Australian Government
Department of Health

Vaccine safety in Australia

AusVaxSafety summary report

2020

National Immunisation Program

A joint Australian, State and Territory Government Initiative

AusVaxSafety
An NCIRS led collaboration

Title: Vaccine safety in Australia: AusVaxSafety summary report 2020

Overview

- In Australia, vaccines against serious diseases are provided under the National Immunisation Program. Children receive these vaccines at key ages (called schedule points): 2, 4, 6, 12 and 18 months, and 4 years.
- The National Immunisation Program also provides vaccines to adolescents, pregnant women, older people and other groups at risk of serious diseases.
- The AusVaxSafety system actively monitors vaccine safety throughout Australia. Participating clinics send SMS messages to people receiving vaccines (or their parents and carers) to ask if they had any reactions after receiving a vaccine. These reactions are called adverse events.
- Independent experts keep track of the responses to make sure that any safety issues are detected quickly.
- The AusVaxSafety network is growing every year. In 2020, more than 370 immunisation clinics participated in the AusVaxSafety system.
- Between January and December 2020, more than 600,000 SMS messages were sent, and more than 430,000 responses were received.
- Most adverse events after vaccination are mild and go away within a few days. No safety issues were identified for any vaccines monitored under AusVaxSafety.
- The results confirm that vaccines in the National Immunisation Program are very safe.

What's new in the 2020 report

- **Older adults** – Older adults receive vaccines against pneumococcal disease (Aboriginal and Torres Strait Islander adults aged 50 years, and non-Indigenous adults aged 70 years) and shingles (all adults aged 70–79 years) under the National Immunisation Program. The 2020 report includes data on the safety of these vaccines in older adults – no safety issues were identified.
- **Aboriginal and Torres Strait Islander people** – Aboriginal and Torres Strait Islander people receive the same vaccinations as non-Indigenous people, as well as some additional vaccinations, under the National Immunisation Program. Data from 2020 confirm that vaccines are just as safe for Aboriginal and Torres Strait Islander people as they are for non-Indigenous people.

What's planned for 2021

In 2021, AusVaxSafety plans to:

- increase surveillance sites including clinics run by state and territory health departments, Aboriginal Community Controlled Health Organisations, and pharmacies
- start vaccine safety surveillance on all COVID-19 vaccines used in Australia
- continue vaccine safety surveillance for all NIP vaccines

What is AusVaxSafety?

AusVaxSafety is a national system for monitoring vaccine safety in Australia. The system is led by the National Centre for Immunisation Research and Surveillance. It is funded by the Australian Government Department of Health.

The AusVaxSafety system involves a range of collaborators around Australia.

What does AusVaxSafety do?

AusVaxSafety tracks vaccine safety through:

- SMS responses and surveys from people receiving vaccines, or their parents and carers, using SmartVax or Vaxtracker software
- data from specialist immunisation clinics through the Adverse Events Following Immunisation – Clinical Assessment Network (AEFI-CAN)

Who does AusVaxSafety report to?

AusVaxSafety sends regular reports on vaccine safety to:

- the Australian Government Department of Health
- the Therapeutic Goods Administration (TGA)
- other key stakeholders, such as state and territory health departments

AusVaxSafety also publishes vaccine safety information on its website: www.ausvaxsafety.org.au

How AusVaxSafety works

A few days after a person receives a vaccine at a participating immunisation clinic, the clinic sends an SMS message to that person, or to their parent or carer. The SMS asks whether the person had any reactions in the days after vaccination. They can respond 'Yes', 'No', or 'Stop' to opt out.

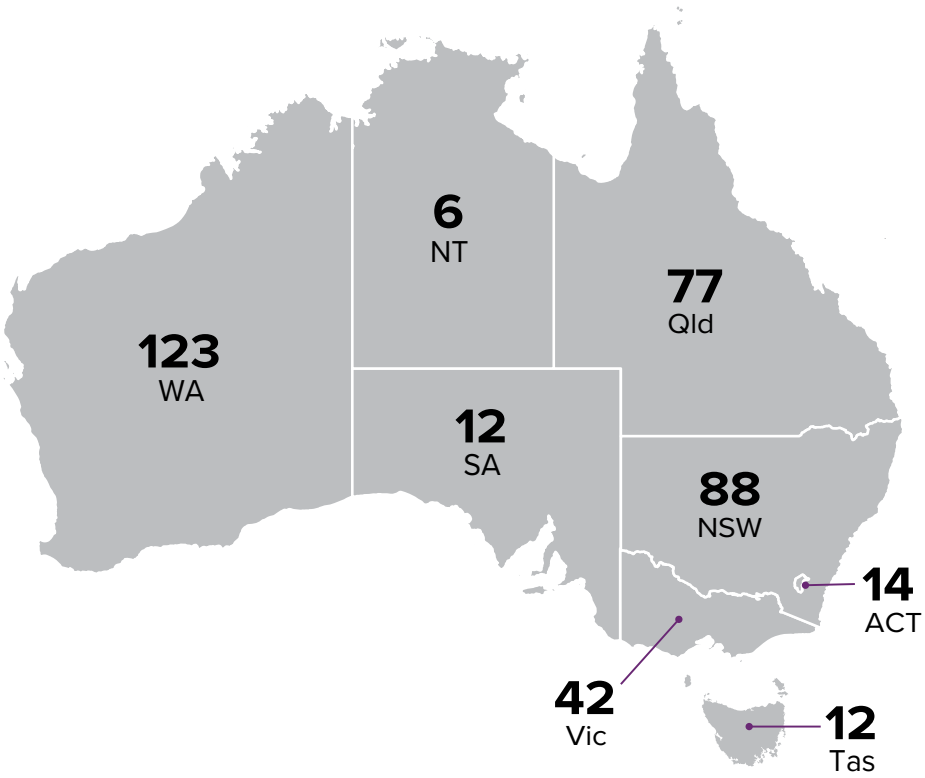
People who respond 'Yes' receive a short survey asking them to describe the adverse event.

AusVaxSafety monitors the responses closely. This means that any potential problems with vaccines can be detected and acted on early.

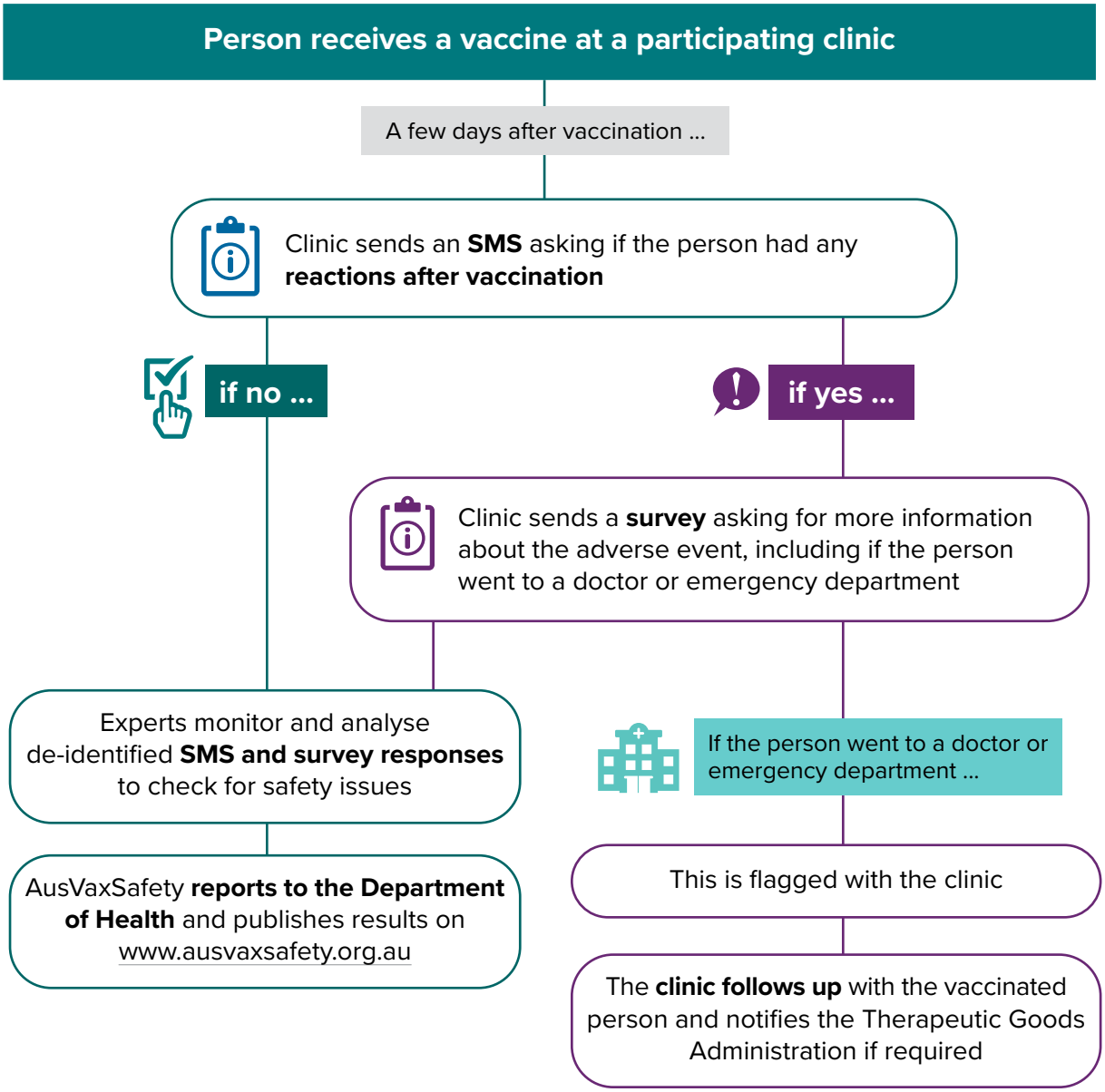
The responses are 'de-identified' to protect privacy. Any information that could identify the person sending the response or their child is removed.

In 2020, 374 immunisation provider sites participated in the AusVaxSafety system (Figure 1). The sites included general practices, hospitals, schools, community clinics and Aboriginal Medical Services.

Figure 1 Number of immunisation provider sites participating in AusVaxSafety, 2020



How AusVaxSafety works

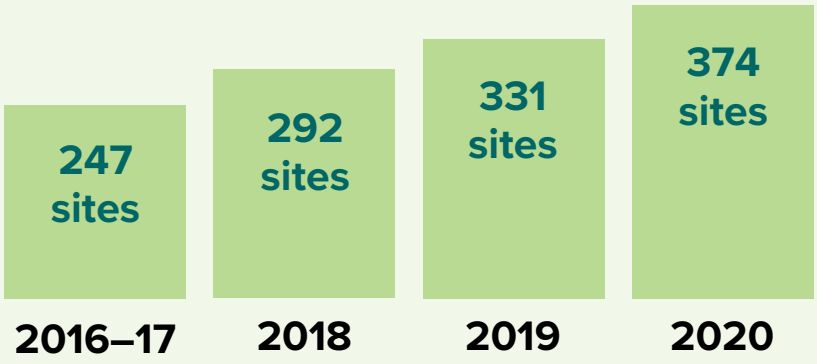


This report reflects data from people who received a vaccine at a participating clinic and responded to the SMS. It does not include data from every person who received a vaccine.

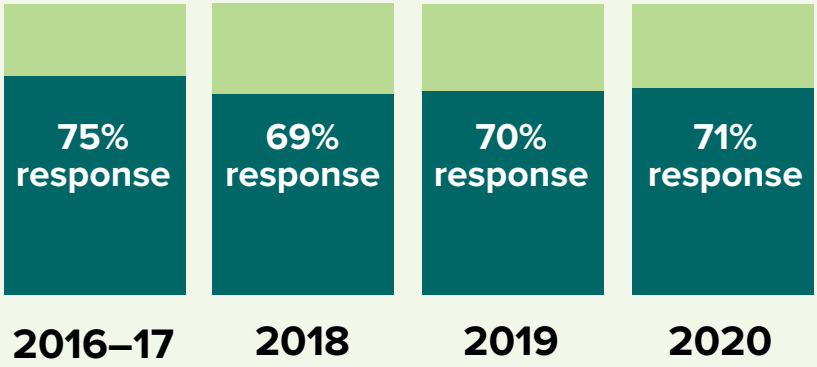
AusVaxSafety monitors adverse events that occur within 3 to 7 days after vaccination. The TGA also monitors adverse events that are reported in other ways. This means the TGA can detect safety issues that are reported outside the 3–7-day window, including rare adverse events.

Since the first AusVaxSafety report in 2016–17 ...

The number of participating sites has increased around Australia, so we have **even greater ability to detect any issues with vaccine safety**



The response rate to SMSs has remained high, so we can be **confident that any safety issues would be identified**



More than **80%** of respondents report **no** adverse events

The types and frequencies of adverse events have remained **as expected from clinical trials**

Most adverse events after vaccination are **mild** and go away within a few days

No safety issues have been detected through AusVaxSafety, which gives us confidence that **the vaccines used in the National Immunisation Program are very safe**

2 months

SCHEDULE POINT

11,990 parents/carers responded to an SMS about their child's health a few days after their 2-month vaccinations.

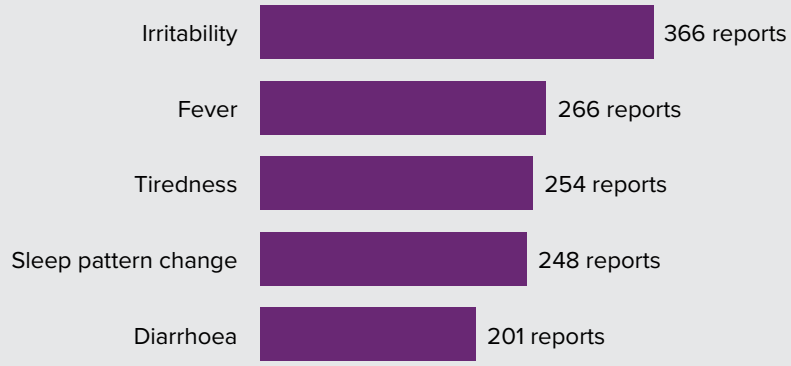
92%
reported **no** adverse events

8%
reported any adverse event, including ...

0.7%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

943 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

These symptoms are also common in young children for other reasons (such as viral infection) and **may not be related to vaccination**.

Aboriginal and Torres Strait Islander children who received these vaccines had the same rates and types of adverse events as other children.

Vaccines given at 2 months in 2020

	Infanrix hexa	Rotarix	Prevenar 13
Protects against	Diphtheria, tetanus, whooping cough, hepatitis B, *Haemophilus influenzae* type b, polio	Rotavirus	Pneumococcal disease

4 months

SCHEDULE POINT

12,071 parents/carers responded to an SMS about their child's health a few days after their 4-month vaccinations.

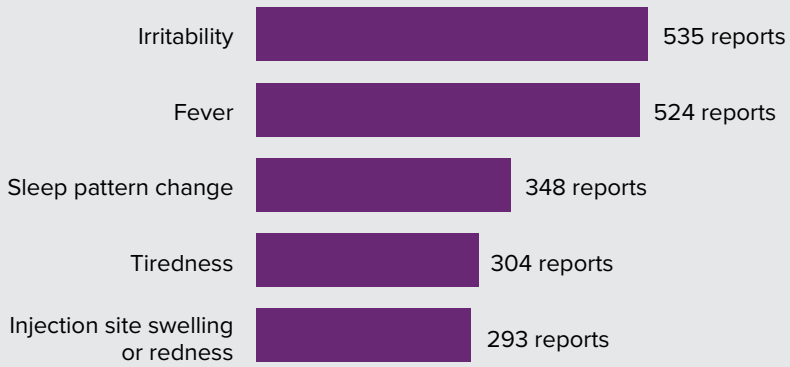
89%
reported **no** adverse events

11%
reported any adverse event, including ...

0.8%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

1,381 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

These symptoms are also common in young children for other reasons (such as viral infection) and **may not be related to vaccination**.

Aboriginal and Torres Strait Islander children who received these vaccines had the same rates and types of adverse events as other children.

Vaccines given at 4 months in 2020

	Infanrix hexa	Rotarix	Prevenar 13
Protects against	Diphtheria, tetanus, whooping cough, hepatitis B, *Haemophilus influenzae* type b, polio	Rotavirus	Pneumococcal disease

6 months

SCHEDULE POINT

12,367 parents/carers responded to an SMS about their child's health a few days after their 6-month vaccination.

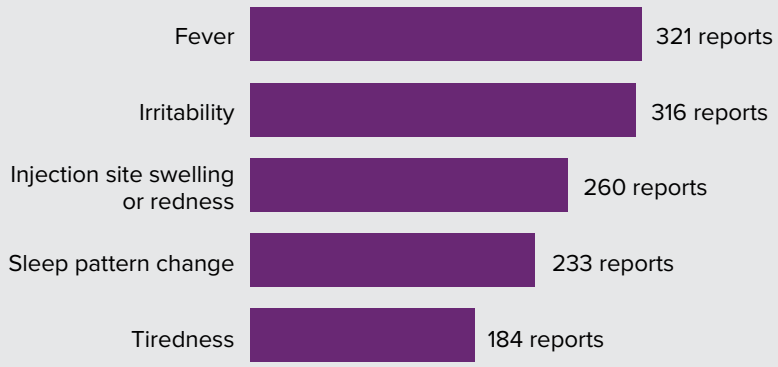
92%
reported **no** adverse events

8%
reported any adverse event, including ...

0.7%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

964 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

These symptoms are also common in young children for other reasons (such as viral infection) and **may not be related to vaccination**.

Aboriginal and Torres Strait Islander children who received this vaccine had the same rates and types of adverse events as other children.

Vaccines given at 6 months in 2020

Infanrix hexa

Protects against — Diphtheria, tetanus, whooping cough, hepatitis B, *Haemophilus influenzae* type b, polio

12 months

SCHEDULE POINT

11,575 parents/carers responded to an SMS about their child's health a few days after their 12-month vaccinations.

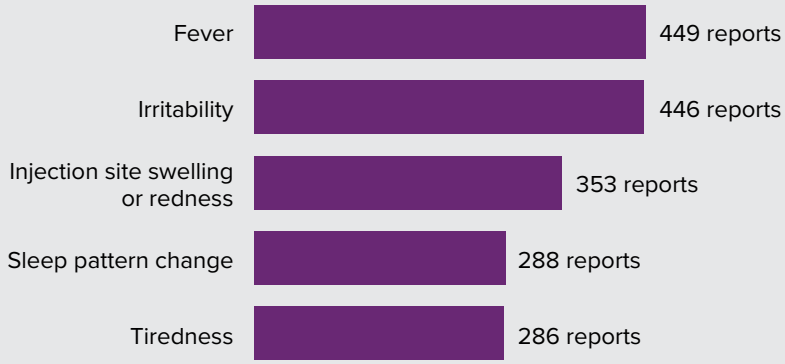
89%
reported **no** adverse events

11%
reported any adverse event, including ...

1.1%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

1,247 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

These symptoms are also common in young children for other reasons (such as viral infection) and **may not be related to vaccination**.

Aboriginal and Torres Strait Islander children who received these vaccines had the same rates and types of adverse events as other children.

Vaccines given at 12 months in 2020

	Priorix or **M-M-R II**	**Nimenrix**	**Prevenar 13**
Protects against	Measles, mumps, rubella	Meningococcal disease (types A, C, W and Y)	Pneumococcal disease

18 months

SCHEDULE POINT

11,342 parents/carers responded to an SMS about their child's health a few days after their 18-month vaccinations.

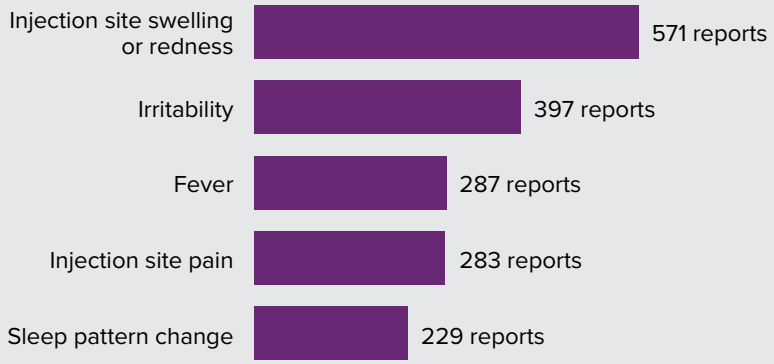
88%
reported **no** adverse events

12%
reported any adverse event, including ...

1.4%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

1,360 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

These symptoms are also common in young children for other reasons (such as viral infection) and **may not be related to vaccination**.

Aboriginal and Torres Strait Islander children who received these vaccines had the same rates and types of adverse events as other children.

Vaccines given at 18 months in 2020

	Priorix-tetra or **ProQuad**	**Infanrix** or **Tripacel**	**Act-HIB**
Protects against	Measles, mumps, rubella, chickenpox	Diphtheria, tetanus, whooping cough	*Haemophilus influenzae* type b

4 years

SCHEDULE POINT

12,839 parents/carers responded to an SMS about their child's health a few days after their 4-year vaccinations.

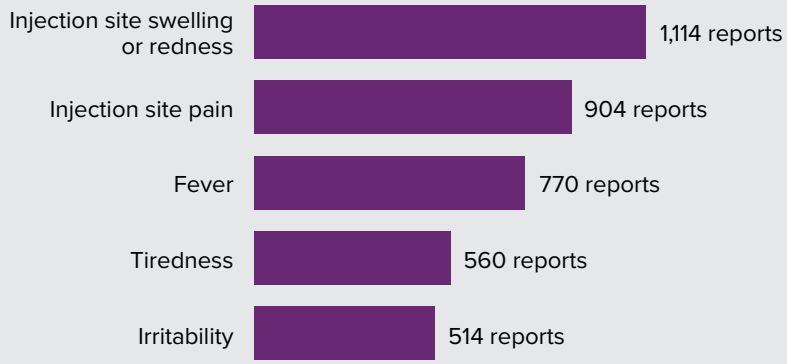
81%
reported **no** adverse events

19%
reported any adverse event, including ...

1.7%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

2,452 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

These symptoms are also common in young children for other reasons (such as viral infection) and **may not be related to vaccination**.

Aboriginal and Torres Strait Islander children who received these vaccines had the same rates and types of adverse events as other children.

Vaccines given at 4 years in 2020

Infanrix IPV or **Quadracel**

Protects against Diphtheria, tetanus, whooping cough, polio

12–13 years

SCHEDULE POINT

12–13-year-olds receive vaccines for diphtheria, tetanus and whooping cough (included in the dTpa vaccine) and HPV.

	HPV (1st dose) and dTpa vaccines **together**	HPV vaccine (2nd dose) **alone**
Number of parents/carers who responded to an SMS about their child's health a few days after their vaccinations	**11,487**	**28,572**
Percentage who reported **no** adverse events	**91%**	**92%**
Percentage who reported any adverse event, including ...	**9%**	**8%**
... percentage who reported taking their child to a doctor or emergency department in the days after vaccination The adverse events they reported were similar to the types of adverse events reported overall.	**0.6%**	**0.3%**
Number of parents/carers who reported one or more adverse events	**1,021**	**2,270**

Most commonly reported adverse events

These symptoms are known to occur after vaccination. They are generally mild and short-lived.

Aboriginal and Torres Strait Islander children who received these vaccines had the same rates and types of adverse events as other children.

Injection site pain 349 reports

Injection site swelling or redness 261 reports

Tiredness 229 reports

Headache 181 reports

Fever 130 reports

Injection site pain 1,258 reports

Injection site swelling or redness 845 reports

Headache 588 reports

Tiredness 585 reports

Fever 256 reports

Vaccines given at 12–13 years in 2020

	Gardasil 9	Boostrix
Protects against	HPV (human papillomavirus)	Diphtheria, tetanus, whooping cough (dTpa)

14–16 years

SCHEDULE POINT

14,209 parents/carers responded to an SMS about their child's health a few days after their meningococcal ACWY vaccination.

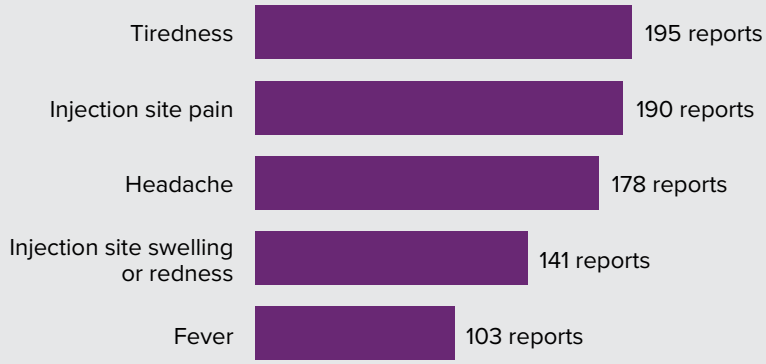
95%
reported **no** adverse events

5%
reported any adverse event, including ...

0.3%
who reported taking their child to a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

655 parents/carers reported one or more adverse events. The most commonly reported were:



These symptoms are known to occur after vaccination. They are generally mild and short-lived.

Aboriginal and Torres Strait Islander children who received this vaccine had the same rates and types of adverse events as other children.

Vaccines given at 14–16 years in 2020

	Nimenrix
Protects against	Meningococcal disease (types A, C, W and Y)

Pregnant women

SCHEDULE POINT

Pregnant women receive vaccines for whooping cough (included in the dTpa vaccine) and influenza.

	dTpa vaccine **alone**	Seasonal influenza and dTpa vaccines **together**
Number of pregnant women who responded to an SMS about their health a few days after their vaccination	**4,713**	**1,128**
Percentage who reported **no** adverse events	**95%**	**93%**
Percentage who reported any adverse event, including ...	**5%**	**7%**
... percentage who reported visiting a doctor or emergency department in the days after vaccination The adverse events they reported were similar to the types of adverse events reported overall.	**0.2%**	**0.4%**
Number of pregnant women who reported one or more adverse events	**253**	**81**

Most commonly reported adverse events

These symptoms are known to occur after vaccination. They are generally mild and short-lived.

Adverse events were similar in pregnant women who had one vaccine and pregnant women who had both vaccines at the same time.

Aboriginal and Torres Strait Islander pregnant women who received these vaccines had the same rates and types of adverse events as other pregnant women.

dTpa vaccine **alone**	Seasonal influenza and dTpa vaccines **together**
Injection site pain 124 reports	**Injection site pain** 31 reports
Injection site swelling or redness 103 reports	**Tiredness** 27 reports
Tiredness 64 reports	**Injection site swelling or redness** 20 reports
Headache 43 reports	**Fever** 9 reports
Fever 21 reports	**Headache** 9 reports

Vaccines given to pregnant women in 2020

	Afluria Quad, **Fluarix Tetra**, **FluQuadri**, **Influvac Tetra** or **Vaxigrip Tetra**	**Adacel** or **Boostrix**
Protects against	Influenza	Diphtheria, tetanus, whooping cough (dTpa)

Older adults

SCHEDULE POINT

Older adults receive vaccines for pneumococcal disease and shingles, either together or at separate times. Prevenar 13 replaced Pneumovax 23 as the pneumococcal vaccine on the National Immunisation Program from 1 July 2020.

	Pneumococcal vaccine (Prevenar 13)	Shingles vaccine
Number of older adults who responded to an SMS about their health a few days after their vaccination	10,403	6,625
Percentage who reported **no** adverse events	93%	92%
Percentage who reported any adverse event, including ...	7%	8%
... percentage who reported visiting a doctor or emergency department in the days after vaccination The adverse events they reported were similar to the types of adverse events reported overall.	0.2%	0.3%
Number of older adults who reported one or more adverse events	687	526

Most commonly reported adverse events

These symptoms are known to occur after vaccination. They are generally mild and short-lived.

Aboriginal and Torres Strait Islander people who received these vaccines had the same rates and types of adverse events as other older adults.

Injection site pain 238 reports

Injection site swelling or redness 153 reports

Tiredness 149 reports

Headache 99 reports

Sleep pattern change 58 reports

Injection site swelling or redness 182 reports

Injection site pain 154 reports

Tiredness 112 reports

Headache 87 reports

Sleep pattern change 42 reports

Vaccines given to older adults in 2020

	Prevenar 13	Zostavax
Protects against	Pneumococcal disease	Shingles

Seasonal influenza

SCHEDULE POINT

289,971 people responded to an SMS about their health a few days after their influenza vaccination, between April and August 2020.

94%
reported **no** adverse events

16,127 people reported one or more adverse events.
The most commonly reported were:

Children

Injection site pain, injection site swelling or redness, fever, tiredness, irritability

Adults

Injection site pain, tiredness, injection site swelling or redness, headache, fever

These symptoms are known to occur after vaccination. They are generally mild and short-lived.

Aboriginal and Torres Strait Islander people and pregnant women who received influenza vaccine had the same rates and types of adverse events as other people.

6%
reported any adverse event, including ...

0.3%
who reported visiting a doctor or emergency department in the days after vaccination.

The adverse events they reported were similar to the types of adverse events reported overall.

Influenza vaccines given in 2020

Afluria Quad, Fluad Quad, Fluarix Tetra, FluQuadri, Influvac Tetra or **Vaxigrip Tetra**

Protects against Influenza