Surveillance of adverse events following immunisation in Australia annual report, 2013

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Abstract

This report summarises Australian passive surveillance data for adverse events following immunisation (AEFI) for 2013 reported to the Therapeutic Goods Administration (TGA) for 2013 and describes reporting trends over the 14-year period 1 January 2000 to 31 December 2013. There were 3,161 AEFI records for vaccines administered in 2013. This is an annual AEFI reporting rate of 13.9 per 100,000 population, the 2nd highest since 2000 and an increase of 59% compared with 2012 (1,994 AEFI records; 8.8 per 100,000 population). The increase was partly due to implementation of enhancements to vaccine safety reporting. This included stimulated reporting of AEFI as part of the extension of national human papillomavirus (HPV) vaccination under the National Immunisation Program to males aged 12–13 years, along with a catch-up program for males aged 14 and 15 years in February 2013 (n=785; includes males and females), in which certain events, such as syncope, were closely monitored. Eighty-two per cent (n=341/414) of the syncope reports were following HPV vaccination and of these 57% (n=195) were males and 43% (n=146) were females. In addition, reporting rates for most other the vaccines were higher in 2013 compared with 2012. The majority of AEFI reports described non-serious events while 5% (n=158) were classified as serious. There were 4 reports of death; however, all deaths were investigated by the TGA and no clear causal relationship with vaccination was found. The most commonly reported reactions were injection site reaction (13%), rash (10%), pyrexia (8%), and syncope (7%). *Commun Dis Intell* 2015;39(3):E369–E386.

Keywords: AEFI, adverse events, vaccines, surveillance, immunisation, vaccine safety

Introduction

This report summarises national passive surveillance data for adverse events following immunisation (AEFI) reported to the Therapeutic Goods Administration (TGA) by 28 February 2014. The report focuses on AEFI reported for vaccines administered during 2013 and trends in AEFI reporting over the 14-year period 1 January 2000 to 31 December 2013.

An adverse event following immunisation is defined as any untoward medical occurrence that 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.[2–13] Trends in reported adverse events following immunisation are heavily influenced by changes to vaccine funding and availability provided through the National Immunisation Program (NIP). These changes impact on the interpretation of trend data and have been described in detail in previous reports published regularly since 2003.[2–13] These are listed in Table 1 in chronological order. Recent changes that impact on AEFI surveillance data presented in this report are:

1. In February 2013, the National HPV Vaccination Program (quadrivalent HPV vaccine Gardasil® – CSL Biotherapies/Merck & Co. Inc.) was extended to males aged 12–13 years through the school-based program, including a 2 year catch up program for males aged 14–15 years until the end of 2014.
2. From July 2013, the 2nd dose of MMR vaccine, previously given at 4 years, was brought forward to 18 months of age and delivered as a combination MMRV vaccine.

- From July 2013, combined *Haemophilus influenzae* type b (Hib) and meningococcal serogroup C (MenC) vaccine, Menitorix®, was listed on the NIP replacing the separate administration of monovalent meningococcal C conjugate vaccine (MenCCV) and Hib vaccine previously scheduled at 12 months of age.

To assist readers, at the end of this report there is a glossary of the abbreviations of the vaccines referred to in this report.

Table 1: Changes to the Australian Standard Vaccination Schedule (2003–2013)[2–15]

Date	Intervention
2003	Commencement of the meningococcal C conjugate vaccine (MenCCV) immunisation program. 18-month dose of DTPa vaccine removed from the National Immunisation Program.
2004	dTpa funded at 15–17 years of age replacing the diphtheria-tetanus dose.
2005	From 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. From 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 funded to replace OPV, in combination vaccines.
2007	From 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. From 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®).
2008	Western Australia commenced a seasonal influenza vaccination program for all children aged 6 months to <5 years (born after 1 April 2003). In March 2008, Queensland, South Australia and Victoria changed from using 2 combination vaccines (quadrivalent DTPa-IPV and Hib-HepB) to the single hexavalent DTPa-IPV-HepB-Hib vaccine.
2009	By 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. 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.
2010	Annual vaccination with seasonal trivalent influenza vaccine (TIV, containing 3 influenza strains: A/H1N1, A/H3N2 and B) was funded under the National Immunisation Program (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 2 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.
2011	From 1 July 2011, Prevenar 13® 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. 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® On 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.
2012	From 1 October 2012, a fourth dose of Prevenar 13®, (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.
2013	From 1 February 2013, 4vHPV 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. From July 2013, the 2nd dose of MMR vaccine, previously given at 4 years, was brought forward to 18 months of age and delivered as a combination MMRV vaccine. From July 2013, 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.

Abbreviations of vaccine names are defined in the Appendix.

Methods

AEFI are notified to the TGA by state and territory health departments, health professionals, vaccine companies and members of the public.[14, 15] All reports are assessed using internationally consistent criteria[16] and entered into the Australian Adverse Drug Reactions System (ADRS) database. The TGA medical officers review all serious reports for drugs and vaccines. Reports are used in data mining and signal detection activities. Where there is insufficient information in a report to determine causality for a serious adverse event the TGA will contact the reporter on up to 3 occasions to elicit further information.

Adverse events following immunisation data

De-identified information on all AEFI reported to the TGA from 1 January 2000 to 31 December 2013 and stored in the ADRS database were released to the National Centre for Immunisation Research and Surveillance (NCIRS) in March 2014. Readers are referred to previous AEFI surveillance reports for description of the surveillance system.[2,5]

Records*contained in the ADRS database were eligible for inclusion in the analysis if a vaccine was recorded as 'suspected'† of involvement in the reported adverse event and either

(a) the vaccination occurred between 1 January 2000 and 31 December 2013, 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 2013.

Study definitions of adverse events following immunisation outcomes and reactions

AEFI were defined as 'serious' or 'non-serious' based on information in the report sent to the TGA and criteria similar to those used by the World Health Organization[16] and the US Vaccine Adverse Events Reporting System (VAERS).[17] In this report, an AEFI is defined as 'serious' if it meets one or more of the following criteria: (1) results in death; (2) is life-threatening; (3) requires inpatient hospitalisation or prolongation of existing hospitalisation; (4) results in persistent or significant disability/incapacity; (5) is a congenital anomaly/birth defect or; (6) is a medically important event or reaction.

Typically, each record lists several reaction terms that is 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®).[18,19]

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 reactions listed in previous *Australian Immunisation Handbooks*.[14,15] However, the methodological framework of reporting of adverse events have been recently reviewed by NCIRS in collaboration with TGA and a revised format for AEFI analyses using MedDRA preferred terms (PTs) was evaluated.[20] For this report, the new format using MedDRA PTs is used for data analysis. Grouping of reactions using PTs is more comparable with data from other countries and internationally accepted.[21–23] In conjunction with the new national vaccine-specific reporting form,[24] the use of PTs will allow better reflection of post-marketing surveillance data on vaccines in Australia.

Data analysis

All data analyses were performed using SAS software version 9.3.[25] Average annual population-based reporting rates were calculated for each state and territory and by age group using population estimates obtained from the Australian Bureau of Statistics.

Reporting rates per 100,000 administered doses were estimated where information was available on the number of doses administered. This was done for vaccines funded through the NIP for children aged less than 7 years.

Denominator data to estimate reporting rates for influenza and 23vPPV for people aged ≥ 18 years were obtained from a national adult coverage survey conducted in 2009.[26] For 23vPPV, the number of people vaccinated in 2013 was derived from the number of people in this survey who reported receipt of the vaccine within the previous 5 years, divided by five. The number of administered doses of each of the childhood vaccines was obtained from the Australian Childhood Immunisation Register (ACIR), a national population-based register of approximately 99% of children aged less than 7 years.[27]

* The term 'AEFI record' is used throughout this report because a single AEFI notification/report to the Office of Product review can generate more than one record in the ADRS database. This may occur if there is a time sequence of separate adverse reactions in a single patient, such as systemic and local reactions.

† Vaccines are classified as 'suspected' if the report contains sufficient information to be valid and the relationship between reported reactions and the vaccine is deemed at least possible.

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 4th quarter of 2013. Data published in previous reports for 2000–2012 may differ from that 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 reports may be updated and recoded when follow-up information is received or when vaccine-specific analyses are conducted.

The information collated in the ADRS database is intended primarily for signal detection and hypothesis generation. While 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.[2–13,28]

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

Comparison with online Database of Adverse Events Notifications

In August 2012, the TGA made a searchable database; the Database of Adverse Event Notifications (DAEN) available to the public on its website. DAEN contains reports of all adverse event reports for medicines and vaccines.[29] The data in this report have not been downloaded from DAEN. This annual report uses data from the ADRS database sent to NCIRS by TGA in March 2014, and includes more detailed data than are provided by DAEN. The numbers published in this report may be different to the numbers in the DAEN database 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 the DAEN database, including long-term trends and population and dose-based reporting rates, put in the context of changes in vaccine policy and use, and reporting practices.

Results

The ADRS database included a total of 3,161 records where the date of vaccination (or onset of adverse event, if vaccination date was not reported) was between 1 January and 31 December 2013.

In 2013, 88% of AEFI (n=2,768) were reported to the TGA via states and territories (except for Tasmania where all AEFIs are directly reported to TGA), while the rest were reported directly to the TGA by doctors or health care providers (7% n=231), members of the public (3% n=94), hospitals (1% n=30), and vaccine companies (1% n=38).

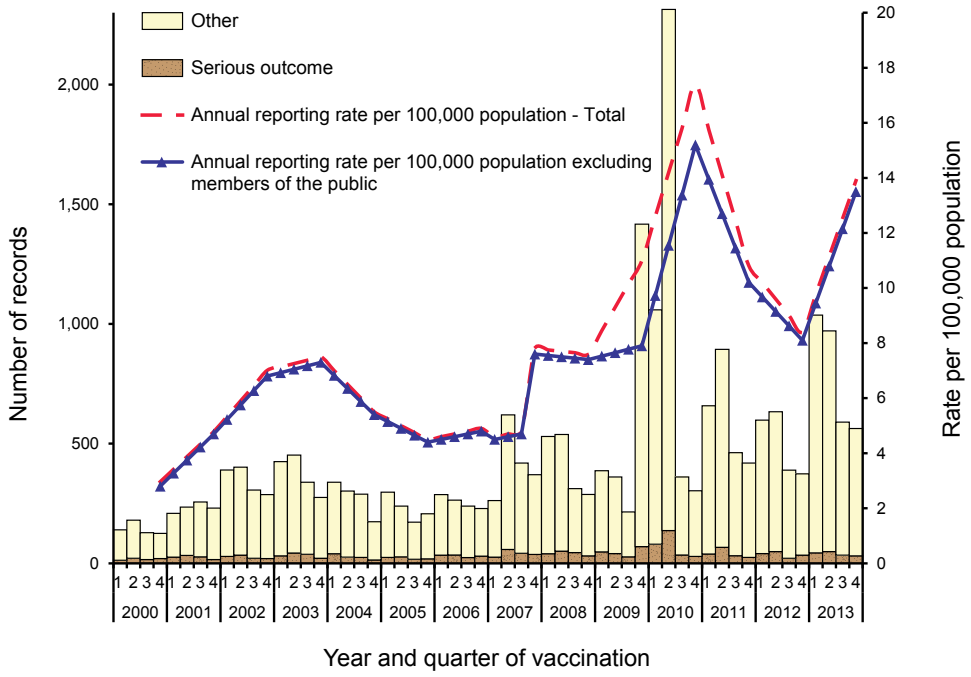
Reporting trends

The overall reporting rate for 2013 was 13.9 per 100,000 population compared with 8.4 per 100,000 in 2012. This was the 2nd highest rate in the 14-year period 2000–2013. The highest peak was observed in 2010 (17.4 per 100,000) predominantly due to reports in children following vaccination with the pandemic and 2010 seasonal trivalent influenza vaccines.[11]

The vast majority of reported events in 2013 (from all reporter types) were of a non-serious nature similar to the previous years (Figure 1).[9,10] Figures 2a, 2b and 2c demonstrate marked variations in reporting levels in association with previous changes to the NIP from 2000 onwards. The increase in reports in 2013 was predominantly due to an increase in reports following HPV vaccines in adolescents, and was associated with the extension of HPV vaccination to males (Figure 2a). An increase was observed in estimated reporting rates for the majority of vaccines in children aged less than 7 years in 2013 compared with 2012, but it was not statistically significant for rotavirus and varicella vaccines (Table 2, Figure 2c). The reporting rates for new NIP vaccines, MMRV and HibMenC, were 75.1 and 73.7 per 100,000 doses, respectively (Table 2, Figure 2b).

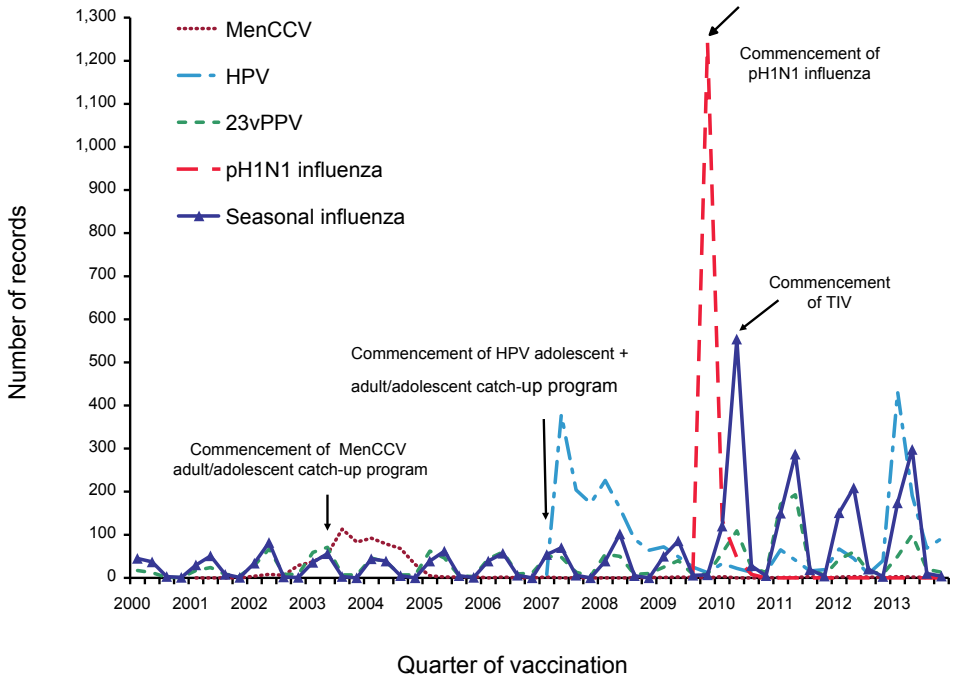
A seasonal pattern of AEFI reporting was apparent in 2013 as in previous years, with the highest number of AEFI notifications for vaccinations administered in the 1st half of the year (Figure 1). This corresponds to the months when influenza vaccine is given and older Australians receive 23vPPV (March to June). However, more AEFI reports following influenza vaccine were received in each of the last 4 years than years prior to 2009 (pre-pandemic era) (Figure 2a).

Figure 1: Adverse events following immunisation, ADRS database, 2000 to 2013, by quarter of vaccination



Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to the Therapeutic Goods Administration was used as a proxy for vaccination date.

Figure 2a: Adverse events following immunisation for people aged ≥7 years in frequently reported vaccines, ADRS database, 2000 to 2013, by quarter of vaccination



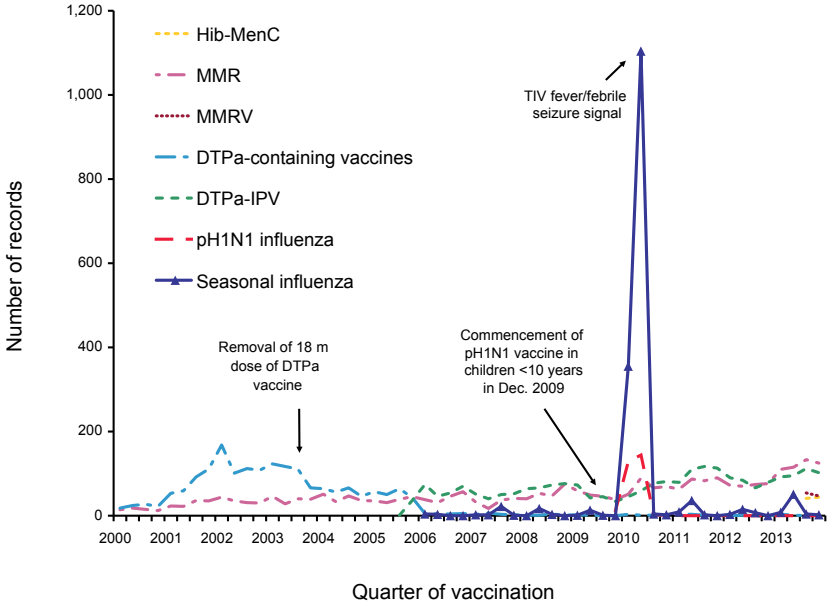
* Safety signal for fever and febrile convulsion found to be due to bioCSL Fluvax 2010 TIV in children.

Meningococcal C conjugate vaccine was introduced onto the National Immunisation Program 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 September 2009; seasonal trivalent influenza vaccine in 2010, which was an extension of existing adult and Indigenous programs to at-risk populations; and human papillomavirus program extended to boys in February 2013 (Table 1).

Abbreviations of vaccine names are defined in the Appendix.

Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to Therapeutic Goods Administration was used as a proxy for vaccination date.

Figure 2b: Adverse events following immunisation for children aged 1 to <7 years in frequently reported vaccines, ADRS database, 2000 to 2013, by quarter of vaccination



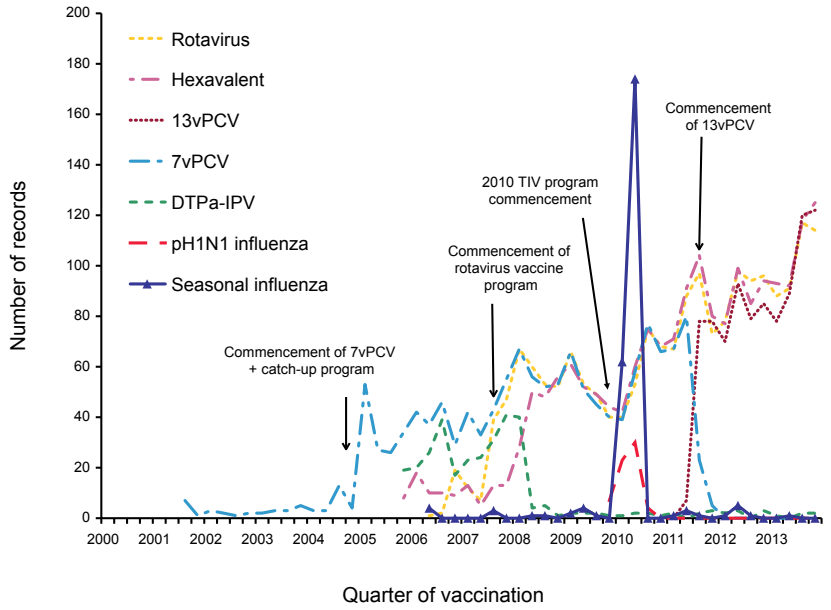
* Safety signal for fever and febrile convulsion found to be due to bioCSL Fluvax 2010 TIV in children.

DTPa-IPV was introduced onto the National Immunisation Program schedule in November 2005 replacing DTPa and OPV; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Indigenous programs to at-risk populations; MMRV and HibMenC vaccines on July 2013, and HPV program extended to boys in February 2013 (Table 1).

Abbreviations of vaccine names are defined in the Appendix.

Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to Therapeutic Goods Administration was used as a proxy for vaccination date.

Figure 2c: Adverse events following immunisation for children aged <1 year, ADRS database, 2000 to 2013, by quarter of vaccination



* Safety signal for fever and febrile convulsion found to be due to bioCSL Fluvax 2010 TIV in children.

DTPa-IPV and DTPa-IPV-HepB-Hib (hexavalent) vaccines were introduced onto the National Immunisation Program 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 (Table 1).

Abbreviations of vaccine names are defined in the Appendix.

Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to Therapeutic Goods Administration was used as a proxy for vaccination date.

Table 2: Vaccine types listed as 'suspected' in records of adverse events following immunisation for 4 age groups, ADRS database, 2013

Vaccines*	AEFI records† (n)	Vaccine doses‡ (n)	Reporting rate per 100,000 doses§ (95% CI) 2013	2012
<7 years				
DTPa-containing vaccines	869	1,156,146	75.2 (70.3–80.3)	57.6 (53.3–62.1)
Hexavalent (DTPa-IPV-HepB-Hib)	461	857,760	53.7 (49.0–58.9)	40.2 (36.0–44.6)
DTPa-IPV	408	298,386	136.7 (123.8–150.7)	107.1 (95.7–119.5)
Measles-mumps-rubella	502	600,467	83.6 (76.4–91.2)	47.8 (42.4–53.8)
Pneumococcal conjugate - PCV	458	866,915	52.8 (48.1–57.9)	37.2 (33.5–41.2)
Rotavirus vaccine	415	537,413	77.2 (70.0–85.0)	62.9 (56.4–70.0)
Meningococcal C conjugate	107	184,674	57.9 (47.5–70.0)	26.6 (21.0–33.1)
Measles-mumps-rubella-varicella	102	135,832	75.1 (61.3–91.1)	na
Haemophilus influenzae type b	96	170,932	56.2 (45.5–68.6)	23.2 (18.0–29.5)
Hib-MenC	92	124,918	73.7 (59.4–90.3)	na
Seasonal influenza	66	na	na	na
Varicella	60	160,579	37.4 (28.5–48.1)	23.9 (18.5–30.3)
Total (<7 years)‖	1,423	3,937,876	36.1 (34.3–38.1)	23.5 (22.1–25.0)
7–17 years				
HPV	770	na	na	na
Hepatitis B	263	na	na	na
dTpa	198	na	na	na
Varicella	95	na	na	na
Seasonal influenza	41	na	na	na
Total (7–17 years)	961	na	na	na
18–64 years				
Seasonal influenza¶	334	3,170,300	10.5 (9.4–11.7)	8.6 (7.9–9.6)
dTpa	58	na	na	na
23vPPV¶	56	132,520	42.3 (31.9–54.9)	30.2 (21.6–41.1)
Total (18–64 years)**	549	3,302,820	11.8 (10.7–13.0)	9.4 (8.4–10.5)
≥65 years				
Seasonal influenza¶	93	2,176,000	4.3 (3.5–5.2)	3.6 (2.8–4.5)
23vPPV¶	114	317,400	35.9 (29.6–43.1)	24.3 (19.2–30.3)
dTpa	3	na	na	na
Total (≥65 years)**	192	2,493,400	8.3 (7.2–9.5)	6.2 (5.3–7.3)**

Abbreviations of vaccine names are defined in the Appendix.

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

† Number of AEFI records in which the vaccine was coded as 'suspected' of involvement in the reported adverse event and the vaccination was administered between 1 January and 31 December 2013. More than 1 vaccine may be coded as 'suspected' if several were administered at the same time.

‡ Number of vaccine doses recorded on the Australian Childhood Immunisation Register and administered between 1 January and 31 December 2013.

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

‖ Number of AEFI records excluding influenza vaccines.

¶ Number of administered doses of seasonal influenza vaccine estimated from the 2009 AIHW national adult vaccination survey.[22]

** Seasonal influenza and 23vPPV only.

Na Not applicable.

Age distribution

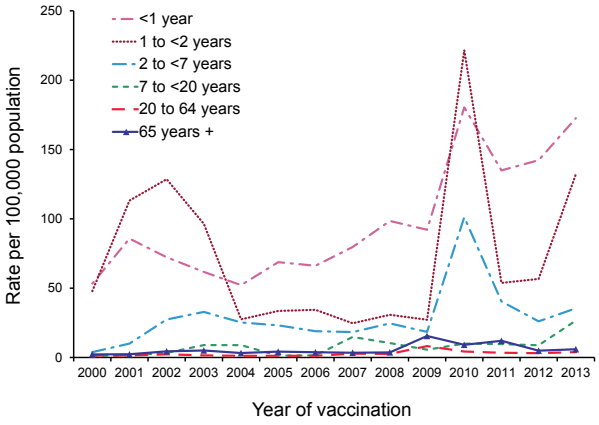
In 2013, the highest population-based AEFI reporting rate occurred in infants less than 1 year of age; the age group that received the highest number of vaccines (Figure 3). Compared with 2012, AEFI reporting rates in children increased substantially in all age groups but the magnitude differed: among the under 1 year age group, it increased 1.2-fold (from 142.3 to 172.6 per 100,000 population); in the 1 to less than 2 years age group it increased approximately 2-fold from 56.7 to 132.1; and in the 2 to less than 7 years age group the increase was 1.4-fold from 26.1 to 35.5 (Figure 3). In the 7 to less than 20 years age group the increase was 3-fold from 8.8 to 26.6 (Figure 3).

Reporting rates per 100,000 doses increased overall and for most individual vaccines in 2013 compared with 2012 (Table 2). This excludes influenza due to the absence of reliable dose data. This should be interpreted with caution due to the lack of recent denominator data and extrapolation of 2009 denominator data.

Geographical distribution

Population-based reporting patterns varied between states and territories during 2013 (Table 3) as in previous years.[2–13] The highest reporting rates were from the Australian Capital Territory, the Northern Territory, Victoria, and Western Australia (40.8, 28.1, 17.9, and 15.2 per 100,000, respectively) while Tasmania had the lowest rate (8.0 per 100,000). Reporting rates increased in most jurisdictions in 2013 compared with 2012 except Tasmania, which experienced a slight drop. The Australian Capital Territory observed a 3-fold increase followed by New South Wales and Queensland, which experienced a 2-fold increase compared with 2012.

Figure 3: Reporting rates of adverse events following immunisation per 100,000 population, ADRS database, 2000 to 2013, by age group and year of vaccination



Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to Therapeutic Goods Administration was used as a proxy for vaccination date.

Table 3: Adverse events following immunisation records, ADRS database, 1 January to 31 December 2013, by state or territory

State or territory	AEFI records n	AEFI records %	Annual reporting rate per 100,000 population* Overall	'Serious' outcome‡	Aged <7 years
Australian Capital Territory	153	5	40.8 (34.6–47.8)	0.8	8.5
New South Wales	641	20	8.8 (8.1–9.5)	0.3	2.5
Northern Territory	66	2	28.1 (21.7–35.7)	2.6	12.3
Queensland	692	22	15.2 (14.0–16.3)	0.8	6.9
South Australia	201	6	12.1 (10.5–13.9)	0.8	5.9
Tasmania	41	1	8.0 (5.7–10.9)	0.4	2.9
Victoria	1005	32	17.9 (16.8–18.9)	0.7	10.2
Western Australia	317	10	13.0 (11.6–14.5)	0.9	7.2
Other§	45	2	na	na	na
Total	3,161	100	13.9 (13.4–14.4)	0.7	6.3

* Average annual rates per 100,000 population calculated using mid-2013 population estimates (Australian Bureau of Statistics).

† See previous reports[2,3] for criteria used to assign causality ratings.

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

§ Records where the jurisdiction in which the AEFI occurred was not reported or was unclear. AEFI records in this category were notified mainly by pharmaceutical companies (n=38), general practitioners (n=5), members of the public (n=1) and nurses (n=1).

Vaccines

Thirty-one different vaccines were included in the 3,161 records received in 2013 (Table 4). The percentage of records where only 1 vaccine was reported as being the suspected vaccine differed by vaccine administered, typically varying according to whether multiple vaccines were routinely co-administered for the patient's age. There were slight variations in the numbers with outcomes defined as 'serious', which have remained low as in previous years.

The most frequently reported individual vaccine was HPV vaccine with 786 records (25%) followed by seasonal influenza vaccine with 552 records (17%), MMR (n=534; 17%), hexavalent DTPa-IPV-HepB-Hib (n=465; 15%) and 13vPCV (n=462; 15%), (Table 4).

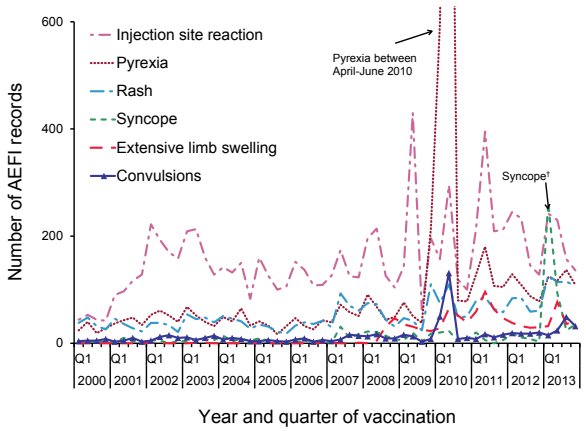
Reactions

In 2013, there was a total of 5,790 events reported for 3,161 AEFI records. The most frequently reported adverse events were injection site reactions (ISRs) (n = 765; 13%), rash (n = 561; 10%), pyrexia (n = 486; 8%), syncope (n = 414; 7%), and extensive swelling of vaccinated limb (n = 187; 3%) (Table 5, Figure 4). Some of the other reactions of interest were convulsions (n = 120; 2%), including 84 cases of febrile convulsion, hypotonic-hyporesponsive episode (HHE) (n=52; 1%), intussusception (n = 11; 0.2%), Guillain-Barré syndrome (GBS) (n = 6; 0.1%), and anaphylaxis (n = 1; 0.02%) (Table 5).

Of the total 765 cases of ISR, 364 (48%) were in children aged less than 7 years. The most commonly suspected vaccines for children aged less than 7 years related to ISR were: DTPa-IPV (n = 237); MMR (n=206); and hexavalent vaccine (n = 56) either given alone or co-administered with other vaccines. For those aged ≥7 years (n = 391), these were seasonal influenza vaccine (n = 158); 23vPPV (n = 70); HPV (n = 66); and dTpa (n = 65), either given alone or co-administered with other vaccines. As expected, reports of ISR associated with 23vPPV were predominantly in the ≥ 65 years age group (74%), while ISR associated with seasonal influenza vaccine was most commonly reported in those 18–64 years of age (69%). The dTpa vaccine was the vaccine most commonly recorded in association with ISR in records from those aged 7–17 years (51%) and 18–64 years (46%).

The number of reports in each reaction category has changed over time (Figure 4). Much of the variation in reporting of ISR related to specific changes in the immunisation schedules for vaccines that are known to have higher rates of ISR, including DTPa-containing vaccines, MenCCV, 23vPPV and HPV vaccine.[2–13,30,31] Increases in reports of fever were largely associated with time periods when new vaccines were added to the NIP in the reporting period, such as PCV 7 and HPV; the extension of seasonal influenza vaccine on the NIP to include persons less than 65 years of age at high risk of influenza in 2010; 13vPCV replaced 7vPCV in July 2011; and the extension of HPV to males in 2013.

Figure 4: Selected frequently reported adverse events following immunisation, ADRS database, 2000 to 2013, by year and quarter of vaccination



* Associated with administration of bioCSL Fluvax 2010 TIV and associated stimulated reporting.

† The peak in syncope coincided with the enhanced human papillomavirus surveillance program in which there was stimulated reporting of syncope for the first 6 months of 2013.

Abbreviations of vaccine names are defined in the Appendix.

Note: For reports where the date of vaccination was not recorded, the date of onset or date event was reported to Therapeutic Goods Administration was used as a proxy for vaccination date. Also, grouping for reactions are different for this report though these reactions have been mapped back to 2000 as mentioned in the Methods section.

The majority of the reports of pyrexia were following vaccination with MMR (n = 157), DTPa/HepB/IPV/Hib (n = 94), PCV (n = 87), and DTPa/IPV (n = 84) either given alone or co-administered.

The most commonly suspected vaccines for syncope were: HPV (n = 341); HepB (n = 151), 76% of which were co-administered with HPV vaccine; and dTpa vaccine (n = 86), 71% of which were co-administered with HPV vaccine.

Severity of outcomes

Summary data on outcomes are presented in Table 6. Eighty-three per cent of reported events

Table 4: Vaccine types listed as 'suspected' in records of adverse events following immunisation, ADRS database, 2013

Suspected vaccine type*	AEFI records	One suspected vaccine or drug only†		'Serious' outcome§		Age group‖			
						<7 years		≥7 years	
	n	n	%¶	n	%¶	n	%¶	n	%¶
HPV	786	396	50	20	3	2	0.3	780	99
Influenza	552	467	85	36	7	66	12	468	85
MMR	534	74	14	29	5	502	94	28	5
DTPa-IPV-HepB-Hib	465	14	3	44	9	461	99	4	1
PCV	462	15	3	43	9	458	99	4	1
Rotavirus	415	32	8	42	10	415	100	0	0
DTPa-IPV	414	170	41	8	2	408	99	6	1
Hepatitis B	312	44	14	9	3	8	3	300	96
dTpa	265	123	46	6	2	3	1	259	98
23vPPV	194	132	68	8	4	11	6	178	92
Varicella	163	66	40	6	4	60	37	103	63
MenCCV	114	6	5	11	10	107	94	5	4
MMRV	104	98	94	3	3	102	98	2	2
HibMenC	92	5	5	7	7	91	99	1	1
Hib	96	0	0	9	9	95	99	0	0
Hepatitis A	33	13	39	3	9	13	39	20	61
Typhoid	25	3	12	1	4	4	16	21	84
DTPa	22	8	36	1	5	9	41	13	59
dT	18	18	100	0	0	0	0	18	100
Rabies	16	10	63	1	6	2	13	14	88
Hepatitis A + B	14	7	50	1	7	0	0	14	100
Q fever	14	14	100	1	7	0	0	12	86
BCG	13	13	100	0	0	13	100	0	0
Hepatitis A-typhoid	13	5	38	1	8	0	0	13	100
Yellow fever	5	5	100	1	20	0	0	5	100
dTpa-IPV	4	1	25	0	0	0	0	4	100
Japanese encephalitis	4	0	0	0	0	0	0	4	100
IPV	3	2	67	2	67	0	0	3	100
Cholera	2	0	0	0	0	0	0	2	100
Men4PV	2	0	0	0	0	0	0	2	100
Tetanus	2	2	100	1	50	0	0	2	100
Total**	3,161	1,739	55	158	5	1,423	45	1,702	54

* Abbreviations of vaccine names are defined in the Appendix.

† Adverse events following immunisation (AEFI) records where only 1 vaccine was suspected of involvement in a reported adverse event.

‡ Causality ratings were assigned to AEFI records using criteria described previously.[2,3]

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

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

¶ Percentages are calculated for the number of AEFI records where the vaccine was suspected of involvement in the AEFI, e.g. HPV was 'suspected' in 785 AEFI records; this was the only suspected vaccine in 50% of the 785 AEFI records, 3% were defined as 'serious' and 99% were for those aged ≥7 years.

** Total number of AEFI records analysed, not the total in each column as categories are not mutually exclusive and an AEFI record may list more than 1 vaccine.

Table 5: Selected reported adverse events and reactions of interest* classified by MedDRA preferred terms in records of adverse events following immunisation, ADRS database, 2013†

MedDRA preferred terms (Adverse events)	AEFI records n	Only reaction reported‡		'Serious' outcome§		Age group‖			
						<7 years		≥7 years	
		n	%¶	n	%¶	n	%¶	n	%¶
Injection site reaction**	765	415	54	15	2	364	48	391	51
Rash††	561	252	45	12	2	371	66	188	34
Pyrexia	486	34	7	33	7	315	65	161	33
Syncope	414	353	85	9	2	14	3	399	96
Vomiting	242	17	7	15	6	139	57	102	42
Extensive swelling of vaccinated limb	187	118	63	1	0.5	117	63	69	37
Headache	171	7	4	12	7	10	6	158	92
Nausea	154	2	1	7	5	11	7	143	93
Diarrhoea	131	17	13	7	5	103	79	28	21
Urticaria	131	67	51	4	3	70	53	60	46
Convulsions‡‡	120	89	74	25	21	107	89	12	10
Dizziness	117	24	21	2	2	2	2	115	98
Presyncope	116	75	65	1	1	8	7	105	91
Malaise	98	4	4	5	5	19	19	79	81
Lethargy	92	1	1	6	7	46	50	44	48
Irritability	70	7	10	3	4	68	97	2	3
Pallor	61	3	5	3	5	42	69	19	31
Myalgia	59	3	5	4	7	2	3	53	90
Erythema	56	10	18	1	2	37	66	19	34
Hypotonic-hyporesponsive episodes	52	44	85	8	15	52	100	0	0
Influenza like illness	52	22	42	2	4	6	12	42	81
Pruritus	49	8	16	0	0	10	20	39	80
Decreased appetite	46	0	0	2	4	28	61	17	37
Abdominal pain	42	2	5	4	10	23	55	19	45
Arthralgia	42	5	12	2	5	1	2	39	93
Chills	38	1	3	3	8	3	8	34	89
Cough	36	1	3	2	6	18	50	18	50
Paraesthesia	32	5	16	4	13	0	0	31	97
Fatigue	31	0	0	1	3	5	16	24	77
Screaming	30	3	10	4	13	30	100	0	0
Somnolence	30	3	10	2	7	25	83	5	17
Pain	29	1	3	1	3	9	31	19	66
Lymphadenopathy	28	8	29	1	4	6	21	22	79
Pain in extremity	28	9	32	2	7	3	11	25	89
Chest discomfort	27	1	4	3	11	0	0	27	100
Crying	27	5	19	0	0	27	100	0	0
Dyspnoea	26	1	4	4	15	6	23	19	73
Hypersensitivity	25	20	80	5	20	3	12	21	84
Hyperhidrosis	24	0	0	3	15	4	17	19	79
Oropharyngeal pain	23	0	0	1	4	5	22	18	78
Rhinorrhoea	23	0	0	0	0	19	83	4	17
Swelling face	22	4	18	3	14	8	36	13	59
Abdominal pain upper	20	2	10	4	20	3	15	17	85

Table 5 (cont'd): Selected reported adverse events and reactions of interest* classified by MedDRA preferred terms in records of adverse events following immunisation, ADRS database, 2013†

MedDRA preferred terms (Adverse events)	AEFI records n	Only reaction reported‡		'Serious' outcome§		Age group‖			
						<7 years		≥7 years	
		n	%¶	n	%¶	n	%¶	n	%¶
Local swelling	20	4	20	0	0	11	55	9	45
Guillain-Barré syndrome	6	5	83	4	67	0	0	5	83
Anaphylactic reaction	1	1	100	1	100	0	0	1	100
Encephalitis	1	0	0	1	100	0	0	1	100

* Selected reported adverse events reported during 1 January to 31 December 2013. Note: for injection site reaction, rash and convulsions, preferred terms (PTs) were grouped as described below.

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

‡ Adverse events following immunisation (AEFI) records where only 1 reaction was reported.

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

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

¶ Percentages relate to the number of AEFI records in which the specific reaction term was listed, e.g. of 765 AEFI records listing injection site reaction, 54% listed only 1 type of reaction and 48% were for children aged <7 years.

** Injection site reaction includes the following MedDRA PTs: injection site reaction (400), injection site swelling (110), injection site pain (75), injection site mass (63), injection site erythema (63), injection site cellulitis (22), injection site rash (21), injection site induration (18), injection site abscess (11), injection site pruritus (9), injection site nodule (6), injected limb mobility decreased (6), injection site urticaria (6), injection site inflammation (5), injection site bruising (4), injection site infection (1), and injection site warmth (1).

†† Rash includes the following MedDRA PTs: rash (200), rash generalised (84), rash erythematous (60), rash pruritic (38), rash maculopapular (26), rash macular (24), rash vesicular (19), rash papular (13), rash morbilliform (4), and rash pustular (1).

‡‡ Convulsion includes the following MedDRA PTs: febrile convulsion (84), and convulsion (30), grand mal convulsion (5), and partial seizures (1).

Table 6: Outcomes of adverse events following immunisation, ADRS database, 2013

Outcome	AEFI records		Age group†			
			<7 years		≥7 years	
	n	%*	n	%‡	n	%‡
Non-serious	2,627	83	1,169	45	1,426	54
Not known (missing data)	376	12	164	44	210	56
Serious:	158	5	90	57	66	42
recovered with sequelae	3		–		3	
hospital treatment – admission	140		84		54	
life-threatening event	11		2		9	
death	4		4		–	
Total	3,161	100	1,423	45	1,702	54

* Percentages relate to the total number of adverse events following immunisation (AEFI) records (n=3,161).

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

‡ Percentages relate to the number of AEFI records with the specific outcome, e.g. of 2,627 AEFI records with a 'non-serious' outcome, 45% were for children aged less than 7 years.

in 2013 were defined as 'non-serious'; 5% were defined as 'serious'; while in 12% severity could not be determined due to insufficient data (Table 6). This is similar to the proportions of serious AEFI in previous years.[9,11,12]

The reactions classified as 'serious' (n=158) were fever (n=33; 21%); convulsions (n=25; 16%), including 14 febrile convulsions; ISR (n=15; 9%); rash (n=10; 6%); syncope (n=9; 6%); HHE (n=8; 3%); diarrhoea (n=7; 4%); intussusception (n=6; 4%); GBS (n=4; 3%); and anaphylaxis (n=1; 1%). There were 4 reports of death (3%). Other relatively severe reactions which were not classified as 'serious', either because they did not satisfy the criteria, or due to a lack of information about the outcome

and/or hospitalisation status, included: convulsion (n=95; 79%), including 70 febrile convulsions; HHE (n=44; 85%); intussusception (n=5; 45%); and GBS (n=2; 33%).

All the reported cases of HHE (52) were in children aged less than 7 years and 79% (n=41) were in children aged less than 1 year. Of the 52 cases, 56% (n=29) were reported from Victoria. For the majority of the reports of HHE (n=37; 71%) the event followed co-administration of hexavalent, PCV and rotavirus vaccines. Of the 6 reported cases of GBS, three were following seasonal influenza vaccine (Fluvax®), one each was influenza vaccine (not otherwise specified), dTpa (Boostrix) and quadrivalent HPV vaccine (Gardasil) co-administered and MMR vaccine.

The only reported case of anaphylaxis was in a person over 18 years of age following seasonal influenza vaccine (Influvac®). The person recovered.

Of the 11 reports of intussusception, 9 (82%) were in infants (<1 year of age) following hexavalent, 13vPCV and rotavirus vaccines co-administered; 1 report was following rotavirus vaccine administered alone; and one was following typhoid and cholera vaccines co-administered.

Four deaths were recorded as temporally associated with receipt of vaccines.

- A 5-year-old child with multiple underlying medical problems who had received seasonal influenza vaccine (Fluarix®) 2 days prior to death.
- A 15-month-old child who had received Hib, MenC and MMR vaccines 9 days prior to death.
- A one-year-old child who had received Hib, MenC and MMR vaccines 5 days prior to death.
- A 2-month-old child who received hexavalent, 13vPCV and rotavirus vaccines 1 day prior to death.

All deaths were investigated by the TGA and no clear causal relationship with vaccination was found.

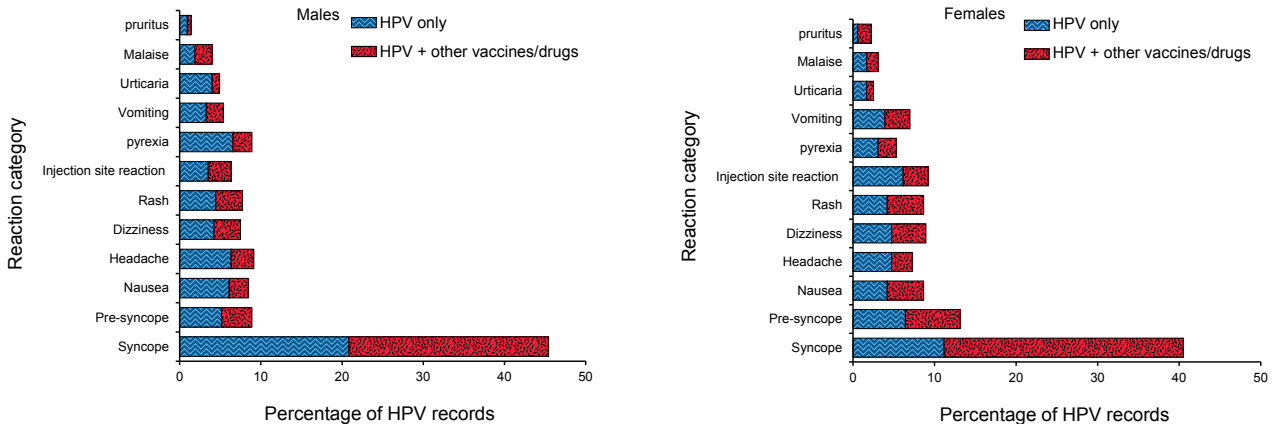
New national immunisation schedule vaccines

Human papillomavirus vaccine

Of the 786 AEFI reports for HPV vaccine in 2013, there were 779 reports for which age was known and all were in the age range 11–30 years. Twenty of these cases were coded as serious. Fifty-four per cent of cases were reported in males with 46% from females. HPV vaccine was the only suspected vaccine in 396 records (50%) (Table 4). Thirty-one per cent (n=245) of cases were reported from New South Wales followed by Victoria (n=188; 24%), Queensland (n=181; 23%), the Australian Capital Territory (n=99; 13%), Western Australia and South Australia (n=28; 4%) each, Tasmania (n=9; 1%), and the Northern Territory (n=7; 1%).

The most commonly reported AEFI were syncope (n=339; 43%), pre-syncope (n=85; 11%), nausea (n=67; 9%), headache (n=65; 8%), dizziness and rash (n=64; 8%) each, injection site reactions (n=60; 8%), pyrexia (n=57; 7%), and urticaria (n=30; 4%). The spectrum of reactions for HPV vaccine was similar in boys and girls, however

Figure 5: Most frequently reported adverse events following immunisation with human papillomavirus vaccine,* 2013, by number of vaccines suspected of involvement in the reported adverse event



* Per cent of 427 adverse events following immunisation records (human papillomavirus males) and 358 records (HPV females) where the vaccine was listed as suspected of involvement in the reported adverse event following immunisation.

Source: Adverse Drug Reactions Reporting System database, Therapeutic Goods Administration.

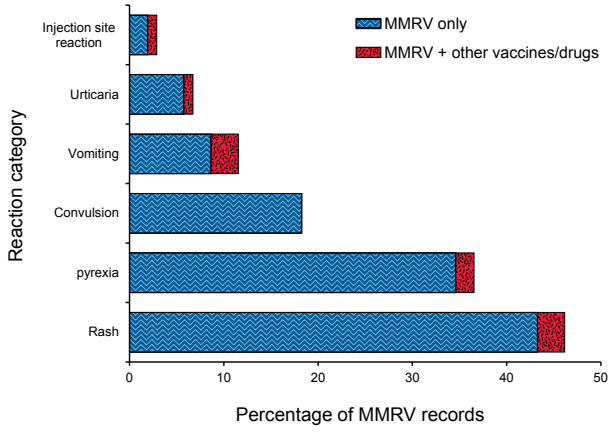
there were more cases in males of pyrexia (67% in males vs 33% in females) and urticaria (70% in males vs 30% in females) (Figure 5).

MMRV vaccine

There was a total of 104 AEFI records for 2013 where MMRV vaccine was recorded (Table 4). In the majority of the records (n=91; 88%), MMRV vaccine was given at 18 months of age. Of all the reported cases, 102 (98%) were in people aged less than 7 years, with three of these cases coded as serious. The reporting rate for children aged less than 7 years was 75.1 per 100,000 doses (Table 2). In 94% of the reports, MMRV (n=98) was administered alone.

The spectrum of reactions for MMRV included 48 (46%) reports of rash; 38 (37%) of pyrexia; 19 cases (18%) of convulsions, including 17 febrile convulsions; 12 cases (12%) of vomiting; 7 cases (7%) of urticaria; 3 cases each of HHE and ISRs (3%); and 2 cases of extensive swelling of the vaccinated limb (Figure 6).

Figure 6: Most frequently reported adverse events following immunisation with measles-mumps-rubella-varicella vaccine,* 2013, by number of vaccines suspected of involvement in the reported adverse event



* Per cent of 104 adverse events following immunisation where measles-mumps-rubella-varicella vaccine was listed as suspected of involvement in the reported adverse event following immunisation.

Source: Adverse Drug Reactions Reporting System database, Therapeutic Goods Administration.

Hib-MenC (Menitorix)

There was a total of 92 AEFI records for 2013 where Hib-MenC vaccine was recorded (Table 4). Of these, 91 (99%) were in people aged less than 7 years, with seven of these cases coded as serious. The reporting rate for children aged less than 7 years was 73.7 per 100,000 doses (Table 2). In 95% of the reports, Hib-MenC vaccine (n=87) was co-administered with MMR vaccine.

The spectrum of reactions for Hib-MenC vaccine included 34 (37%) reports of rash; 30 (32%) of pyrexia; 19 cases (21%) of convulsions, including 16 febrile convulsions; 10 cases (11%) of vomiting; 8 cases (9%) of urticaria; and 6 cases of ISRs (3%).

Discussion

This report uses a different methodology of analysis than that used in previous annual reports for specific AEFIs. The methodological framework used here allows for a clearer reporting of adverse events using MedDRA PTs, as used in the DAEN. This change in methodology needs to be taken into account when comparing with data from previous annual reports on specific reaction terms and categories.

In 2013, there was an increase in both the number of AEFI reports and population-based reporting rates. The increase was predominantly due to the substantial increase in reports in adolescents following HPV vaccination obtained due to a larger vaccine target age group and enhanced safety surveillance, implemented as part of the extension of the National HPV Vaccination Program in February 2013 to males aged 12–13 years, along with a catch-up program for males aged 14 and 15 years.

The TGA, together with state and territory health departments, closely monitored adverse events reported following HPV vaccination as the program was extended to males, through enhanced surveillance using rapid reporting from school-based programs. This aimed to detect 4 acute conditions: a) anaphylaxis; b) generalised allergic reactions; c) loss of consciousness (simple faints [syncope], faints with injury, faints with convulsion); and d) any condition requiring emergency department attendance or hospitalisation. In addition, historical data show that initial high levels of AEFI reporting occur each time a new vaccine is introduced (such as meningococcal C conjugate vaccine in 2003, rotavirus vaccine in 2007, and HPV vaccine in girls in 2007) as immunisation providers are more likely to report milder, less serious AEFIs for vaccines they are not familiar with, followed by a reduction and stabilisation of reporting over time (Weber effect).[26] This enhanced propensity to report events following newer vaccines increases the sensitivity of the system to detect signals of serious, rare or previously unknown events.

The majority of the AEFI reports for HPV vaccine were mild vaccine side effects that had been identified in pre-registration clinical trials.[31] These included injection site reactions, mild allergic reactions, and a range of mild non-specific symptoms including headache, nausea, dizziness, malaise and weakness. A similar range of events has previously been reported to the TGA in secondary school students following receipt of meningococcal C conjugate vaccine as part of the national catch-up program in 2003 and 2004.[4,5] [32,33] The enhanced surveillance implemented in schools in February 2013 resulted in increased reporting of syncope following HPV vaccine. Syncope, usually due to a vasovagal response to having an injection is recognised as a potential AEFI following any immunisation, with highest reporting rates for syncope in adolescents.[34,35]

Reporting rates per 100,000 doses were higher for all individual vaccines in 2013 compared with 2012. The increase in reports for children aged less than 1 years is primarily due to vaccination with hexavalent, 13vPCV and rotavirus vaccines either administered alone or together. The increase in reports for children aged 1 to less than 2 years is primarily due to vaccination with MMR, MMRV, Hib, HibMenC and MenC vaccines either administered alone or together. As two of these were new vaccines on the NIP in 2013, this increased rate of reporting is not unexpected. In addition, active surveillance for febrile seizures following measles-containing vaccines was implemented in paediatric hospitals (in the PAEDS network)[36] as part of enhanced surveillance for the introduction of MMRV to the NIP, and likely contributed to the increased number of reports and awareness of the potential for AEFI following these vaccines. The increase in reports for children aged 2 to less than 7 years is primarily due to ISR following vaccination with DTPa-IPV and MMR co-administered together. The increase was largely seen in Victoria, Queensland and New South Wales.

Conclusion

The total number of reported AEFI in 2013 increased by 59% compared with 2012, due to an increasing trend in propensity to report. The higher reporting rates may also be in response to the activities undertaken by the TGA and the state and territory health departments to encourage and facilitate reporting of AEFI. Reporting rates for the majority of the vaccines were higher than 2012. Increases were most marked in the 7 to under 20 year age group following extension of HPV to boys and associated enhanced surveillance. The majority of AEFIs reported to the TGA were mild transient events. The data reported here are consistent with an overall high level of safety for vaccines included in the NIP schedule.

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Abbreviations of vaccine types

7vPCV	7-valent pneumococcal conjugate vaccine
10vPCV	10-valent pneumococcal conjugate vaccine
13vPCV	13-valent pneumococcal conjugate vaccine
23vPPV	23-valent pneumococcal polysaccharide vaccine
BCG	bacille Calmette-Guérin (i.e. tuberculosis)
dT	diphtheria-tetanus – adolescent and adult formulation
DTPa	diphtheria-tetanus-pertussis (acellular) – paediatric formulation
dTpa	diphtheria-tetanus-pertussis (acellular) – adolescent and adult formulation
dTpa-IPV	combined dTpa and inactivated poliovirus
DTPa-HepB	combined diphtheria-tetanus-pertussis (acellular) and hepatitis B
DTPa-IPV	combined diphtheria-tetanus-pertussis (acellular) and inactivated poliovirus (quadrivalent)
DTPa-IPV-HepB	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus and hepatitis B (pentavalent)
DTPa-IPV-HepB-Hib	combined diphtheria-tetanus-pertussis (acellular), inactivated poliovirus, hepatitis B and *Haemophilus influenzae* type b vaccine (hexavalent)
HepB	hepatitis B
Hib	*Haemophilus influenzae* type b
Hib-HepB	combined *Haemophilus influenzae* type b and hepatitis B
HPV	human papillomavirus
IPV	inactivated poliovirus vaccine
Men4PV	meningococcal polysaccharide tetravalent vaccine
MenCCV	meningococcal C conjugate vaccine
MMR	measles-mumps-rubella
MMRV	measles-mumps-rubella-varicella
pH1N1	pandemic H1N1 influenza 2009
TIV	trivalent influenza vaccine

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