of vaccination. These events are often coincidental, rather than being caused by the vaccine.

Conclusion

Overall, AEFI reporting rates for non-COVID-19 vaccines decreased in 2021 compared with 2020, with the majority of reported AEFI being common, expected adverse events. The data reported here are consistent with an overall high level of safety for vaccines included in the NIP schedule when administered according to clinical recommendations.

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Tables

Table 1. Vaccines listed as 'suspected' in reports of adverse events following immunisation (AEFI) in the Adverse Event Management System database from NSW in 2021 (excluding COVID-19 vaccines), by age group

Age group	Vaccine	AEFI reports (n)[a]	Vaccine Doses[b]	Reporting rate per 100,000 doses (95% CI)
<7 years	13vPCV	90	271,399	33.2 (26.7–40.8)
	DTPa-HepB-IPV-Hib	77	274,372	28.1 (22.1–35.1)
	Rotavirus	59	177,218	33.3 (25.3–42.9)
	DTPa-IPV	58	93,349	62.1 (47.2–80.3)
	MMR	43	90,849	47.3 (34.3–63.7)
	MenB	41	81,935	50 (35.9–67.9)
	Influenza (seasonal - standard formulation)	37	147,579	25.1 (17.7–34.6)
	MenACWY	35	91,202	38.4 (26.7–53.4)
	DTPa	27	90,073	30 (19.8–43.6)
	Hib	15	90,298	16.6 (9.3–27.4)
	MMRV	14	90,157	15.5 (8.5–26.1)
	Influenza (seasonal - high-dose or adjuvanted)	1	111	900.9 (22.8–4917.3)
7-17 years	HPV	20	142,450	14 (8.6–21.7)
	dTpa	12	88,986	13.5 (7–23.6)
	MenACWY	9	65,000	13.8 (6.3–26.3)
	Influenza (seasonal - standard formulation)	8	143,358	5.6 (2.4–11)
	MenB	1	2,555	39.1 (1–217.9)
	MMR	1	2,350	42.6 (1.1–236.9)
18-64 years	Influenza (seasonal - standard formulation)	122	1,332,342	9.2 (7.6–10.9)
	dTpa	23	206,375	11.1 (7.1–16.7)
	Hepatitis B	7	68,421	10.2 (4.1–21.1)
	23vPPV	6	3,690	162.6 (59.7–353.6)
	HPV	5	15,359	32.6 (10.6–76)
	MMR	4	22,769	17.6 (4.8–45)
	Influenza (seasonal - high-dose or adjuvanted)	3	12,500	24 (4.9–70.1)
	Zoster (RZV)	3	1,777	168.8 (34.8–492.6)
	MenB	2	5,135	38.9 (4.7–140.6)
	Zoster (ZVL)	2	2,669	74.9 (9.1–270.4)
	Hepatitis A and hepatitis B	1	7,104	14.1 (0.4–78.4)
	MMRV	1	591	169.2 (4.3–939.1)
	13vPCV	1	8,630	11.6 (0.3–64.5)
	Typhoid and hepatitis A	1	1,440	69.4 (1.8–386.3)
≥w65 years	Influenza (seasonal - high-dose or adjuvanted)	55	893,038	6.2 (4.6–8)
	13vPCV	24	98,299	24.4 (15.6–36.3)
	Zoster (ZVL)	12	53,266	22.5 (11.6–39.3)
	Influenza (seasonal - standard formulation)	8	74,662	10.7 (4.6–21.1)
	dTpa	4	36,583	10.9 (3–28)
	23vPPV	4	9,274	43.1 (11.8–110.4)
	Zoster (RZV)	2	3,270	61.2 (7.4–220.8)

[a]Number of AEFI reports 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 2021. More than one vaccine may be coded as 'suspected' if several were administered or reported at the same time

[b]Number of vaccine doses recorded on the Australian Immunisation Register and administered between 1 January and 31 December 2021

Table 2. Vaccines listed as 'suspected' in reports of adverse events following immunisation in the Adverse Event Management System database from NSW in 2021 (excluding COVID-19 vaccines)

Vaccine[a]	AEFI reports n (%)[b]	One suspected vaccine only n (%)[cf]	Serious AEFI n (%)[df]	Aged <7 years n (%)[ef]	Aged ≥7 years n (%)[ef]
Influenza (seasonal - standard formulation)	183 (29.6)	163 (89.1)	24 (13.1)	37 (20.2)	138 (75.4)
13vPCV	119 (19.3)	20 (16.8)	23 (19.3)	90 (75.6)	25 (21)
DTPa-HepB-IPV-Hib	82 (13.3)	16 (19.5)	18 (22)	77 (93.9)	1 (1.2)
DTPa-IPV	61 (9.9)	54 (88.5)	2 (3.3)	58 (95.1)	2 (3.3)
Rotavirus	60 (9.7)	0 (0)	18 (30)	59 (98.3)	0 (0)
Influenza (seasonal - high-dose or adjuvanted)	59 (9.5)	57 (96.6)	13 (22)	1 (1.7)	58 (98.3)
MMR	51 (8.3)	10 (19.6)	9 (17.6)	43 (84.3)	6 (11.8)
MenB	47 (7.6)	24 (51.1)	8 (17)	41 (87.2)	3 (6.4)
MenACWY	45 (7.3)	10 (22.2)	5 (11.1)	35 (77.8)	9 (20)
dTpa	39 (6.3)	25 (64.1)	3 (7.7)	0 (0)	39 (100)
DTPa	30 (4.9)	9 (30)	6 (20)	27 (90)	3 (10)
HPV	26 (4.2)	16 (61.5)	4 (15.4)	0 (0)	25 (96.2)
Hib	16 (2.6)	0 (0)	1 (6.2)	15 (93.8)	1 (6.2)
MMRV	15 (2.4)	2 (13.3)	2 (13.3)	14 (93.3)	1 (6.7)
Zoster (ZVL)	15 (2.4)	11 (73.3)	1 (6.7)	0 (0)	14 (93.3)
23vPPV	14 (2.3)	7 (50)	1 (7.1)	1 (7.1)	11 (78.6)
Varicella	10 (1.6)	5 (50)	3 (30)	3 (30)	7 (70)
DT	7 (1.1)	6 (85.7)	1 (14.3)	1 (14.3)	6 (85.7)
Hepatitis B	7 (1.1)	4 (57.1)	0 (0)	0 (0)	7 (100)
Zoster (RZV)	5 (0.8)	5 (100)	0 (0)	0 (0)	5 (100)
Meningococcal (unspecified)	3 (0.5)	1 (33.3)	3 (100)	2 (66.7)	1 (33.3)
7vPCV	3 (0.5)	0 (0)	1 (33.3)	3 (100)	0 (0)
Pneumococcal (unspecified)	3 (0.5)	0 (0)	2 (66.7)	3 (100)	0 (0)
DTP	2 (0.3)	0 (0)	1 (50)	2 (100)	0 (0)
DTPa-Hib	1 (0.2)	0 (0)	1 (100)	1 (100)	0 (0)
Hepatitis A and hepatitis B	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (100)
Hib and MenCY	1 (0.2)	0 (0)	1 (100)	1 (100)	0 (0)
Hib and tetanus	1 (0.2)	0 (0)	0 (0)	1 (100)	0 (0)
Tick-borne encephalitis	1 (0.2)	1 (100)	0 (0)	0 (0)	1 (100)
Typhoid and hepatitis A	1 (0.2)	1 (100)	0 (0)	0 (0)	1 (100)

[a]See appendix for abbreviations of vaccine names
[b]Number of AEFI reports 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 2021. More than one vaccine may be coded as 'suspected' if several were administered or reported at the same time
[c]AEFI reports where only one vaccine was suspected of causal involvement in a reported adverse event
[d]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
[e]Includes only AEFI reports where an age or date of birth has been reported
[f]Percentages are calculated for the number of AEFI reports where the vaccine was suspected of causal involvement in the event

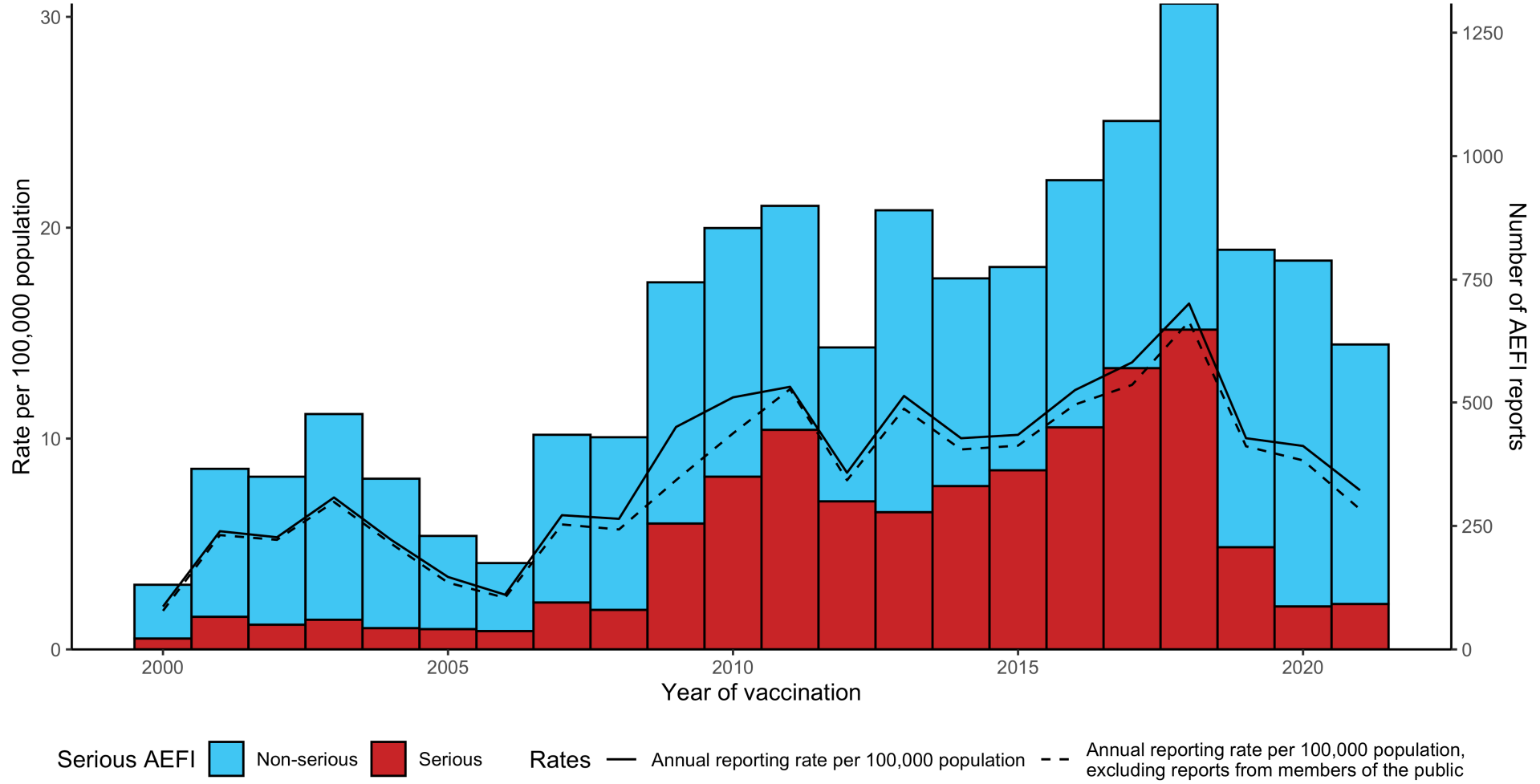
Table 3. The 50 most frequently reported adverse events classified by MedDRA Preferred Terms or Standardised MedDRA queries in reports of adverse events following immunisation in the Adverse Event Management System database from NSW in 2021 (excluding COVID-19 vaccines)

PT or SMQ	AEFI reports n (%)[a]	One PT only n (%)[be]	Serious AEFI n (%)[ce]	Aged <7 years n (%)[de]	Aged ≥7 years n (%)[de]
Hypersensitivity	122 (19.7)	48 (39.3)	5 (4.1)	66 (54.1)	54 (44.3)
Injection site reaction	104 (16.8)	49 (47.1)	4 (3.8)	46 (44.2)	56 (53.8)
Pyrexia	104 (16.8)	5 (4.8)	11 (10.6)	62 (59.6)	39 (37.5)
Gastrointestinal nonspecific symptoms and therapeutic procedures	77 (12.5)	8 (10.4)	12 (15.6)	36 (46.8)	39 (50.6)
Headache	46 (7.4)	0 (0)	6 (13)	2 (4.3)	44 (95.7)
Haemodynamic oedema, effusions and fluid overload	44 (7.1)	15 (34.1)	4 (9.1)	27 (61.4)	17 (38.6)
Dyspnoea	28 (4.5)	1 (3.6)	6 (21.4)	6 (21.4)	21 (75)
Convulsions	25 (4)	13 (52)	18 (72)	21 (84)	2 (8)
Fatigue	25 (4)	1 (4)	2 (8)	0 (0)	24 (96)
Malaise	23 (3.7)	1 (4.3)	1 (4.3)	2 (8.7)	21 (91.3)
Lethargy	22 (3.6)	0 (0)	5 (22.7)	14 (63.6)	8 (36.4)
Angioedema	21 (3.4)	4 (19)	2 (9.5)	8 (38.1)	12 (57.1)
Arthralgia	20 (3.2)	2 (10)	1 (5)	0 (0)	20 (100)
Medication errors	19 (3.1)	10 (52.6)	0 (0)	4 (21.1)	13 (68.4)
Pain in extremity	19 (3.1)	2 (10.5)	0 (0)	1 (5.3)	17 (89.5)
Cough	18 (2.9)	0 (0)	3 (16.7)	6 (33.3)	12 (66.7)
Dizziness	17 (2.8)	0 (0)	1 (5.9)	0 (0)	17 (100)
Irritability	17 (2.8)	1 (5.9)	3 (17.6)	15 (88.2)	1 (5.9)
Myalgia	17 (2.8)	0 (0)	2 (11.8)	0 (0)	16 (94.1)
Paraesthesia	15 (2.4)	0 (0)	1 (6.7)	0 (0)	14 (93.3)
Tachycardia	15 (2.4)	0 (0)	3 (20)	5 (33.3)	10 (66.7)
Syncope	14 (2.3)	5 (35.7)	5 (35.7)	2 (14.3)	10 (71.4)
Anaphylactic/anaphylactoid shock conditions	13 (2.1)	8 (61.5)	5 (38.5)	5 (38.5)	8 (61.5)
Chills	13 (2.1)	0 (0)	1 (7.7)	1 (7.7)	12 (92.3)
Injection site pain	13 (2.1)	3 (23.1)	0 (0)	1 (7.7)	12 (92.3)
Rhinorrhoea	13 (2.1)	0 (0)	2 (15.4)	5 (38.5)	7 (53.8)
Chest pain	12 (1.9)	2 (16.7)	2 (16.7)	0 (0)	11 (91.7)
Pallor	12 (1.9)	0 (0)	2 (16.7)	7 (58.3)	4 (33.3)
Respiratory failure	12 (1.9)	2 (16.7)	2 (16.7)	12 (100)	0 (0)
Decreased appetite	10 (1.6)	0 (0)	1 (10)	8 (80)	2 (20)
Injection site cellulitis	10 (1.6)	5 (50)	0 (0)	6 (60)	4 (40)
Influenza like illness	9 (1.5)	1 (11.1)	0 (0)	0 (0)	9 (100)
Pruritus	9 (1.5)	0 (0)	0 (0)	3 (33.3)	6 (66.7)
Erythema	8 (1.3)	0 (0)	1 (12.5)	3 (37.5)	5 (62.5)
Hypotonia	8 (1.3)	1 (12.5)	2 (25)	8 (100)	0 (0)
Asthenia	7 (1.1)	0 (0)	0 (0)	0 (0)	7 (100)
Bradycardia	7 (1.1)	0 (0)	1 (14.3)	7 (100)	0 (0)
Concomitant disease aggravated	7 (1.1)	2 (28.6)	4 (57.1)	1 (14.3)	5 (71.4)
Hypotonic-hyporesponsive episode	7 (1.1)	4 (57.1)	3 (42.9)	6 (85.7)	1 (14.3)
Lymphadenopathy	7 (1.1)	1 (14.3)	1 (14.3)	0 (0)	7 (100)
Neonatal disorders	7 (1.1)	1 (14.3)	1 (14.3)	6 (85.7)	0 (0)
Confusional state	6 (1)	0 (0)	1 (16.7)	1 (16.7)	5 (83.3)
Herpes zoster	6 (1)	4 (66.7)	0 (0)	0 (0)	6 (100)
Migraine	6 (1)	1 (16.7)	0 (0)	0 (0)	6 (100)
Pain	6 (1)	1 (16.7)	0 (0)	0 (0)	6 (100)
Somnolence	6 (1)	0 (0)	2 (33.3)	5 (83.3)	1 (16.7)
Bell's palsy	5 (0.8)	4 (80)	3 (60)	1 (20)	3 (60)
Hypoaesthesia	5 (0.8)	2 (40)	0 (0)	0 (0)	5 (100)
Muscular weakness	5 (0.8)	1 (20)	1 (20)	1 (20)	3 (60)
Oxygen saturation decreased	5 (0.8)	0 (0)	1 (20)	5 (100)	0 (0)
Palpitations	5 (0.8)	0 (0)	0 (0)	0 (0)	5 (100)
Presyncope	5 (0.8)	2 (40)	0 (0)	0 (0)	5 (100)
Tremor	5 (0.8)	0 (0)	0 (0)	1 (20)	4 (80)
Wheezing	5 (0.8)	0 (0)	2 (40)	1 (20)	3 (60)

[a]Number of AEFI reports in which the PT or SMQ was reported. More than one PT/SMQ may be recorded on the same report
[b]AEFI reports where only one PT or SMQ was reported
[c]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
[d]Includes only AEFI reports where an age or date of birth has been reported
[e]Percentages are calculated for the number of AEFI reports where the PT or SMQ was reported

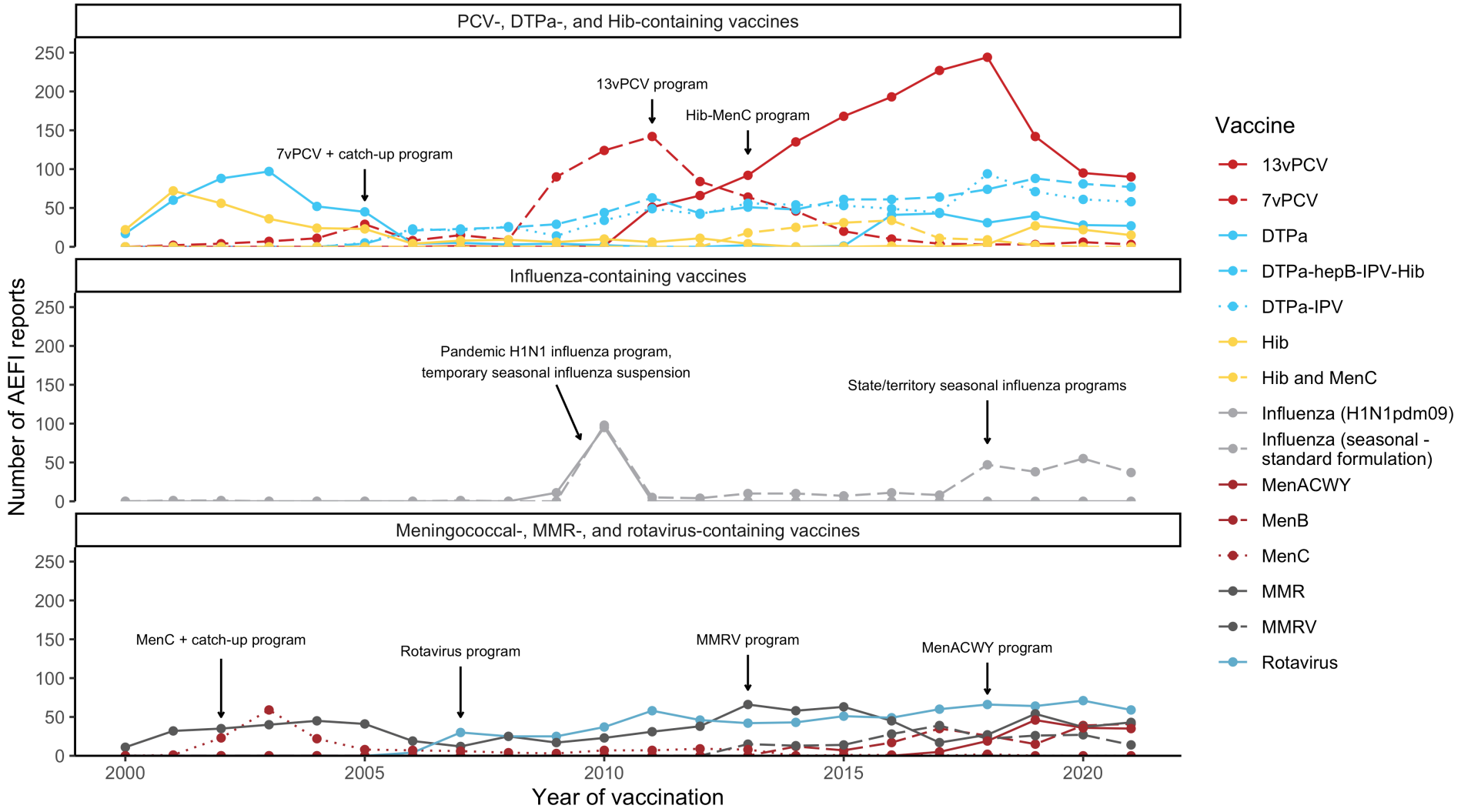
Figures

Figure 1. Adverse event following immunisation reports in the Adverse Event Management System database from NSW, 2000 to 2021 (excluding COVID-19 vaccines), by year



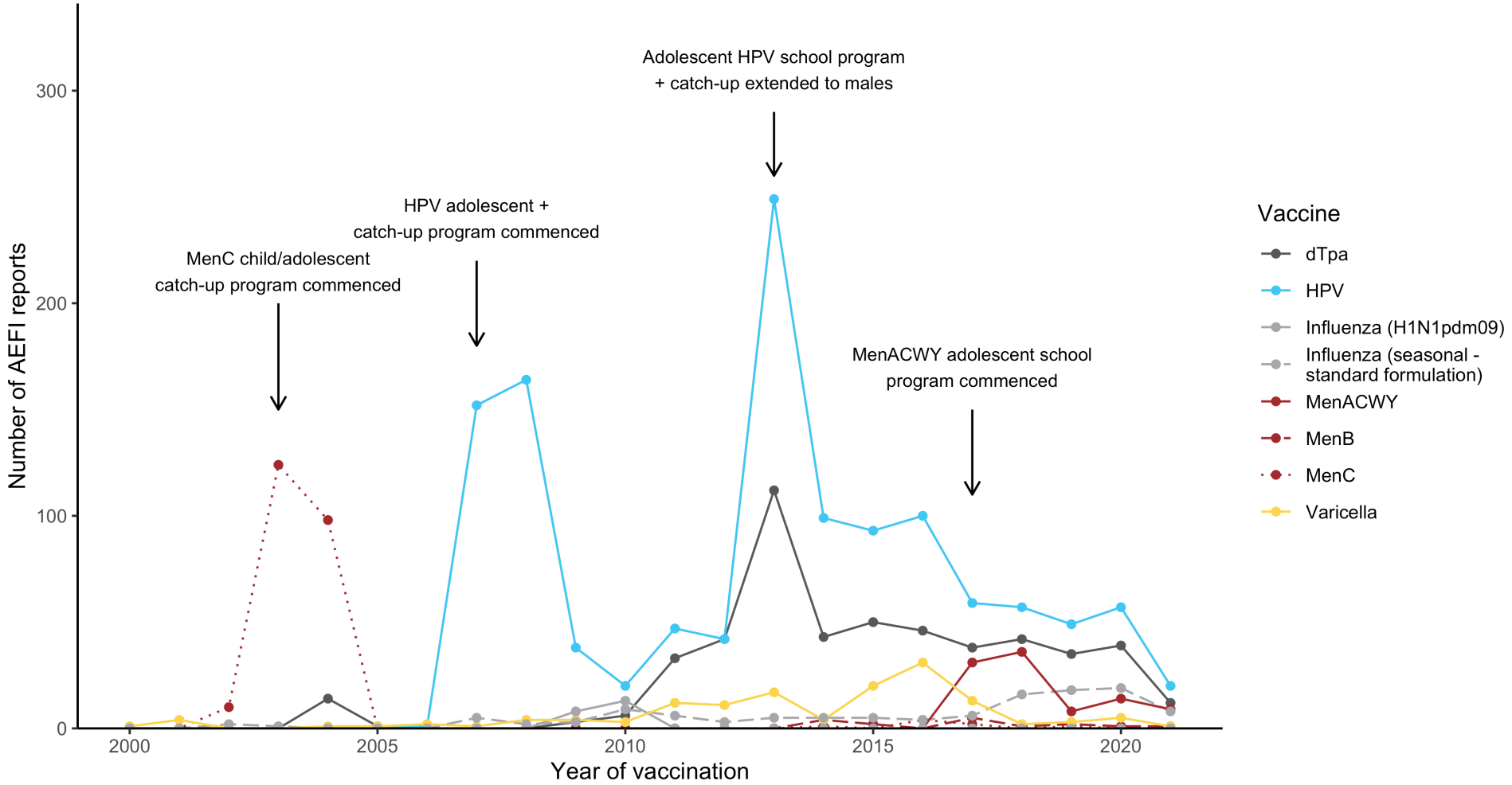
For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1.

Figure 2. Adverse event following immunisation reports in NSW for children aged <7 years in the Adverse Event Management System database from 2000 to 2021 (excluding COVID-19 vaccines), by year and vaccine



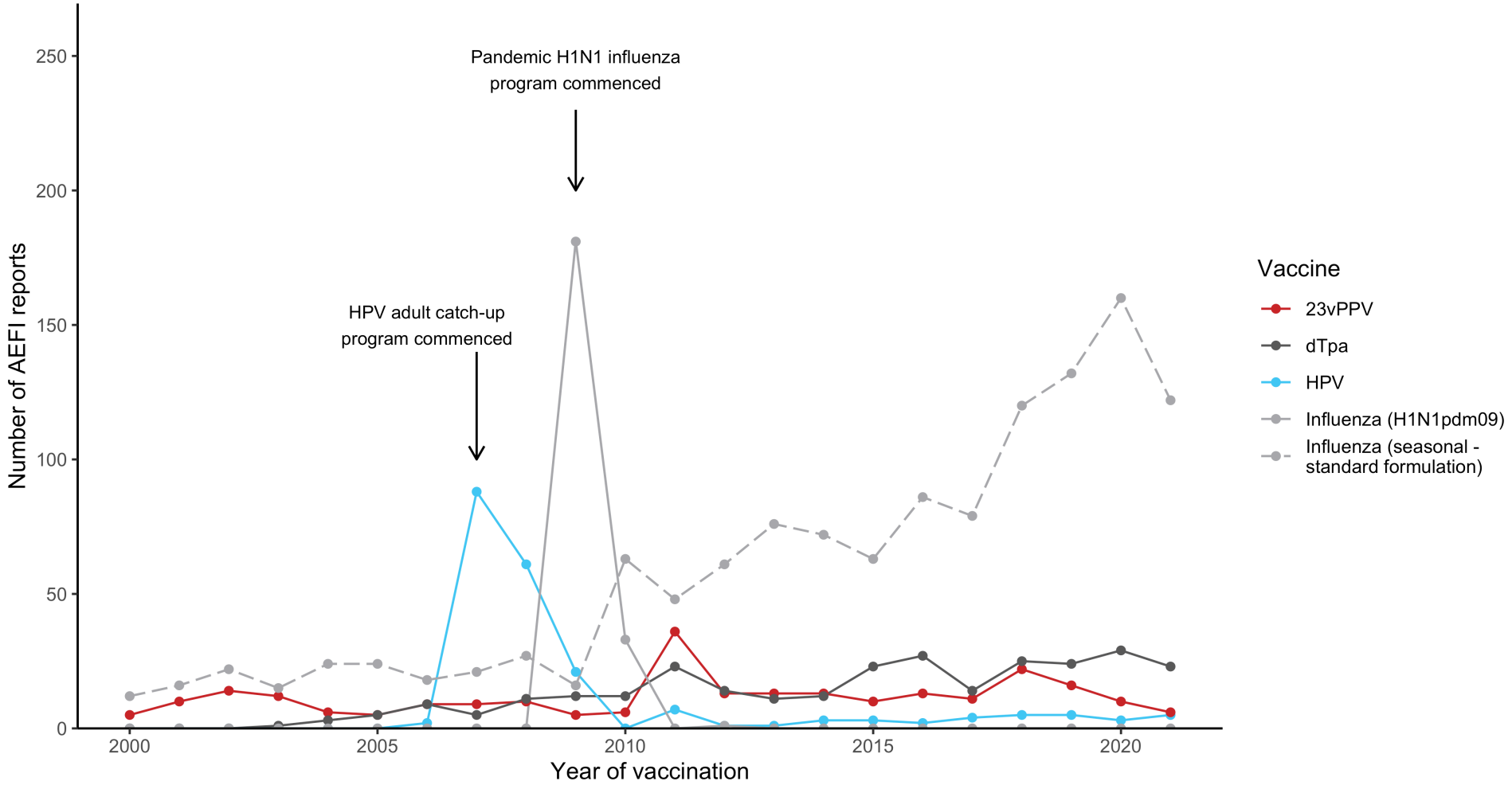
For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1.

Figure 3. Adverse event following immunisation reports in NSW for people aged 7 to 17 years in the Adverse Event Management System database from 2000 to 2021 (excluding COVID-19 vaccines), by year and vaccine



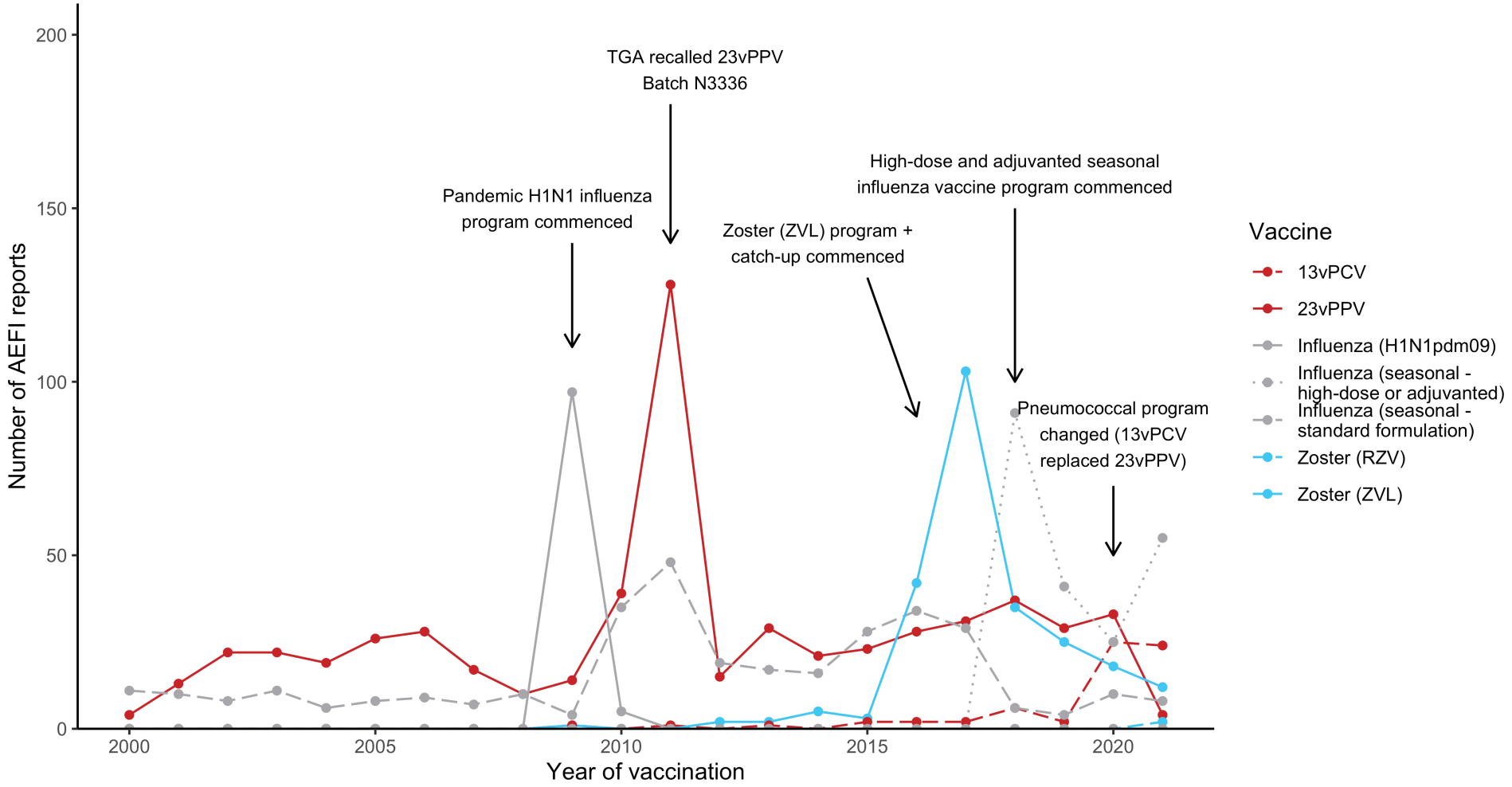
For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1.

Figure 4. Adverse event following immunisation reports in NSW for people aged 18 to 64 years in the Adverse Event Management System database from 2000 to 2021 (excluding COVID-19 vaccines), by year and vaccine



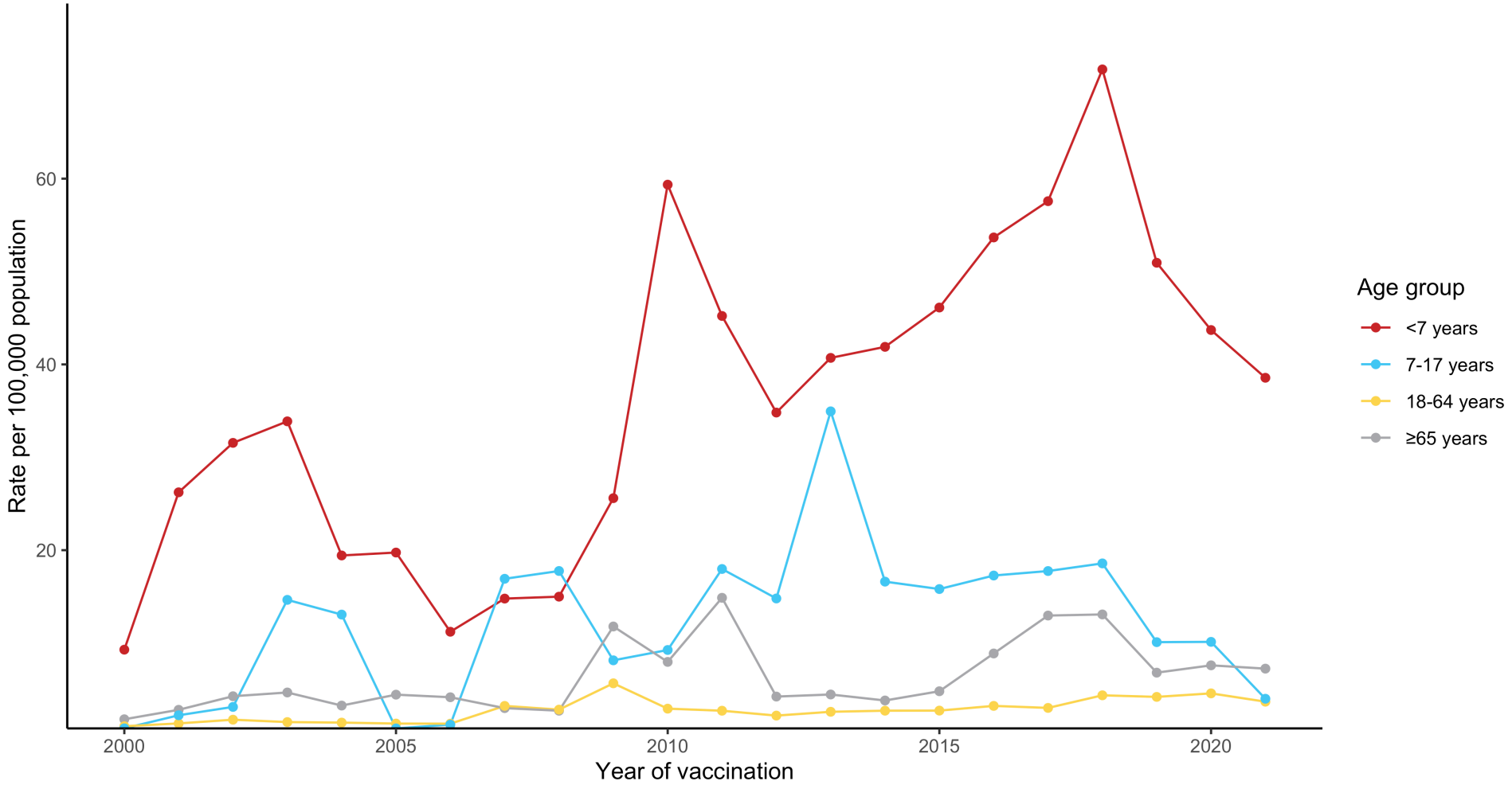
For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1.

Figure 5. Adverse event following immunisation reports in NSW for people aged ≥65 years in the Adverse Event Management System database from 2000 to 2021 (excluding COVID-19 vaccines), by year and vaccine



For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1.

Figure 6. Reporting rates of adverse events following immunisation in NSW per 100,000 population in the Adverse Event Management System database from 2000 to 2021 (excluding COVID-19 vaccines), by year and age group



For reports where the date of vaccination was not recorded, the date of symptom onset or the received date (when the event was reported to the sender of the case) was used. For more details on changes to the National Immunisation Program, please refer to Table S1.

Supplementary Material

Table S7. Changes in immunisation policy and the National Immunisation Program (NSW, 2005–2021)

Year	Change
2020	**July 2020**
	A single dose of 13vPCV is recommended and funded for Aboriginal and Torres Strait Islander adults at 50 years of age, followed by a dose of 23vPPV 12 months later and a 2nd dose of 23vPPV 5–10 years after that.
	A single dose of 13vPCV is recommended and funded for non- Aboriginal and Torres Strait Islander adults at 70 years of age, replacing the previously funded dose of 23vPPV at 65 years of age.
	Meningococcal B vaccine funded for all Aboriginal and Torres Strait Islander children (age <12 months) and individuals of any age with specified high risk medical conditions. Catch-up available for all Aboriginal and Torres Strait Islander children <2 years of age (up to 23 months) for 3 years - until 30 June 2023.
	March 2020
	All children aged 6 months to <5 years funded for influenza vaccine under NIP.
	First enhanced quadrivalent influenza vaccine (adjuvanted) funded nationally for adults aged 65 years and over.
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.
	February 2019
	Annual seasonal influenza vaccination funded on the national childhood vaccination schedule for all Australian children aged 6 months – <5 years.
	Aboriginal and Torres Strait Islander children and adolescents aged 5–14 years of age funded for influenza vaccine under NIP.
2018	**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–<5 years
	February 2018
	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 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.
2016	**November 2016**
	Zoster vaccine (Zostavax®) provided free for people aged 70 years under the National Immunisation Program (NIP) with a five-year catch-up program for people aged 71 – 79 years.

	March 2016 Free booster dose of the diphtheria, tetanus, and acellular pertussis-containing vaccine (DTPa) at 18 months of age.
2015	**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. **March 2015** Seasonal influenza vaccine funded for Aboriginal and Torres Strait Islander children aged 6 months to less than 5 years. From March to June 2015, the dTpa vaccine for women during the third trimester of pregnancy was funded by New South Wales, South Australia, Western Australia, the Australian Capital Territory, Victoria and Tasmania. The Northern Territory had funded it since September 2013 and Queensland since July 2014. A booster dose of DTPa vaccine recommended at 18 months of age (funded in March 2016).
2014	**December 2014** 4vHPV vaccine catch-up program for males aged 14–15 years ceased
2013	**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). **July 2013** Second dose of MMR vaccine, previously given at 4 years, was brought forward to 18 months of age and delivered as MMRV vaccine. Combined *Haemophilus influenzae* type b (Hib) and meningococcal serogroup C (MenC) vaccine, Menitorix®, was funded for infants aged 12 months. This combination vaccine replaced the single dose of monovalent meningococcal C conjugate vaccine (MenCCV) and booster dose of monovalent Hib vaccine previously scheduled at 12 months of age. **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.
2012	**October 2012** A fourth dose of Prevenar 13®, (13vPCV, a 13-valent pneumococcal conjugate vaccine) was listed on the National Immunisation Program (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.
2011	**1 October 2011 to 30 September 2012** All children aged between 12 – 35 months who had completed a primary pneumococcal vaccination course with 7vPCV were eligible to receive a free supplementary dose of Prevenar 13® **25 March 2011** TGA issued a recall of Batch N3336 of the 23 valent pneumococcal polysaccharide vaccine 23vPPV, Pneumovax® 23. April 2011: Health professionals were advised not to administer a second or subsequent dose of Pneumovax 23 vaccine. December 2011: Revised recommendations regarding which patients should be re-vaccinated under the NIP were provided.
2010	Annual vaccination with seasonal trivalent influenza vaccine (TIV, containing 3 influenza strains: A/H1N1, A/H3N2 and B) was funded under the NIP for people aged ≥6 months with

	medical risk factors (previously subsidised through the Pharmaceutical Benefits Scheme) and all Indigenous people aged ≥15 years (previously all Indigenous adults ≥50 years and 15–49 years with medical risk factors). On 23 April 2010, the use of the 2010 seasonal TIV in children <5 years of age was suspended by Australia's Chief Medical Officer due to an increased number of reports of fever and febrile convulsions post vaccination. A subsequent investigation identified that Fluvax® and Fluvax junior® (CSL Biotherapies), but neither of the other two available brands registered for use in young children, were associated with an unacceptably high risk of febrile convulsions. The recommendation to resume the use of seasonal influenza vaccine in children aged 6 months to 5 years, using brands other than Fluvax® and Fluvax junior®, was made in August 2010.
2009	**Late 2009** All states and territories were using the single hexavalent DTPa-IPV-Hib-HepB (Infanrix hexa®) vaccine for all children at 2, 4 and 6 months of age, due to an international shortage of *Haemophilus influenzae* type b (Hib) (PedvaxHib® [monovalent] and Comvax® [Hib-HepB]) vaccines. **September 2009** 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.
2007	**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.
2005	**November 2005** Universal funded immunisation against varicella at 18 months of age with a school-based catch-up program for children at 10–13 years of age not previously vaccinated and without a history of varicella infection (no funded catch-up for children 2–10 years of age). IPV was funded to replace OPV, in combination vaccines. **January 2005** Universal funded infant 7-valent pneumococcal conjugate vaccine (7vPCV) program replaced the previous targeted childhood program, with a catch-up program for children aged <2 years. Universal 23-valent pneumococcal polysaccharide vaccine (23vPPV) for adults aged ≥65 years replaced previous subsidy through the Pharmaceutical Benefits Scheme.

Table S2. Description of PT to SMQ mapping

Number of SMQ mapped	Term reported
0	PT
1	SMQ
>1 (different levels)	SMQ of highest level (most descriptive)
>1 (same level)	SMQ preferred following clinician review and adjudication, or PT if preferred SMQ could not be chosen