Australian Government
Department of Health

Vaccine safety in Australia

AusVaxSafety summary report

2016–17

National Immunisation Program

A joint Australian, State and Territory Government Initiative

AusVaxSafety
An NCIRS led collaboration

Title: Vaccine safety in Australia: AusVaxSafety summary report 2016–17

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Key messages

- In Australia, children receive vaccines against serious diseases under the National Immunisation Program. They receive these vaccines at key ages (called schedule points): 2, 4, 6, 12 and 18 months, and 4 years.
- The AusVaxSafety system actively monitors vaccine safety throughout Australia. Clinics send SMS messages to parents and carers to ask if their child had any reactions after receiving a vaccine. These reactions are called adverse events.
- Independent experts keep track of the responses from parents and carers.
- Between November 2016 and December 2017, SMSs were sent after almost 80,000 vaccination encounters. Almost 60,000 responses were received.
- 87% of parents and carers reported that their child did not have any adverse events.
- 13% of parents and carers reported an adverse event after immunisation. Some of these were events that were not related to the vaccination, such as 'a cold'.
- A very small percentage (1.3%) of parents or carers took their child to a doctor or emergency department in the days after vaccination.
- The most common adverse events after immunisation at 2, 4, 6 and 12 months were irritability and fever.
- The most common adverse events after immunisation at 18 months and 4 years were redness, swelling or pain at the injection site.
- These types of common adverse events are known to occur after vaccination. They are generally mild and go away within a few days.
- The results confirm that vaccines in the National Immunisation Program are very safe.

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 from parents and carers
- 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

How AusVaxSafety works

A few days after a child receives a vaccine, their immunisation clinic sends an SMS message to their parent or carer. The SMS asks whether the child had any reactions in the days after vaccination. Parents and carers can respond ‘Yes’, ‘No’, or 'Stop' to opt out.

Parents and carers who respond ‘Yes’ receive a short survey to describe the adverse event.

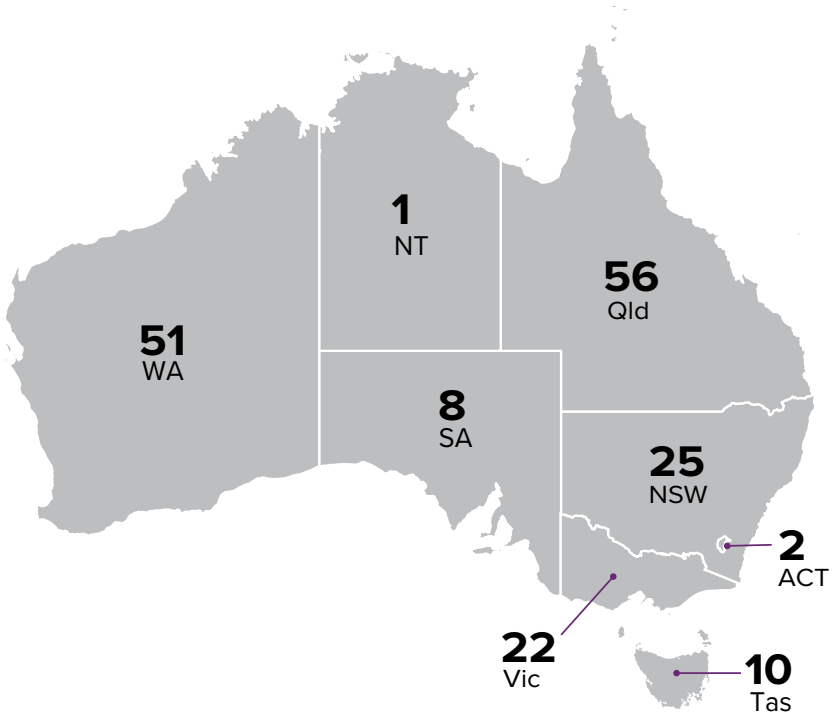
AusVaxSafety monitors the responses closely. This means that any potential problems with vaccines can be seen and acted on early.

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

In 2016–17, 175 immunisation clinics around Australia sent SMS messages to parents or carers after their child’s vaccination (Figure 1). These included general practices, hospitals, community clinics and Aboriginal Medical Services.

The following pages show how parents and carers responded to the SMS at each schedule point in the National Immunisation Program (NIP). The NIP Schedule changes over time based on expert clinical advice. Check the Department of Health website for the latest NIP Schedule.

Figure 1 Number of immunisation clinics participating in AusVaxSafety, 2016–17



2 months

SCHEDULE POINT

10,326 parents/carers responded to an SMS about their child's health a few days after their 2-month vaccinations.

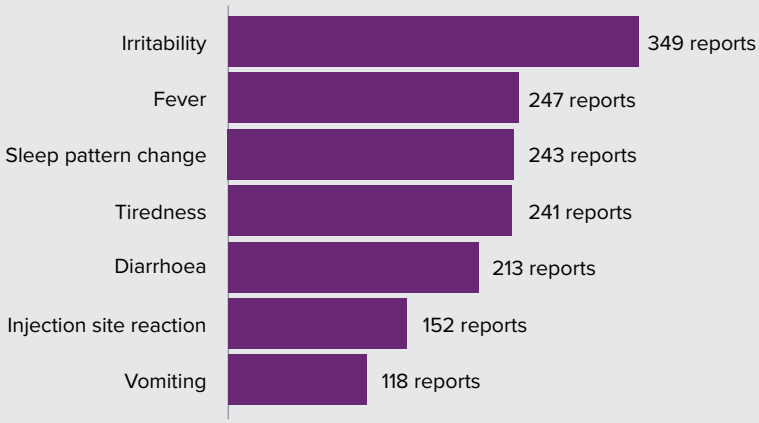
90%
reported **no** adverse events

10%
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.

997 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 2016–17

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

4 months

SCHEDULE POINT

10,129 parents/carers responded to an SMS about their child's health a few days after their 4-month vaccinations.

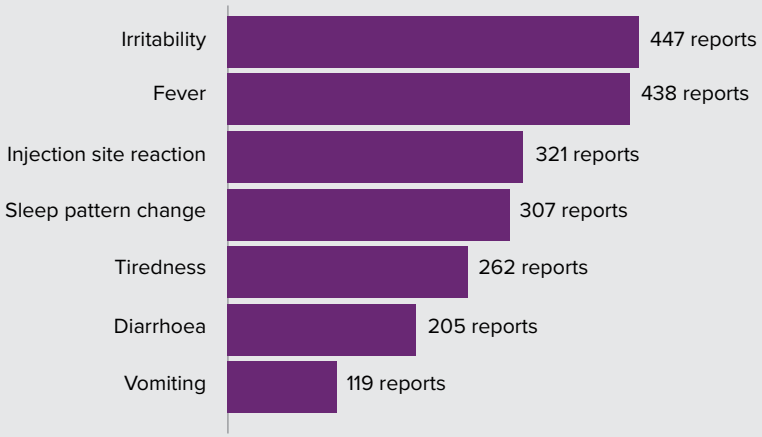
87%
reported **no** adverse events

13%
reported any adverse event, including ...

1.0%
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.

1305 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 2016–17

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

6 months

SCHEDULE POINT

9696 parents/carers responded to an SMS about their child's health a few days after their 6-month vaccinations.

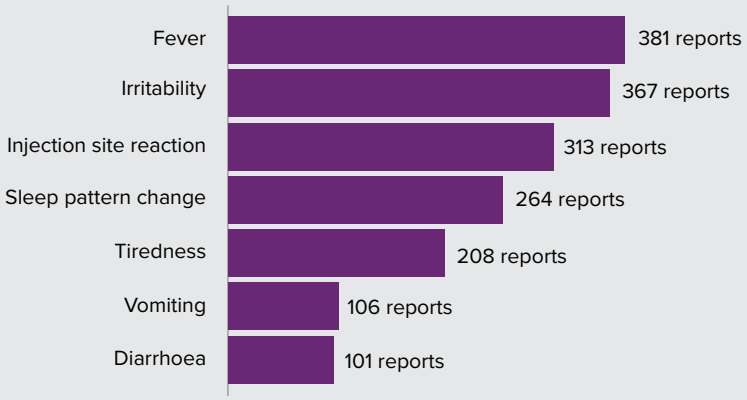
88%
reported **no** adverse events

12%
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.

1121 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.

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Vaccines given at 6 months in 2016–17

	Infanrix hexa	RotaTeq	Prevenar 13
Protects against	Diphtheria, tetanus, whooping cough, hepatitis B, *Haemophilus influenzae* type b, polio	Rotavirus (only in Qld, SA and WA until 30 June 2017)	Pneumococcal disease

12 months

SCHEDULE POINT

10,225 parents/carers responded to an SMS about their child's health a few days after their 12-month vaccinations.

10%

reported any adverse event, including ...

1.4%

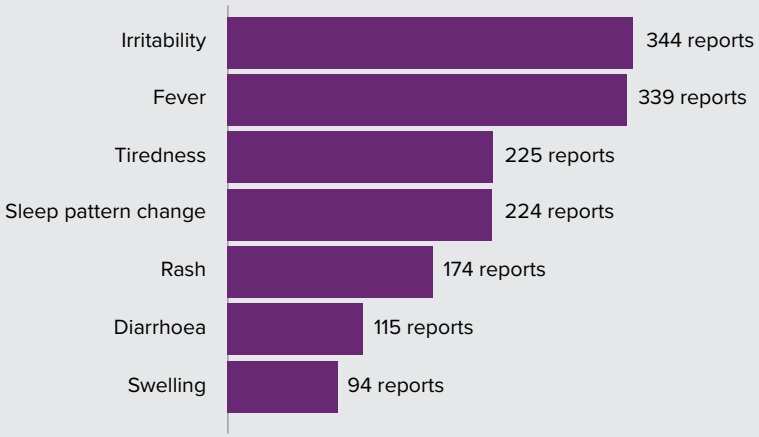
who reported taking their child to a doctor or emergency department in the days after vaccination.

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

90%

reported **no** adverse events

982 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 2016–17

	Priorix or **M-M-R II**	**Menitorix**
Protects against	Measles, mumps, rubella	*Haemophilus influenzae* type b, meningococcal C disease

18 months

SCHEDULE POINT

9675 parents/carers responded to an SMS about their child's health a few days after their 18-month vaccinations.

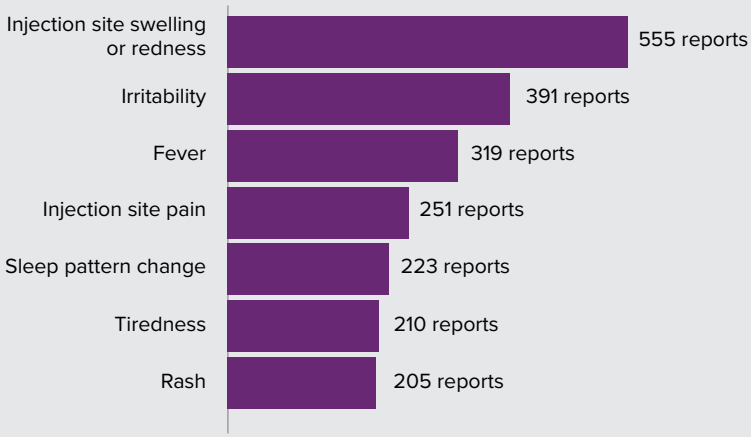
85%
reported **no** adverse events

15%
reported any adverse event, including ...

1.5%
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.

1430 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 2016–17

	Priorix-tetra or **ProQuad**	**Tripacel** or **Infanrix**
Protects against	Measles, mumps, rubella, chickenpox	Diphtheria, tetanus, whooping cough

4 years

SCHEDULE POINT

9869 parents/carers responded to an SMS about their child's health a few days after their 4-year vaccinations.

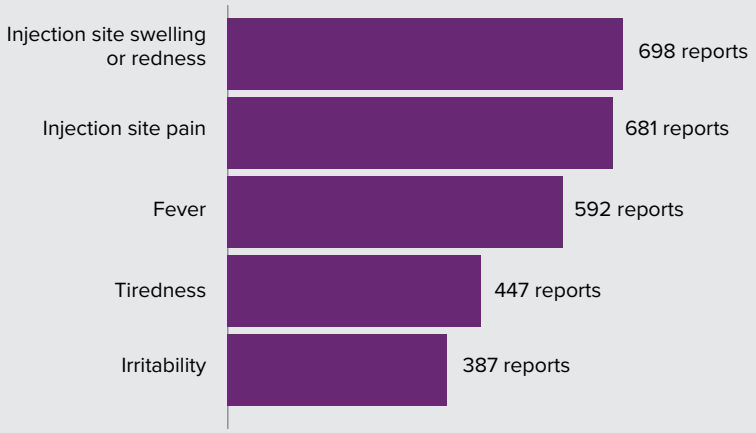
81%
reported **no** adverse events

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.

1918 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**.

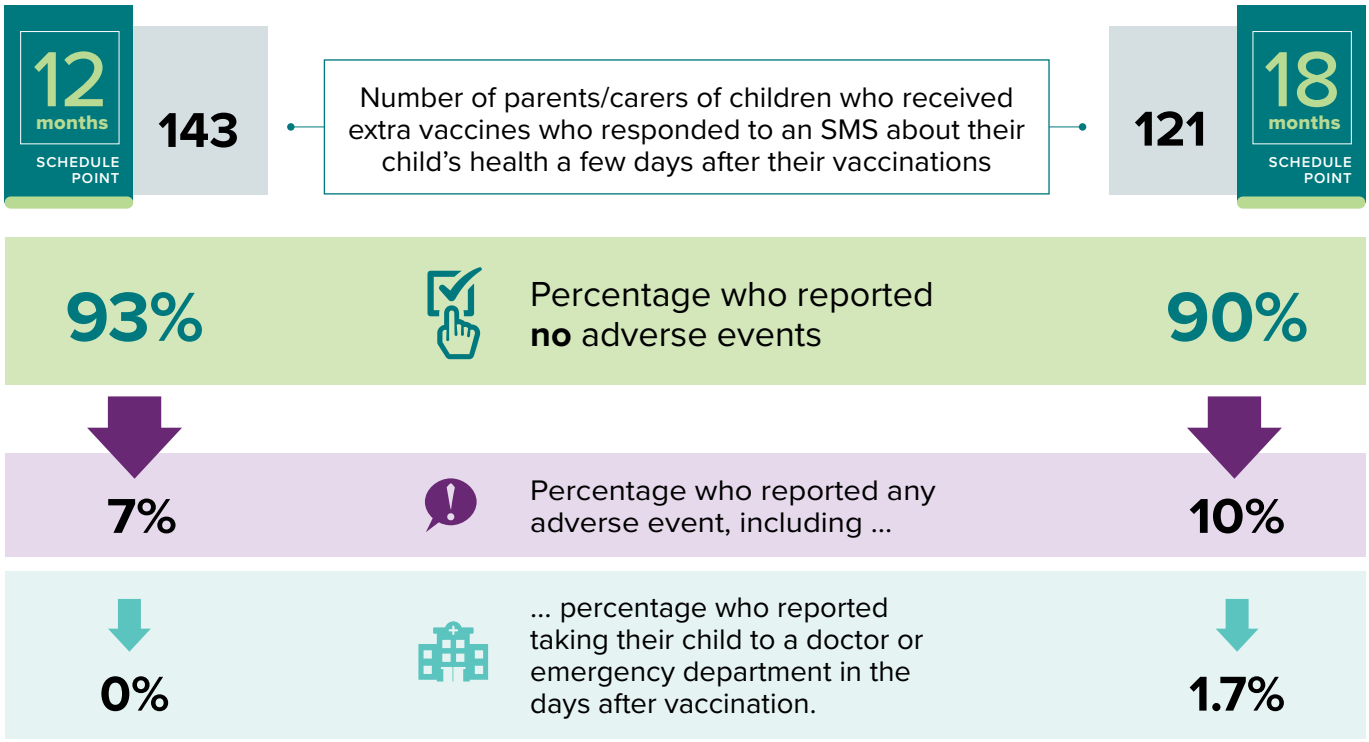
Vaccines given at 4 years in 2016–17

Infanrix IPV or **Quadracel**

Protects against Diphtheria, tetanus, whooping cough, polio

Extra National Immunisation Program vaccines for Aboriginal and Torres Strait Islander children

Aboriginal and Torres Strait Islander children receive hepatitis A vaccine and pneumococcal vaccine in addition to the routinely scheduled vaccines at 12 months and 18 months.



The most commonly reported adverse events were:

Irritability	Injection site swelling or redness
Sleep pattern change	Sleep pattern change

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**.

Extra vaccines given at 12 months and 18 months for Aboriginal and Torres Strait Islander children in 2016–17

	Vaqta Paediatric or Havrix Junior	Prevenar 13
Protects against	Hepatitis A	Pneumococcal disease