Australian Government
Department of Health

Vaccine safety in Australia

AusVaxSafety summary report

2019

National Immunisation Program

A joint Australian, State and Territory Government Initiative

AusVaxSafety
An NCIRS led collaboration

Title: Vaccine safety in Australia: AusVaxSafety summary report 2019

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, older people 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 2019, more than 330 immunisation clinics participated in the AusVaxSafety system.
- Between January and December 2019, more than 470,000 SMS messages were sent, and more than 325,000 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 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
- 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.

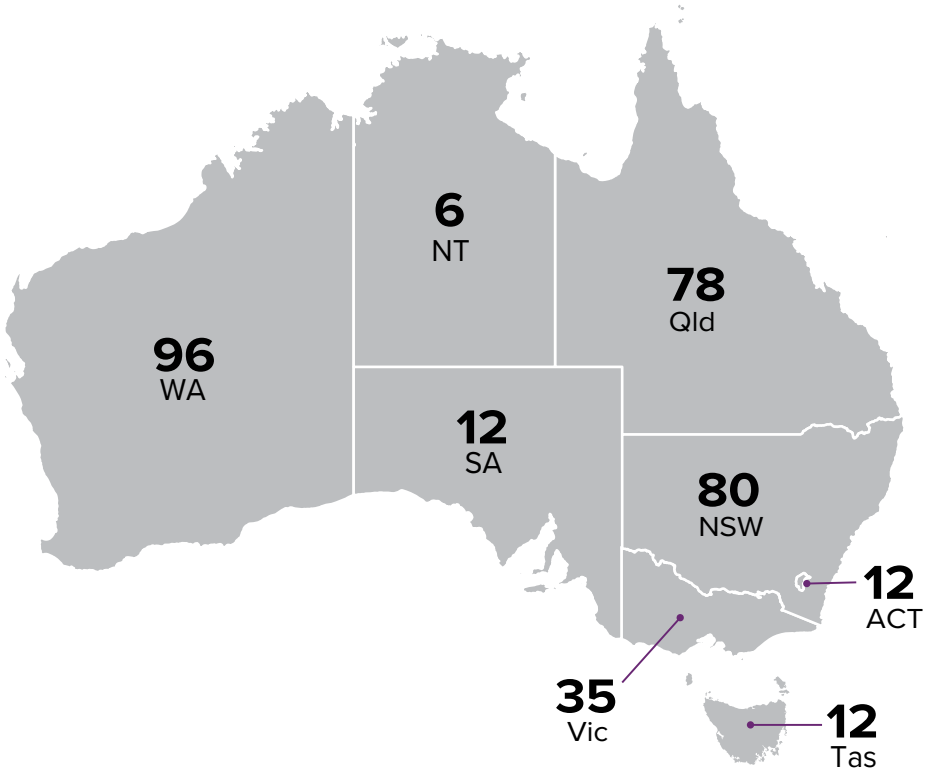
People who respond 'Yes' receive a short survey asking them to describe the adverse event.

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

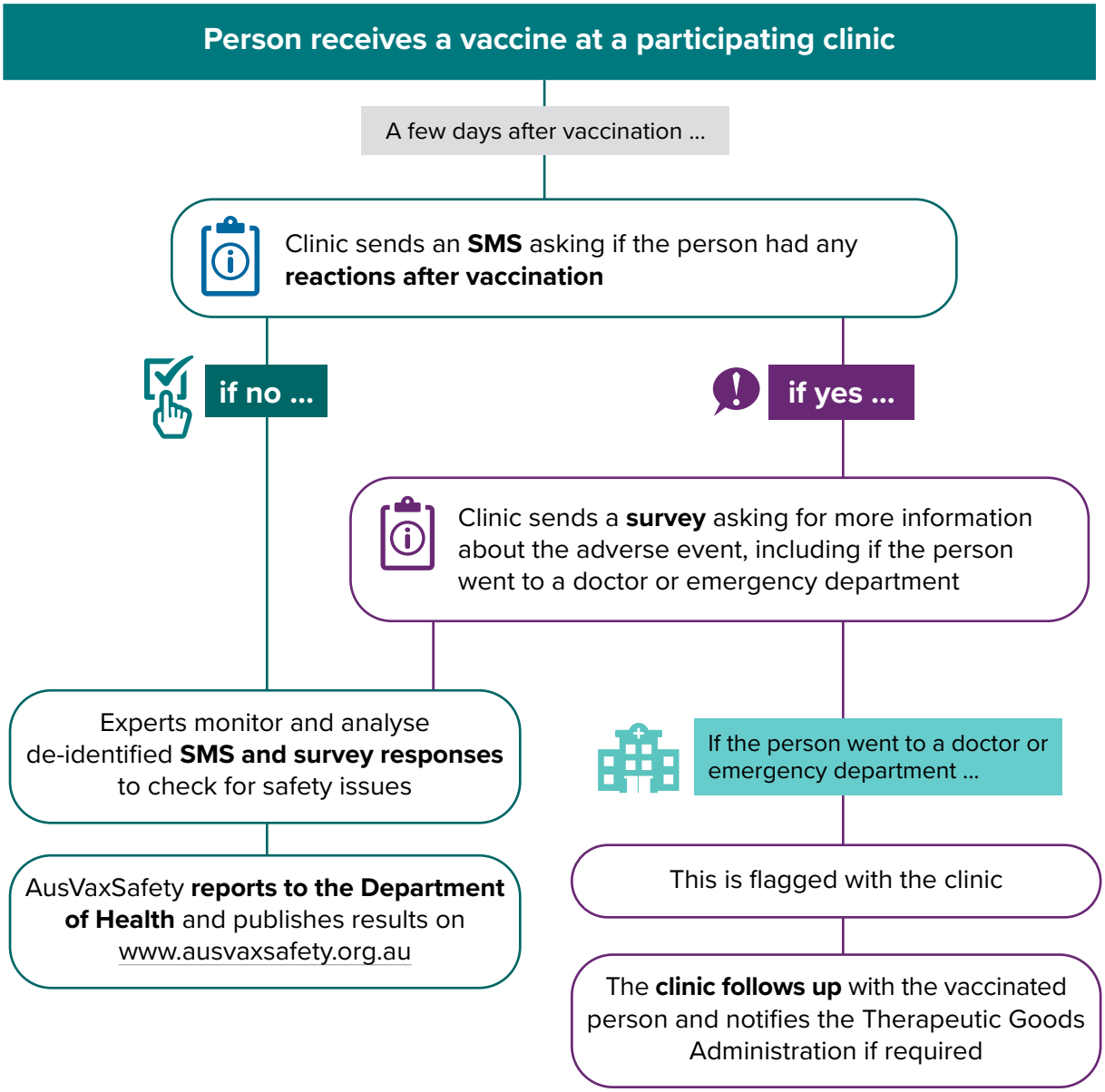
The responses are 'de-identified' to protect privacy. Any information that could identify the person sending the response or their child is removed.

In 2019, 331 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, 2019

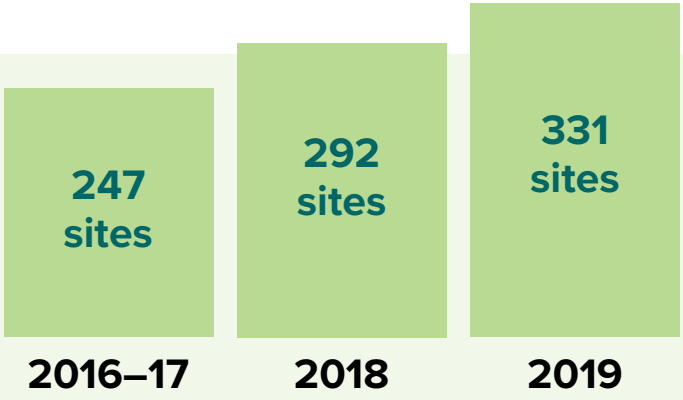


How AusVaxSafety works

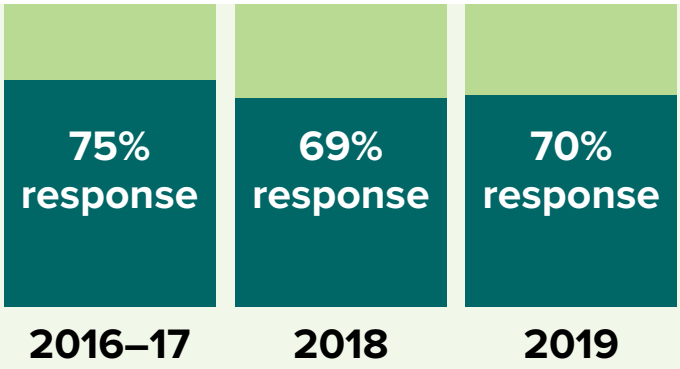


Since the first AusVaxSafety report in 2016–17 ...

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 frequency of adverse events has 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 for any vaccines monitored under AusVaxSafety, which confirms that **the vaccines used in the National Immunisation Program are very safe**

What's new in the 2019 report

- **Meningococcal vaccine for adolescents** – In 2019, a vaccine against meningococcal disease (types A, C, W and Y) was added to the National Immunisation Program for adolescents aged 14 to less than 16 years. Adolescents usually receive this vaccine through their school. This program started in April 2019, and vaccine safety was monitored closely throughout the year. No safety issues were identified.
- **Seasonal influenza vaccines** – The 2019 report includes data on influenza vaccine safety in all age groups and in pregnant women. Data are reported from 1 April to 31 August 2019, during the influenza vaccination season. Data are derived from all influenza vaccinations, not just those funded under the National Immunisation Program.
- **Pregnant women** – Women receive 2 vaccines during pregnancy under the National Immunisation Program – whooping cough (pertussis) vaccine and seasonal influenza vaccine. Some women get both these vaccines at the same time. Data from 2019 confirm that getting both these vaccines at the same time is just as safe as getting one vaccine at a time.
- **Unsolicited adverse events** – People who reply 'Yes' to the AusVaxSafety SMS are sent a survey asking for more details about the adverse event. The survey includes a list of common adverse events that the person can choose from (called 'solicited adverse events') and a free-text option that lets them write other information (called 'unsolicited adverse events'). In 2019, AusVaxSafety collected and analysed data on unsolicited adverse events for the first time. The most commonly reported types of unsolicited adverse events were:
  - for infants and young children – stomach upsets and cold-like symptoms
  - for adolescents – nausea and dizziness
  - for people receiving influenza vaccine – cold-like symptoms
  - for pregnant women – nausea and cold-like symptoms.

  These results confirm that most unsolicited adverse events are not serious.

2 months

SCHEDULE POINT

11,082 parents/carers responded to an SMS about their child's health a few days after their 2-month vaccinations.

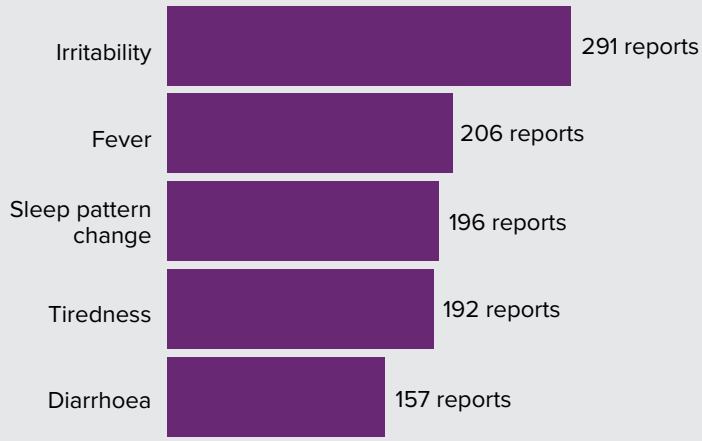
92%
reported **no** adverse events

8%
reported any adverse event, including ...

0.8%
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.

900 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 2019

	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

10,433 parents/carers responded to an SMS about their child's health a few days after their 4-month vaccinations.

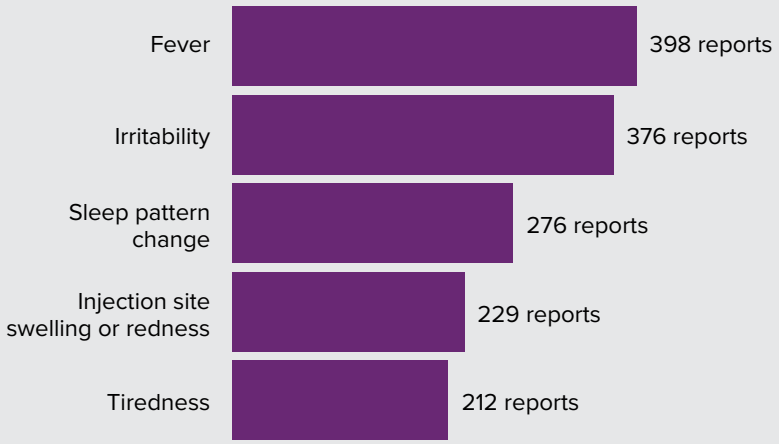
88%
reported **no** adverse events

12%
reported any adverse event, including ...

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.

1,215 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 2019

	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

7,922 parents/carers responded to an SMS about their child's health a few days after their 6-month vaccinations.

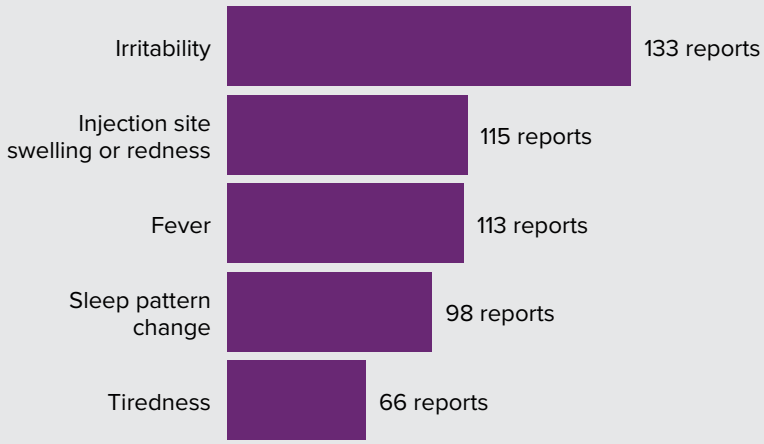
93%
reported **no** adverse events

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.

531 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 2019

Infanrix hexa

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

12 months

SCHEDULE POINT

9,222 parents/carers responded to an SMS about their child's health a few days after their 12-month vaccinations.

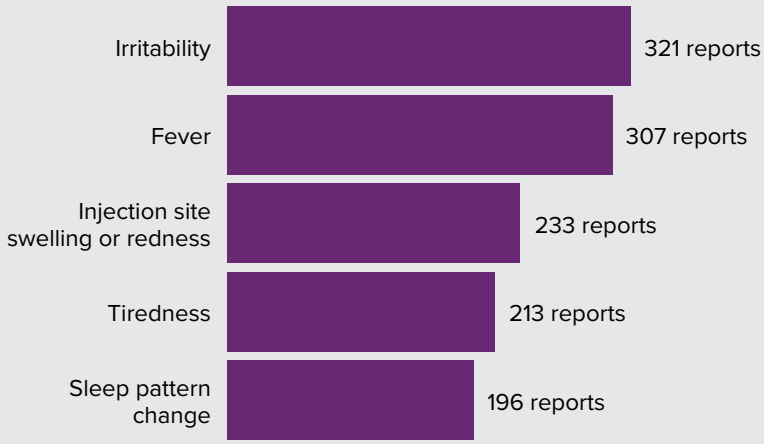
89%
reported **no** adverse events

11%
reported any adverse event, including ...

1.3%
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.

1,044 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 2019

	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

7,772 parents/carers responded to an SMS about their child's health a few days after their 18-month vaccinations.

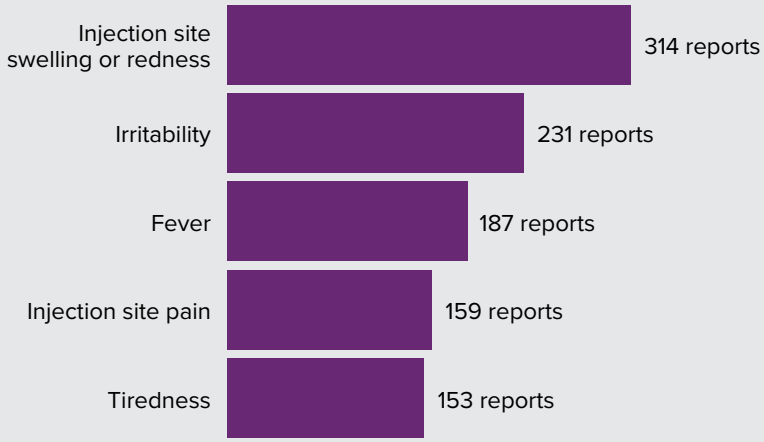
88%
reported **no** adverse events

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.

955 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 2019

	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

8,746 parents/carers responded to an SMS about their child's health a few days after their 4-year vaccinations.

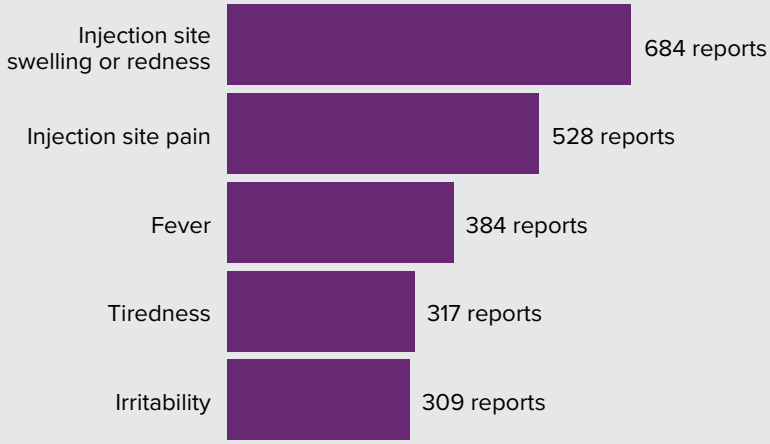
81%
reported **no** adverse events

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.

1,673 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 2019

Infanrix IPV or **Quadracel**

Protects against Diphtheria, tetanus, whooping cough, polio

12–13 years

SCHEDULE POINT

	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	**10,748**	**12,424**
Percentage who reported **no** adverse events	**89%**	**93%**
Percentage who reported any adverse event, including ...	**11%**	**7%**
... 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.	**0.7%**	**0.5%**
Number of parents/carers who reported one or more adverse events	**1,129**	**920**

Most commonly reported adverse events

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

HPV (1st dose) and dTpa vaccines **together**	HPV vaccine (2nd dose) **alone**
Injection site pain 347 reports	**Injection site pain** 245 reports
Injection site swelling or redness 256 reports	**Tiredness** 187 reports
Tiredness 256 reports	**Headache** 162 reports
Headache 211 reports	**Injection site swelling or redness** 151 reports
Fever 169 reports	**Fever** 117 reports

Vaccines given to 12–13-year-olds in 2019

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

14–16 years

SCHEDULE POINT

7,733 parents/carers responded to an SMS about their child's health a few days after their meningococcal ACWY vaccination.

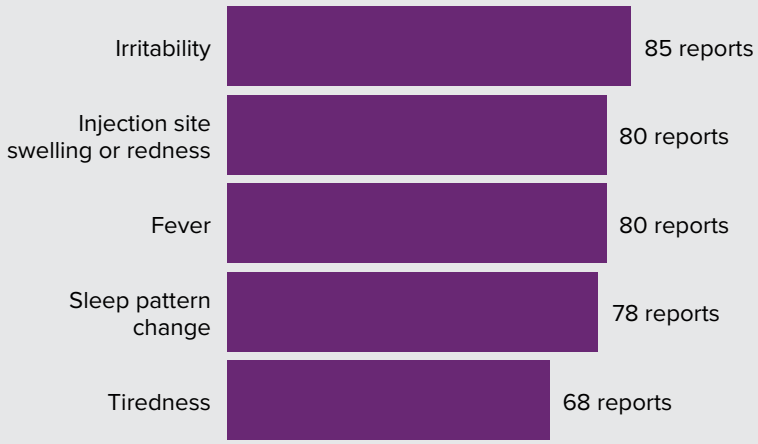
94%
reported **no** adverse events

6%
reported any adverse event, including ...

0.5%
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.

476 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 at 14–16 years in 2019

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 vaccine **together**
Number of pregnant women who responded to an SMS about their health a few days after their vaccination	**4,255**	**1,237**
Percentage who reported **no** adverse events	**94%**	**93%**
Percentage who reported any adverse event, including ...	**6%**	**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.	**0.5%**	**1%**
Number of women who reported one or more adverse events	**263**	**84**

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 women who had one vaccine and women who had both vaccines at the same time.

dTpa vaccine **alone**	Seasonal influenza and dTpa vaccine **together**
Injection site pain 107 reports	**Injection site pain** 37 reports
Injection site swelling or redness 72 reports	**Injection site swelling or redness** 29 reports
Tiredness 60 reports	**Tiredness** 21 reports
Headache 40 reports	**Headache** 15 reports
Fever 34 reports	**Fever** 13 reports

Vaccines given to pregnant women in 2019

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

Seasonal influenza

SCHEDULE POINT

237,124 people responded to an SMS about their health a few days after their influenza vaccination, between April and August 2019.

94%
reported **no** adverse events

6%
reported any adverse event, including ...

0.4%
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.

14,152 people reported one or more adverse events. The most commonly reported were:

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

Adults
injection site pain, tiredness, injection site swelling or redness, headache

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

Pregnant women who received influenza vaccine had the same rates and types of adverse events as other adults.