Australian Government
Department of Health and Aged Care

Vaccine safety in Australia

AusVaxSafety summary report 2021

National Immunisation Program
A joint Australian, State and Territory Government Initiative

AusVaxSafety
An NCIRS led collaboration

What's new in the 2021 report?

Respondent demographics, including gender, age and Aboriginal and Torres Strait Islander status, have been included for each schedule point.

What's planned for 2022?

Implementation of a new, more robust, vaccine safety survey to capture richer data from participants.

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 people, 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 and investigated quickly.

The AusVaxSafety network is growing every year. In 2021, more than 340 immunisation clinics participated in the AusVaxSafety system.

Between January and December 2021, more than 540,000 SMS messages were sent, and more than 395,000 responses were received.

The overwhelming majority of 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 and Aged Care.

The AusVaxSafety system involves a range of collaborators around Australia.

Who does AusVaxSafety report to?

AusVaxSafety sends regular reports on vaccine safety to:

– the Australian Government Department of Health and Aged Care

– 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 2021, 341 immunisation provider sites participated in the AusVaxSafety system (Figure 1). The sites included general practices, hospitals, schools, community clinics and Aboriginal Medical Services.

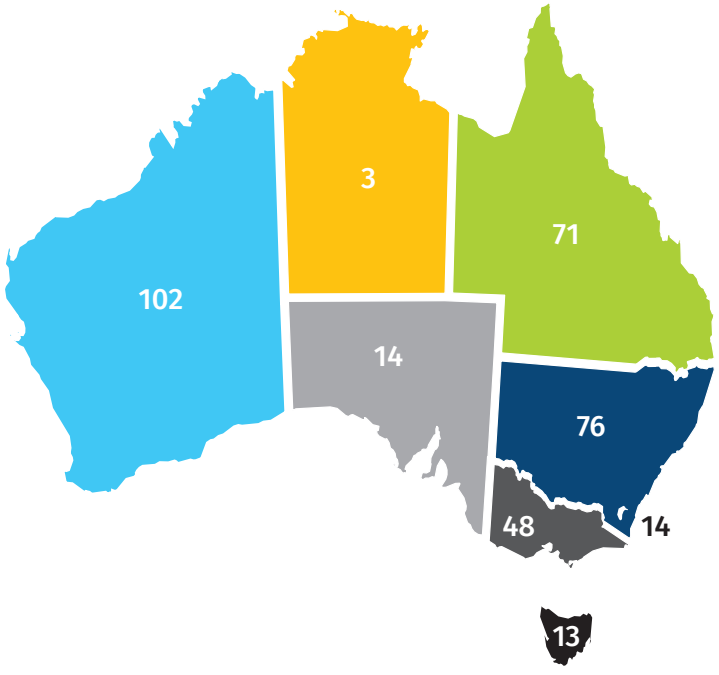
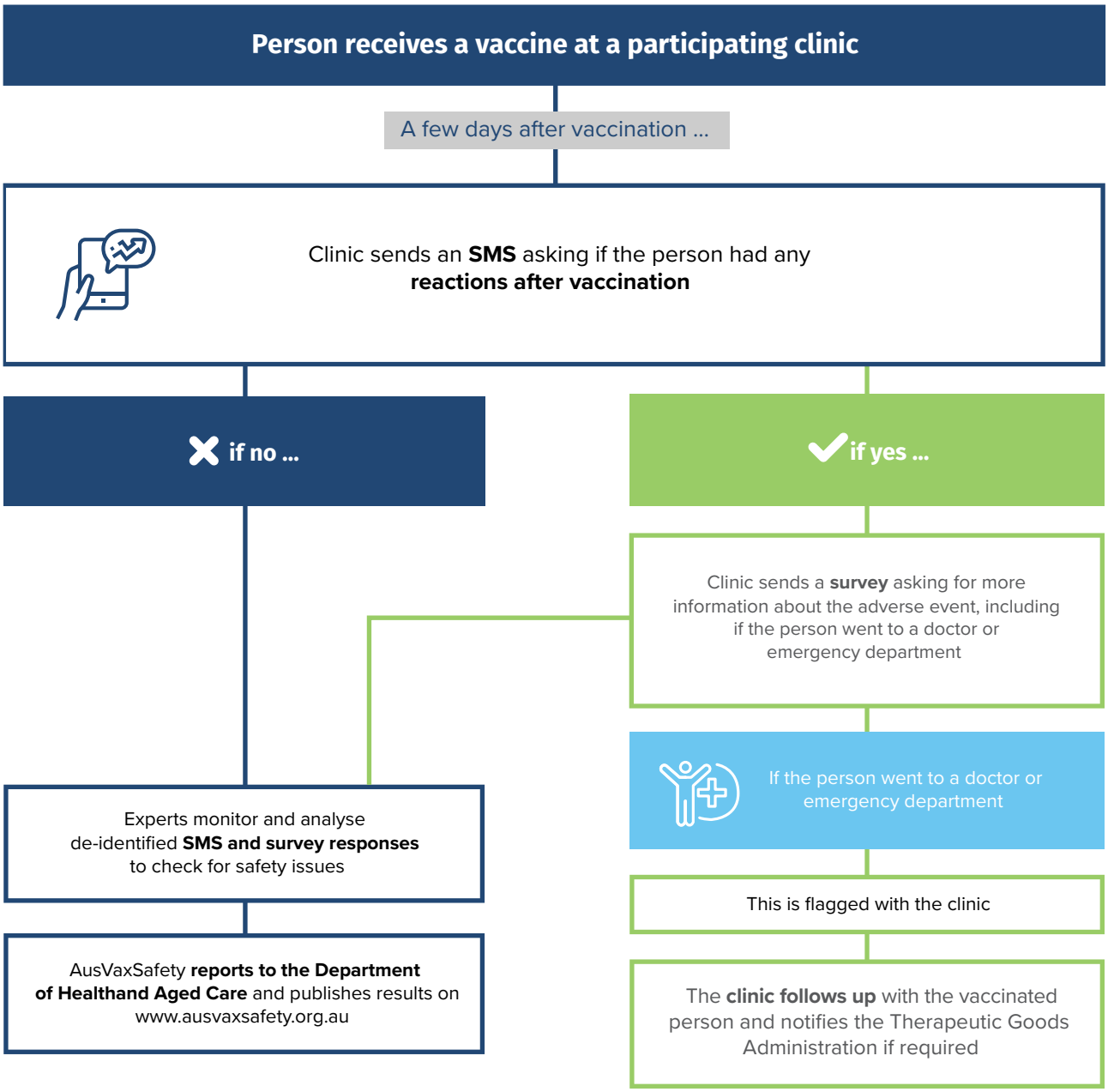


Figure 1 - Number of immunisation provider sites participating in AusVaxSafety, 2021.

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 remained high across Australia, ensuring a high number of participants for surveillance.

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

More than 90% of respondents report **no adverse events**

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

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

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**

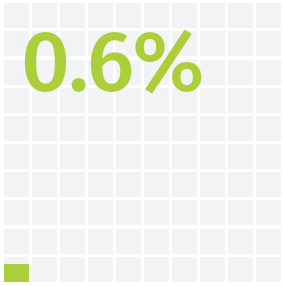
Data on this page show the responses of individuals who received a vaccine on the 2 month schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

13,249

Reported at least one adverse event

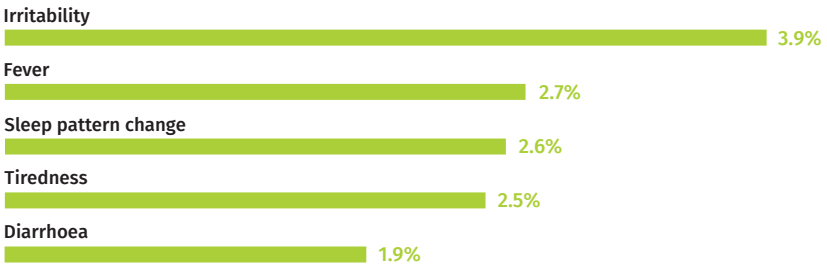
Medical attendance



Those who presented to GPs and emergency departments had similar adverse events to those who did not. AusVaxSafety does not specifically ask participants the reason why they accessed medical care in the days following vaccination. Therefore medical attendance reported may or may not be related to any adverse events reported.

Commonly reported adverse event

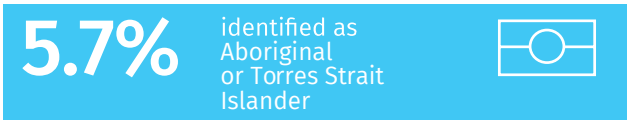
These symptoms are known to occur after vaccination. They are generally mild and short-lived. As with any adverse event reports, not all symptoms reported may be caused by the vaccine; they may be coincidental and due to other causes.



Vaccines given at 2 months in 2021

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

Respondent demographics



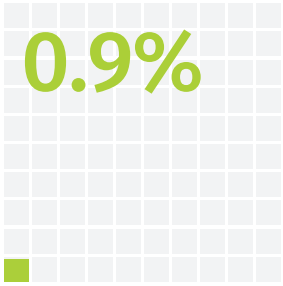
Data on this page show the responses of individuals who received a vaccine on the 4 month schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

12,713

Reported at least one adverse event

Medical attendance



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Commonly reported adverse event

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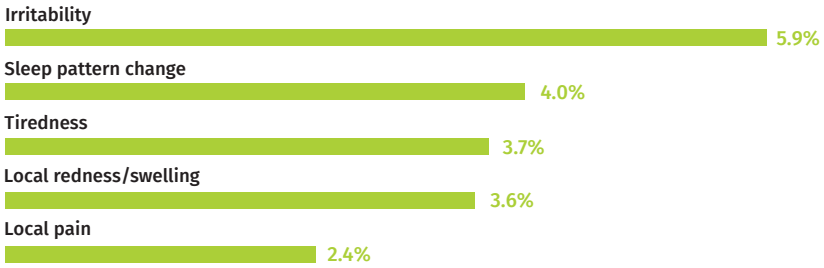
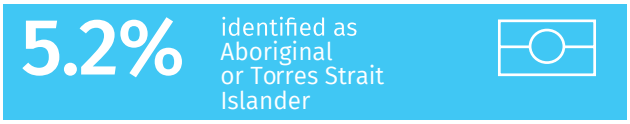


Vaccines given at 4 months in 2021

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

Respondent demographics



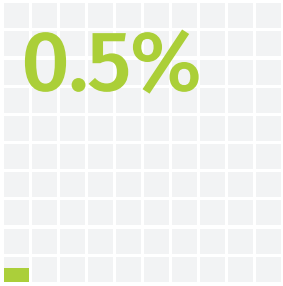
Data on this page show the responses of individuals who received a vaccine on the 6 month schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

12,730

Reported at least one adverse event

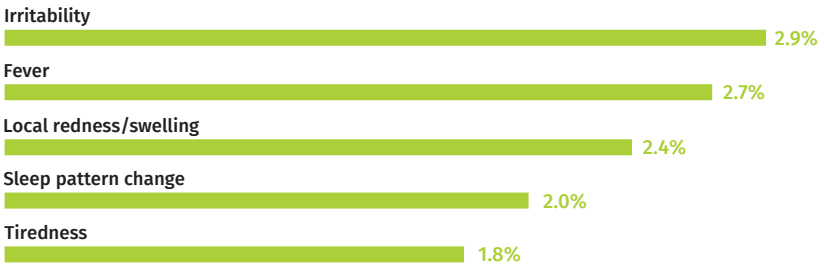
Medical attendance



Those who presented to GPs and emergency departments had similar adverse events to those who did not. AusVaxSafety does not specifically ask participants the reason why they accessed medical care in the days following vaccination. Therefore medical attendance reported may or may not be related to any adverse events reported.

Commonly reported adverse event

These symptoms are known to occur after vaccination. They are generally mild and short-lived. As with any adverse event reports, not all symptoms reported may be caused by the vaccine; they may be coincidental and due to other causes.



Vaccines given at 6 months in 2021

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

Respondent demographics

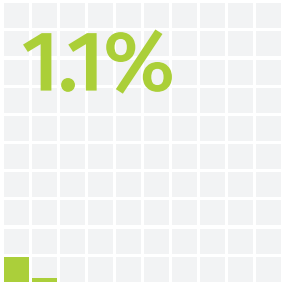
Data on this page show the responses of individuals who received a vaccine on the 12 month schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

11,360

Reported at least one adverse event

Medical attendance



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Commonly reported adverse event

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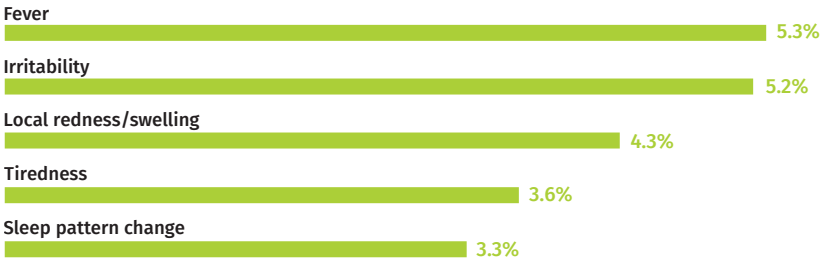
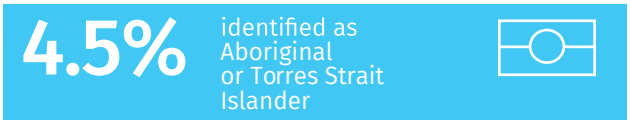


Vaccines given at 12 months in 2021

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

Respondent demographics



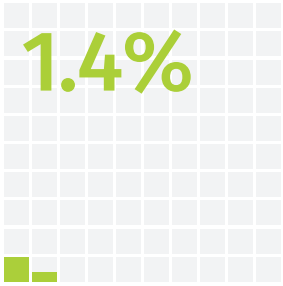
Data on this page show the responses of individuals who received a vaccine on the 18 month schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

11,521

Reported at least one adverse event

Medical attendance



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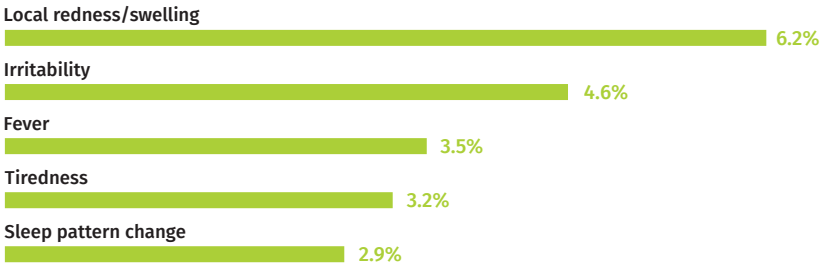
Commonly reported adverse event

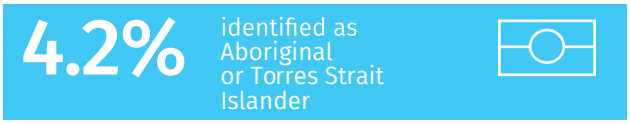
These symptoms are known to occur after vaccination. They are generally mild and short-lived. **As with any adverse event reports, not all symptoms reported may be caused by the vaccine; they may be coincidental and due to other causes.**



Vaccines given at 18 months in 2021

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

Respondent demographics



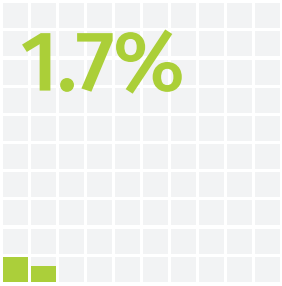
Data on this page show the responses of individuals who received a vaccine on the 4 year schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

12,973

Reported at least one adverse event

Medical attendance



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Commonly reported adverse event

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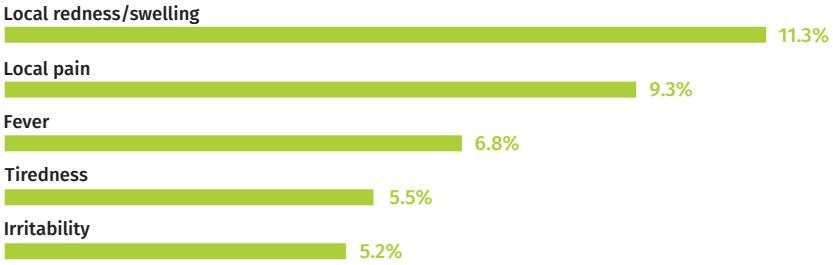


Vaccines given at 4 years in 2021

	Protects against
Infanrix IPV or Quadracel	Diphtheria, tetanus, whooping cough, polio

Respondent demographics

49% female

51% male

3.9% identified as Aboriginal or Torres Strait Islander

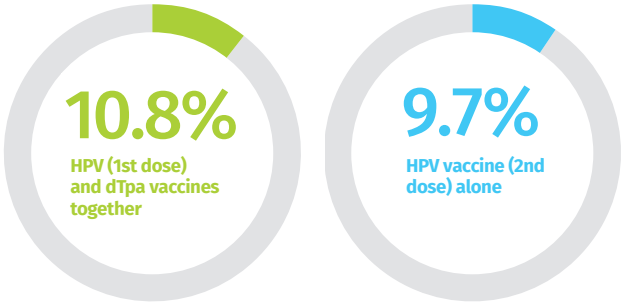
Data on this page show the responses of individuals who received a vaccine on the 12-13 years schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

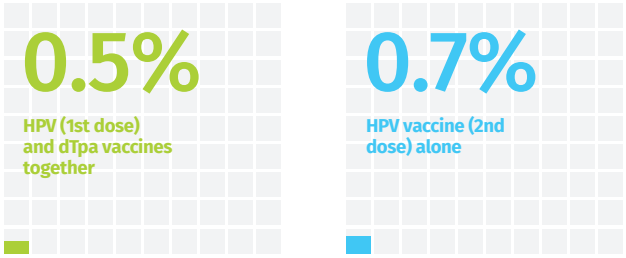
17,678
HPV (1st dose) and dTpa vaccines together

12,165
HPV vaccine (2nd dose) alone

Reported at least one adverse event



Medical attendance



Those who presented to GPs and emergency departments had similar adverse events to those who did not. AusVaxSafety does not specifically ask participants the reason why they accessed medical care in the days following vaccination. Therefore medical attendance reported may or may not be related to any adverse events reported.

Commonly reported adverse event

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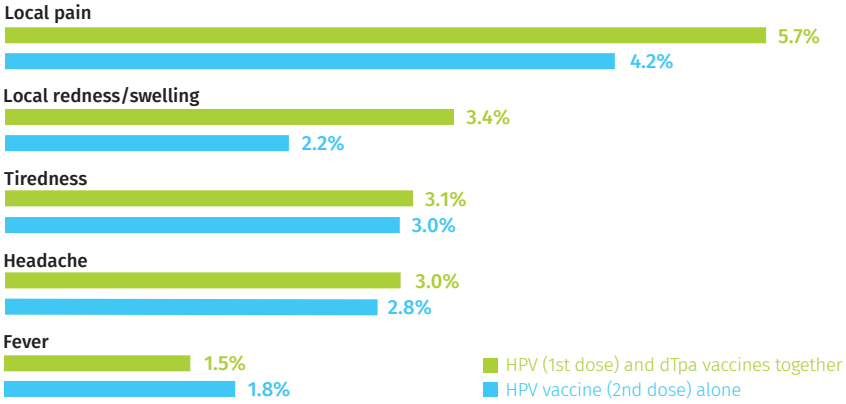


Vaccines given at 12-13 years in 2021

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

Respondent demographics

49% female

51% male

3.0% identified as Aboriginal or Torres Strait Islander

12 - 13 years schedule point

Data date range

1 January 2021 – 31 December 2021

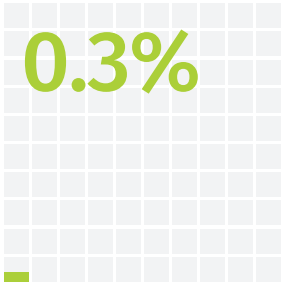
Data on this page show the responses of individuals who received a vaccine on the 14-16 years schedule point and whose parent or carer completed an AusVaxSafety survey on their child's behalf sent in the days following vaccination.

Safety surveys completed

17,192

Reported at least one adverse event

Medical attendance



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Commonly reported adverse event

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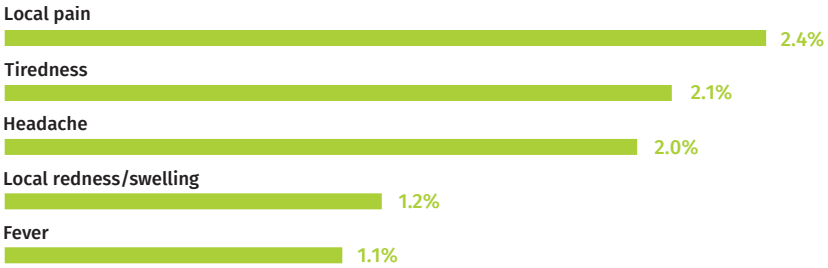


Vaccines given at 14-16 years in 2021

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

Respondent demographics

Data on this page show the responses of pregnant individuals who received a vaccine on the pregnant people schedule point and completed an AusVaxSafety survey sent in the days following vaccination.

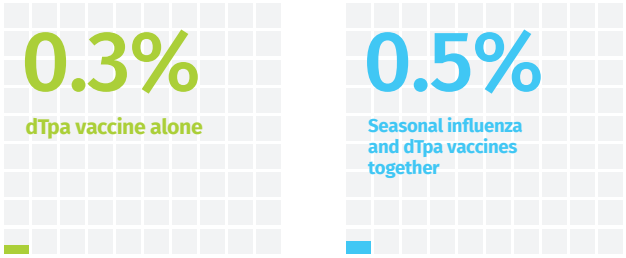
Safety surveys completed

4,678
dTpa vaccine alone

1,572
Seasonal influenza and dTpa vaccines together

Reported at least one adverse event

Medical attendance



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Commonly reported adverse event

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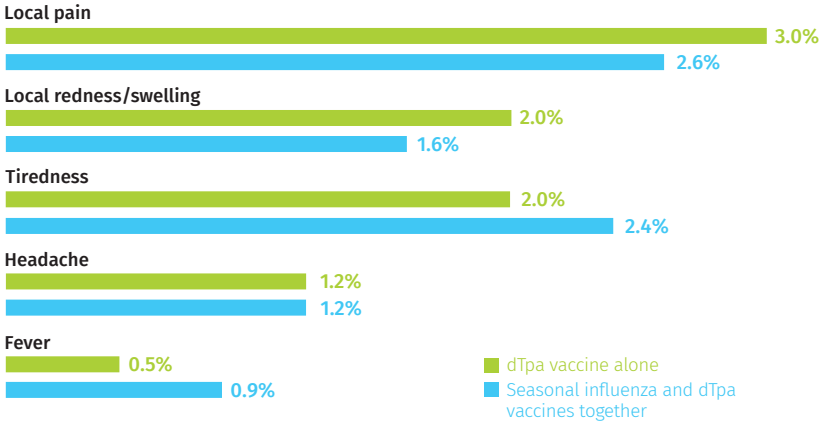


Vaccines given to pregnant people in 2021

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

Respondent demographics

100% female

1.9% identified as Aboriginal or Torres Strait Islander

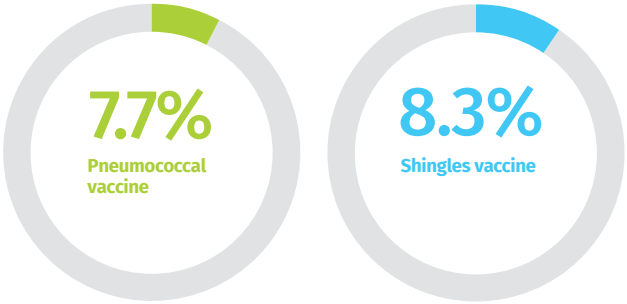
Data on this page show the responses of individuals who received a vaccine on the older adult schedule point and completed an AusVaxSafety survey sent in the days following vaccination.

Safety surveys completed

17,647
Pneumococcal vaccine

5,947
Shingles vaccine

Reported at least one adverse event



Medical attendance

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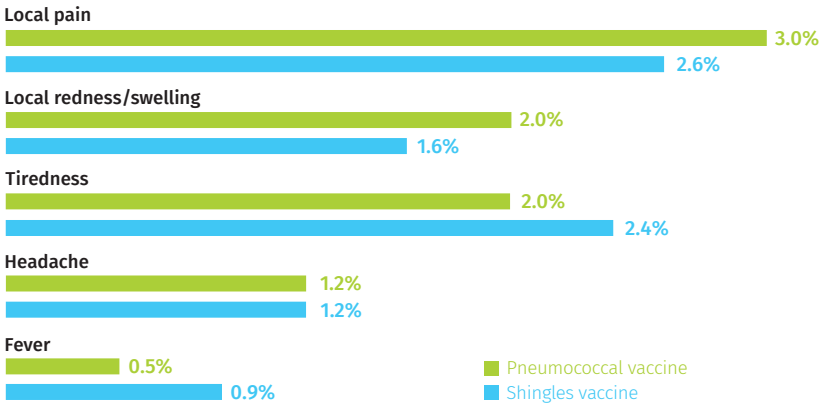


Vaccines given to older adults in 2021

	Protects against
Prevenar 13	Pneumococcal disease
Zostavax	Shingles

Respondent demographics

55% female

45% male

1.7% identified as Aboriginal or Torres Strait Islander

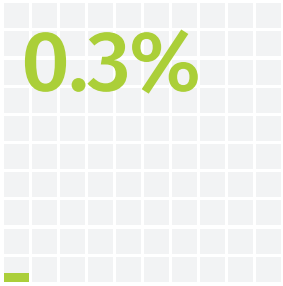
Data on this page show the responses of individuals (or their parent/carer) who received a seasonal influenza vaccine and completed an AusVaxSafety survey sent in the days following vaccination.

Safety surveys completed

231,668

Reported at least one adverse event

Medical attendance



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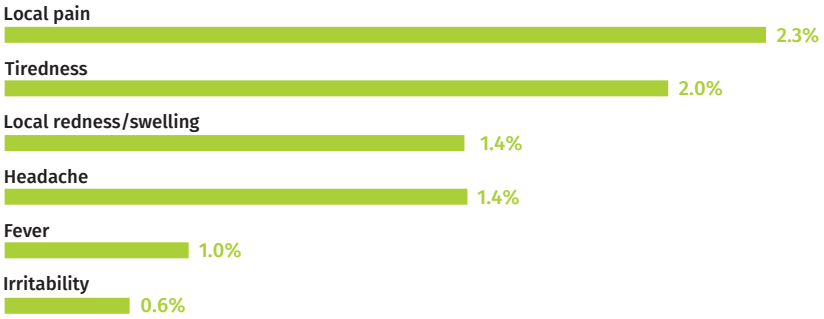

Influenza vaccines given in 2021

	Protects against
Afluria Quad, Fluad Quad, Fluarix Tetra, FluQuadri, Influvac Tetra, Vaxigrip Tetra	Influenza

Respondent demographics