



Australian Government

Department of Health

Vaccine safety in Australia

AusVaxSafety summary report

2018



A joint Australian, State and Territory Government Initiative



Title: Vaccine safety in Australia: AusVaxSafety summary report 2018

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Key messages

- 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 and other groups at risk of serious diseases.
- The AusVaxSafety system actively monitors vaccine safety throughout Australia. 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 2018, more than 290 immunisation clinics participated in the AusVaxSafety system.
- Between January and December 2018, more than 80,000 SMS messages were sent, and more than 58,000 responses were received.
- In 2018, AusVaxSafety began actively monitoring the safety of HPV (human papillomavirus) vaccine in adolescents aged 11–14 years and pertussis (whooping cough) vaccine in pregnant women.
- Most adverse events after vaccination are mild and go away within a few days.
- Overall, the types of adverse events and the percentage of children who had an adverse event stayed about the same after changes in the National Immunisation Program schedule for infants and children.
- The results confirm that vaccines in the National Immunisation Program are very safe.
- The AusVaxSafety system will continue to monitor vaccine safety in Australia.

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)
- data from general practices through the NPS MedicineInsight program

Who does AusVaxSafety report to?

AusVaxSafety sends regular reports on vaccine safety to:

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

AusVaxSafety also publishes vaccine safety information on their website.

How AusVaxSafety works

A few days after a person receives a vaccine at a participating immunisation clinic, the clinic sends an SMS message to the 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. Figure 1 outlines how AusVaxSafety works.

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 2018, 292 immunisation provider sites participated in the AusVaxSafety system (Figure 2). The sites included general practices, hospitals, schools, community clinics and Aboriginal Medical Services.

Figure 1 How AusVaxSafety works

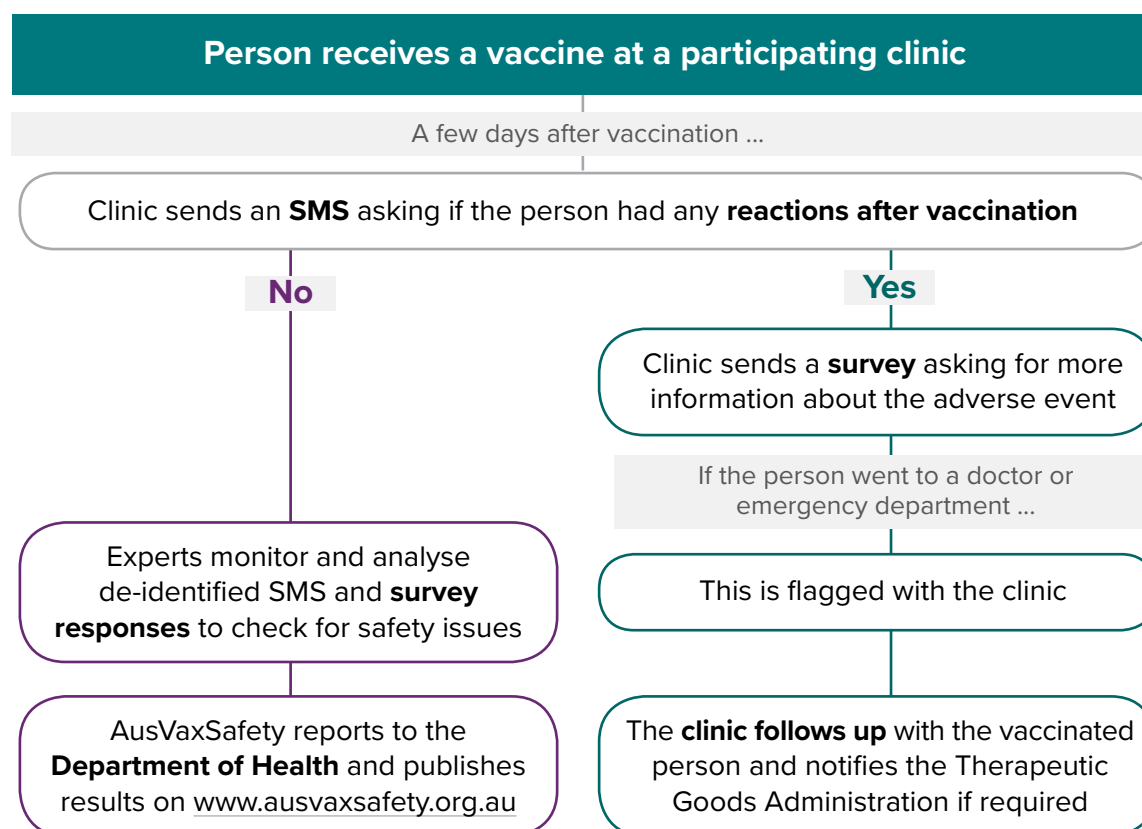
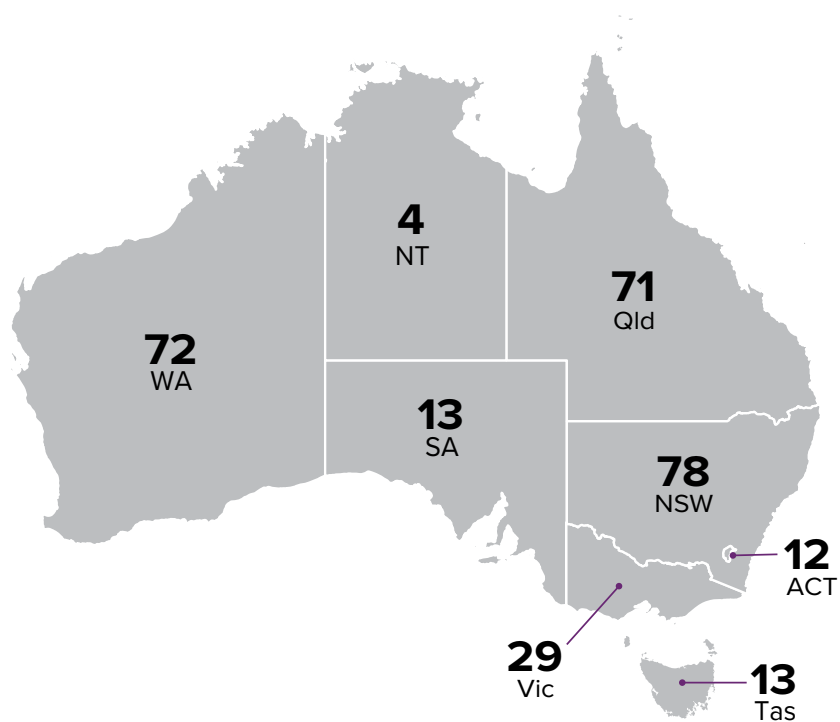


Figure 2 Number of immunisation provider sites participating in AusVaxSafety, 2018



Vaccine safety in 2018

The AusVaxSafety system actively monitors vaccine safety throughout Australia. This includes monitoring safety when:

- new vaccines are included in the National Immunisation Program for the first time
- vaccination recommendations change

Children

The vaccines given to children in the National Immunisation Program changed for some age groups in July 2018:

- most children now receive their 3rd dose of pneumococcal vaccine at 12 months instead of 6 months
- children now receive a vaccine against 4 types of meningococcal disease at 12 months; they no longer receive the combined vaccine against meningococcal C and *Haemophilus influenzae* type b (Hib) at this age
- children now receive a vaccine against Hib at 18 months

The following pages show adverse events reported by parents and carers of children who received the new vaccination schedule.

AusVaxSafety monitored adverse events in children before and after changes to the vaccination schedule and found that:

- the percentage of children who had an adverse event was still low after the changes
- the types of adverse events were similar
- the most common adverse events after immunisation in children were irritability; fever; and redness, swelling or pain at the injection site
- adverse events, especially pain, redness and swelling at the injection site, happened more often at 12 months of age, but less often at 6 months of age; this was expected because children now receive one more vaccine at 12 months, and one less vaccine at 6 months
- there was no change in the number of serious adverse events, like seizures

Aboriginal and Torres Strait Islander children receive extra vaccines:

- 4 doses of pneumococcal vaccine (at 2, 4, 6 and 12 months) instead of 3 doses
- hepatitis A vaccine at 12 and 18 months

The vaccination schedule for Aboriginal and Torres Strait Islander children did not change in 2018.



Adolescents

Adolescents receive vaccines against human papillomavirus (HPV) and diphtheria, tetanus and whooping cough, usually at school.

The HPV vaccine used in the National Immunisation Program for adolescents was changed at the beginning of 2018. Adolescents receive 2 doses of the new vaccine, which protects against 9 types of HPV. (Before 2018, they received 3 doses of vaccine that protected against 4 types of HPV.)

AusVaxSafety monitoring of adverse events in adolescents in 2018 found that:

- 9% of adolescents reported an adverse event after immunisation
- a very small percentage (0.6%) of adolescents visited a doctor or emergency department in the days after vaccination
- the most common adverse events after immunisation in adolescents were pain at the injection site and tiredness

Vaccination in pregnant women

Diphtheria, tetanus and pertussis (whooping cough) (DTPa) vaccine was added to the National Immunisation Program for pregnant women in July 2018. Pregnant women also receive influenza vaccine.

AusVaxSafety monitoring of adverse events in pregnant women in 2018 found that:

- 6% of pregnant women reported an adverse event after immunisation
- a very small percentage (0.3%) of pregnant women visited a doctor or emergency department in the days after vaccination
- the most common adverse events after immunisation in pregnant women were redness, swelling or pain at the injection site

2
months

SCHEDULE
POINT



10,323 parents/carers responded to an SMS about their child's health a few days after their 2-month vaccinations



91%
reported **no** adverse events



9%
reported any adverse event, including ...



0.9%

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.

944 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**.

Vaccines given at 2 months in 2018

Protects against

Infanrix hexa

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

Rotarix

Rotavirus

Prevenar 13

Pneumococcal disease

4

months

SCHEDULE
POINT

10,350 parents/carers responded to an SMS about their child's health a few days after their 4-month vaccinations



88%

reported **no** adverse events

12%

reported any adverse event, including ...

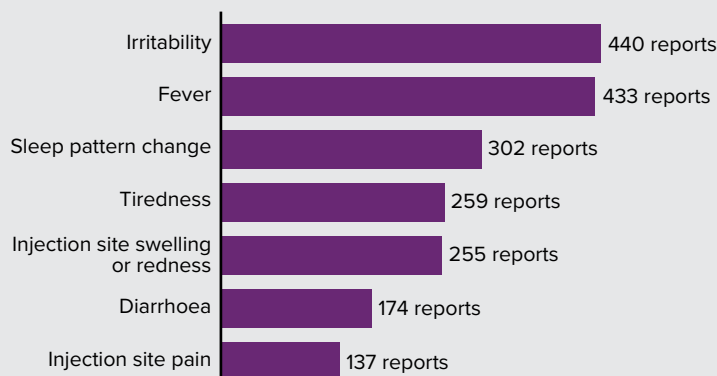


0.9%

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.

1,272 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**.

Vaccines given at 4 months in 2018

Infanrix hexa
Protects against

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

Rotarix

Rotavirus

Prevenar 13

Pneumococcal disease

6
months

SCHEDULE
POINT



4,259 parents/carers responded to an SMS about their child's health a few days after their 6-month vaccinations



93%
reported **no** adverse events



7%
reported any adverse event, including ...

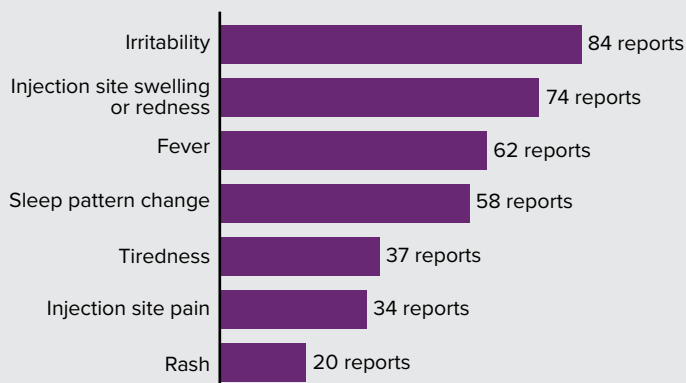


0.7%

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.

304 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**.

Vaccines given at 6 months in 2018

Infanrix hexa

Protects against

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

12 months

SCHEDULE POINT



2,703 parents/carers responded to an SMS about their child's health a few days after their 12-month vaccinations



88%

reported **no** adverse events



12%

reported any adverse event, including ...



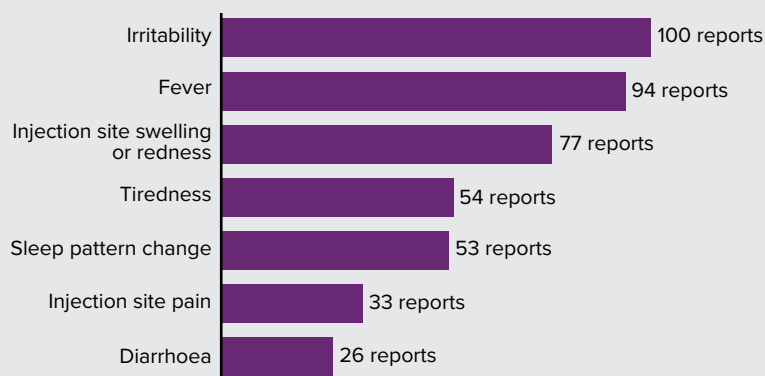
1.2%

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.

317

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.**

Vaccines given at 12 months in 2018

Protects against

M-M-R II or Priorix

Measles, mumps, rubella

Nimenrix

Meningococcal disease (types A, C, W and Y)

Prevenar 13

Pneumococcal disease

18 months

SCHEDULE POINT



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



87% reported **no** adverse events



13%

reported any adverse event, including ...

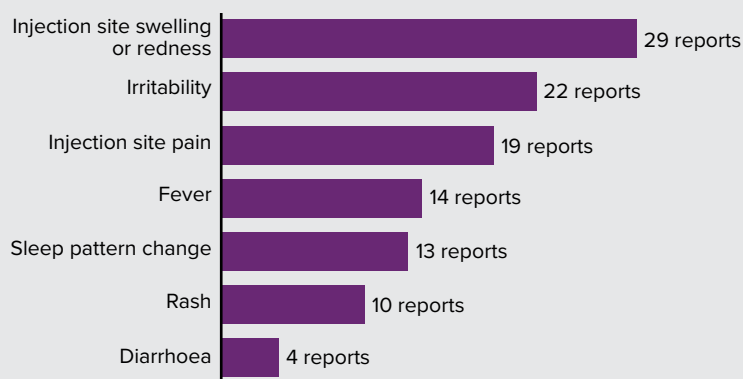


1.6%

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.

92 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**.

Vaccines given at 18 months in 2018

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



6,944 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 ...

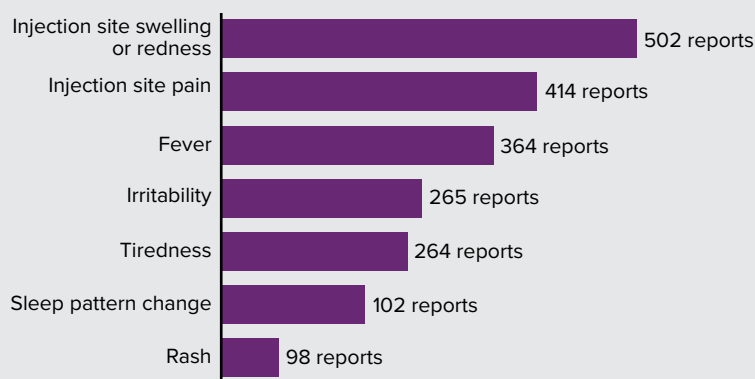


2.0%

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.

1,325 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**.

Vaccines given at 4 years in 2018

Infanrix IPV or Quadracel

Protects against

Diphtheria, tetanus, whooping cough, polio



16,190 parents/carers responded to an SMS about their child's health a few days after their adolescent vaccinations



91%

reported **no** adverse events



9%

reported any adverse event, including ...

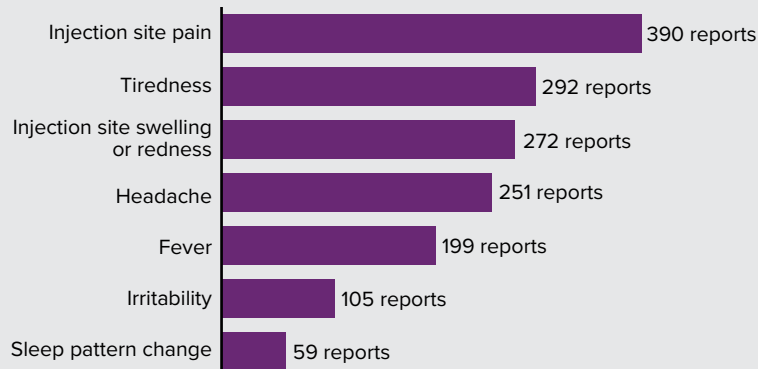


0.6%

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.

1,396 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.

Vaccines given to adolescents in 2018

Gardasil 9

HPV (human papillomavirus)

Boostrix

Diphtheria, tetanus, whooping cough

Protects against



6,909 women responded to an SMS about their health a few days after their vaccinations



6%

reported any adverse event, including ...



0.3%

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

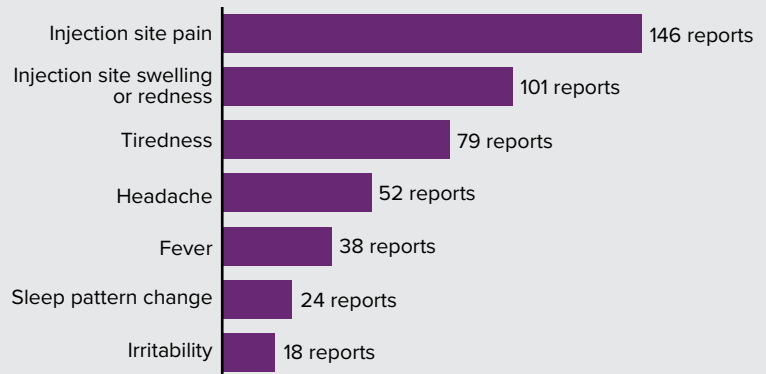
The adverse events they reported were similar to the types of adverse events reported overall.



94%

reported **no** adverse events

406 women 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.

Vaccines given to pregnant women in 2018

Afluria Quad, Fluarix Tetra, FluQuadri or Influvac Tetra

Protects against

Influenza

Adacel or Boostrix

Diphtheria, tetanus, whooping cough

