Australian Government
Department of Health and Aged Care

# AusVaxSafety COVID-19 vaccine surveillance Summary report 2021

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

AusVaxSafety
An NCIRS led collaboration

## What's included in this report?

This report includes safety surveillance data collected by AusVaxSafety for all COVID-19 vaccine brands used in Australia from 22 February 2021 to 31 December 2021 and includes data pages specific to Aboriginal and Torres Strait Islander people.

## What's planned for 2022?

- Ongoing surveillance of COVID-19 vaccines in use in Australia to ensure new doses and eligible age groups are being monitored.
- Surveillance of the Novavax COVID-19 vaccine.
- Surveillance of paediatric formulation of the Pfizer COVID-19 vaccine for children aged 5–11 years.
- Surveillance of paediatric formulation of the Moderna COVID-19 vaccine for children aged 6–11 years.
- Surveillance of paediatric formulation of the Moderna COVID-19 vaccine for children aged 6 months to 5 years.

# Overview

Australia commenced administering Pfizer COVID-19 vaccines in February 2021, AstraZeneca COVID-19 vaccines in March 2021 and Moderna COVID-19 vaccines in August 2021.

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AusVaxSafety active surveillance of COVID-19 vaccines commenced on the first day of the COVID-19 vaccine roll out in Australia. Since this time, AusVaxSafety has been monitoring all doses of all COVID-19 vaccines used in Australia on an ongoing basis.

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A new, more robust, vaccine safety survey was created and used for the first time to capture richer data from participants, with learnings applied to future vaccine surveillance efforts in Australia.

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AusVaxSafety expanded active vaccine safety surveillance sites to ensure timely and representative capture of COVID-19 vaccination encounters, including Aboriginal Community Controlled Health Organisations (ACCHO), pharmacies and vaccination hubs for the first time.

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AusVaxSafety received more than 5 million COVID-19 vaccine safety survey responses generating an unprecedented amount of active safety data for any vaccine ever used in Australia.

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The profile of reported events from AusVaxSafety surveillance of COVID-19 vaccines used in Australia is similar to that reported in clinical trials and from post-marketing surveillance overseas.

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AusVaxSafety data supplemented passive reporting undertaken by the Therapeutic Goods Administration and has played a vital role in the unprecedented national rollout of COVID-19 vaccines.

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# 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.

**What does AusVaxSafety do?**

AusVaxSafety tracks COVID-19 vaccine safety through:

- active surveillance of COVID-19 vaccine recipients through survey responses from people receiving vaccines, or their parents and carers, using SmartVax, Vaxtracker and COVID Vaccine Management System (CVMS) software
- adverse event of special interest follow-up program, which undertakes long-term follow-up surveillance of individuals who experienced an adverse event of special interest (AESI) following COVID-19 vaccination.

This report focuses on the COVID-19 active surveillance activities undertaken by AusVaxSafety in 2021.

**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 COVID-19 vaccine safety surveillance works

Since the rollout of the Australian COVID-19 vaccination program in February 2021, AusVaxSafety has been actively monitoring the safety of all COVID-19 vaccines used in Australia.

To do this, AusVaxSafety surveillance tools distribute a short vaccine safety survey via SMS or email to individuals – or where appropriate their parent or carer – who received their vaccine at a participating AusVaxSafety site or vaccination hub across Australia.

The surveys are designed by vaccine experts and give participants the opportunity to report any adverse events they may have experienced after receiving their vaccination, and if they had to seek medical attention as a result.

De-identified data from completed surveys are analysed and monitored by epidemiologists and vaccine experts who investigate anything unusual or unexpected to ensure that vaccines are performing as safely and effectively as expected in real-world conditions.

In 2021, AusVaxSafety expanded active vaccine safety surveillance sites to ensure timely and representative capture of COVID-19 vaccination encounters. Active surveillance was set up in state - and territory-based vaccination hubs in every jurisdiction, in addition to 380 general practice (GP), 31 Aboriginal Community Controlled Health Organisation (ACCHOs) and 136 pharmacy sites (Figure 1).

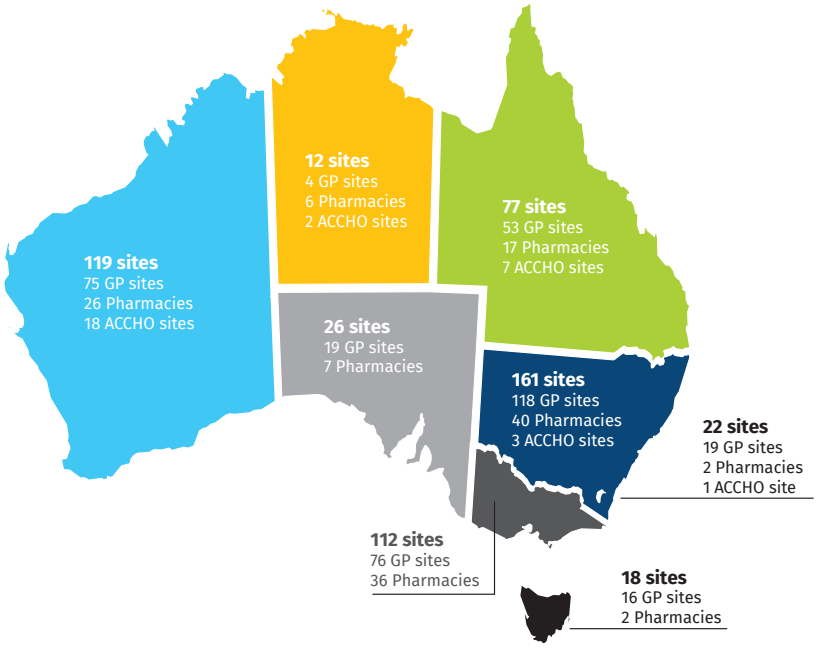



**Figure 1** - Number of immunisation provider sites participating in AusVaxSafety, 2021 (excludes vaccination hubs as their sites evolved over the course of the year).

# How AusVaxSafety COVID-19 surveillance works

## How do we monitor vaccine safety?

**Individual receives vaccination**
Individual receives vaccination at a participating AusVaxSafety clinic across Australia.

**AusVaxSafety sends vaccine safety survey**
AusVaxSafety sends a vaccine safety survey to the participants following vaccination, giving them the opportunity to report any adverse events they may have experienced and if they had to seek medical attention as a result.

**Experts monitor data for safety issues**
Epidemiologist and vaccine experts monitor and analyse de-identified survey responses to check for safety issues.

If a survey participant reported going to the doctor or emergency department, this is flagged with the clinic, allowing the clinic to follow up with them and notify the Therapeutic Goods Administration if required.

**Safety data published on AusVaxSafety website**
AusVaxSafety reports safety data to the Australian Government Department of Health and Aged Care and the Therapeutic Goods Administration to complement the passive reporting system. Safety data for COVID-19, influenza and National Immunisation Program vaccines are published regularly at **ausvaxsafety.org.au**

These data are a great tool for immunisation providers when counselling patients on immunisation. They provide individuals with a profile of what to expect following vaccination and can assist when planning for vaccination.

This report reflects data from people who received a COVID-19 vaccine at a participating immunisation clinic and completed an AusVaxSafety survey sent on day 3 after vaccination. It does not include data from every person who received a COVID-19 vaccine.

**Data on this page show the responses of all individuals aged 12 years and older who received Pfizer COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination.**

## Safety surveys completed

**4,094,999**

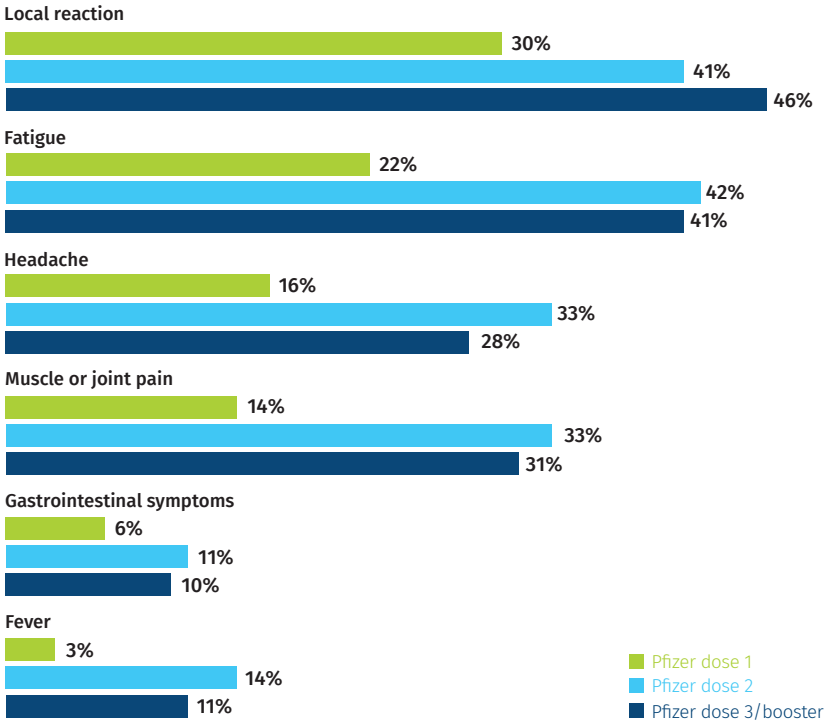
## Reported at least one adverse event


## Medical attendance

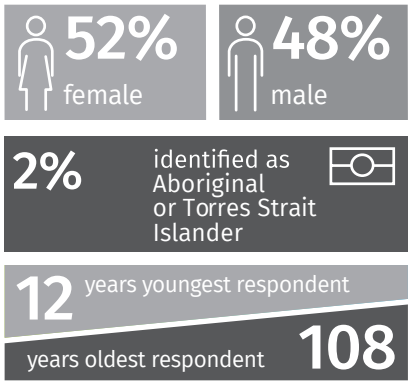

Those who presented to GPs and emergency departments had similar adverse events to those who did not. AusVaxSafety does not specifically ask participants the reason why they accessed medical care in the days following vaccination. Therefore medical attendance reported may or may not be related to any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

## Commonly reported adverse event

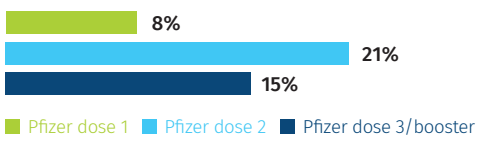
These symptoms are known to occur after vaccination. They are generally mild and short-lived. As with any adverse event reports, not all symptoms reported may be caused by the vaccine; they may be coincidental and due to other causes.




## Respondent demographics




## Impact on routine activities Reported missing work, study or routine duties




The majority reported missing 1 day or less. Most participants who reported not being able to do work or routine duties had lethargy, headache and joint pain. These are common adverse events linked to the immune response following immunisation and understandably meant some people chose to rest after vaccination.

**Data on this page show the responses of Aboriginal and Torres Strait Islander people aged 12 years and older who received Pfizer COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination.**

## Safety surveys completed

**66,271**

## Reported at least one adverse event


## Medical attendance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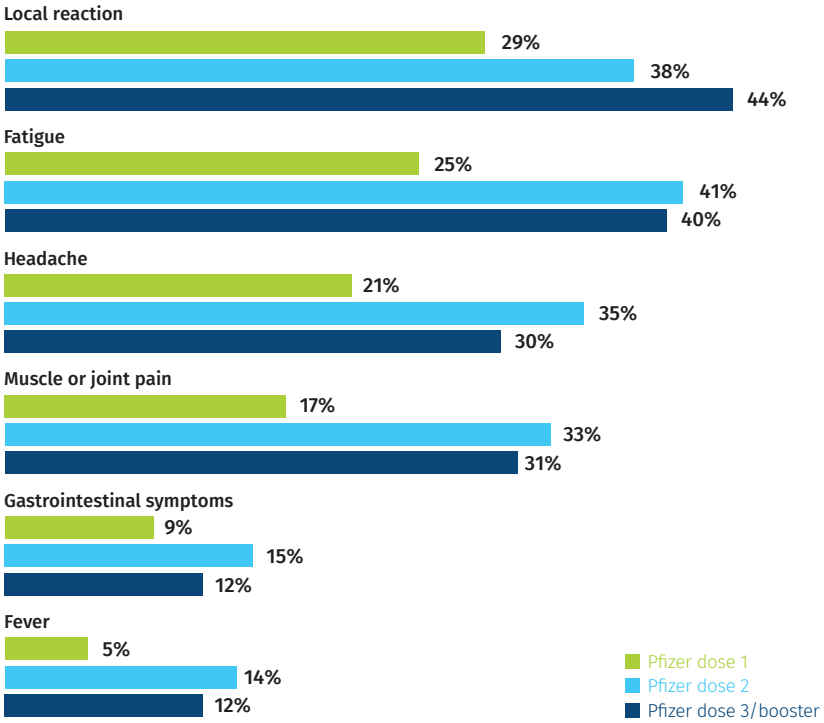


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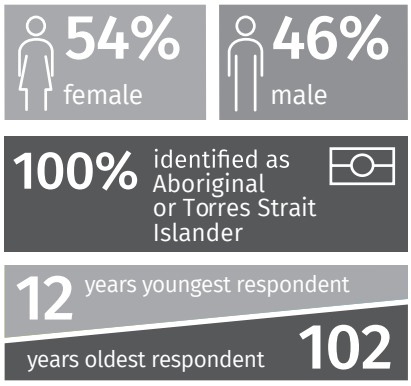


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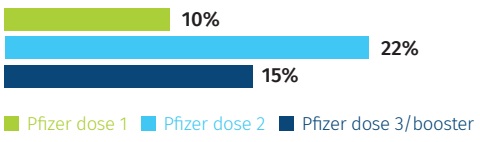


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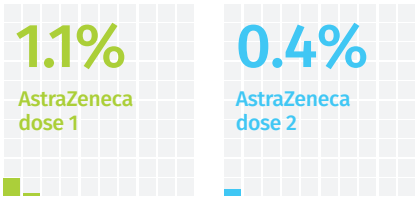
**Data on this page show the responses of all individuals aged 18 years and older who received the AstraZeneca COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination.**

## Safety surveys completed

**972,044**

## Reported at least one adverse event


## Medical attendance

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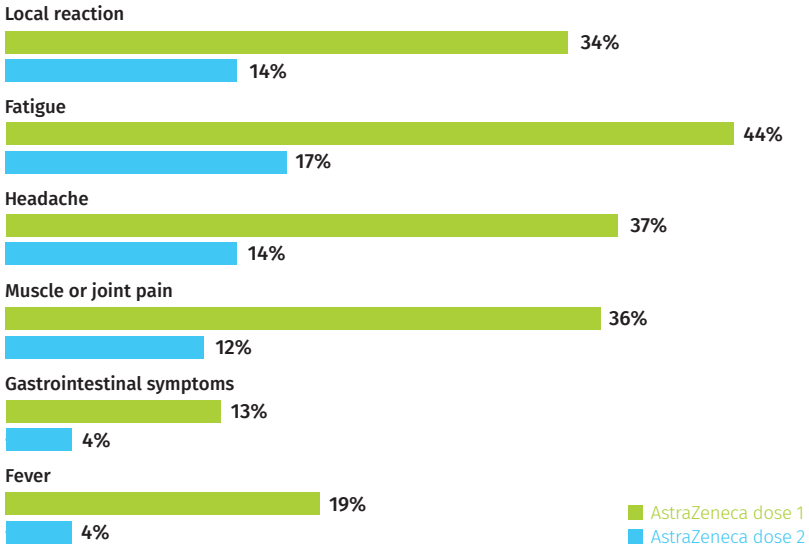


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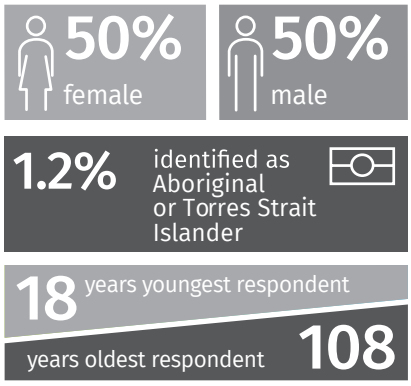
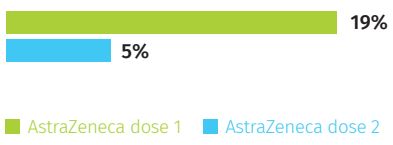



## Impact on routine activities

Reported missing work, study or routine duties

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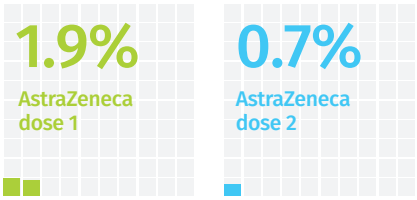
**Data on this page show the responses of Aboriginal and Torres Strait Islander people aged 18 years and older who received the AstraZeneca COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination.**

## Safety surveys completed

**10,107**

## Reported at least one adverse event


## Medical attendance

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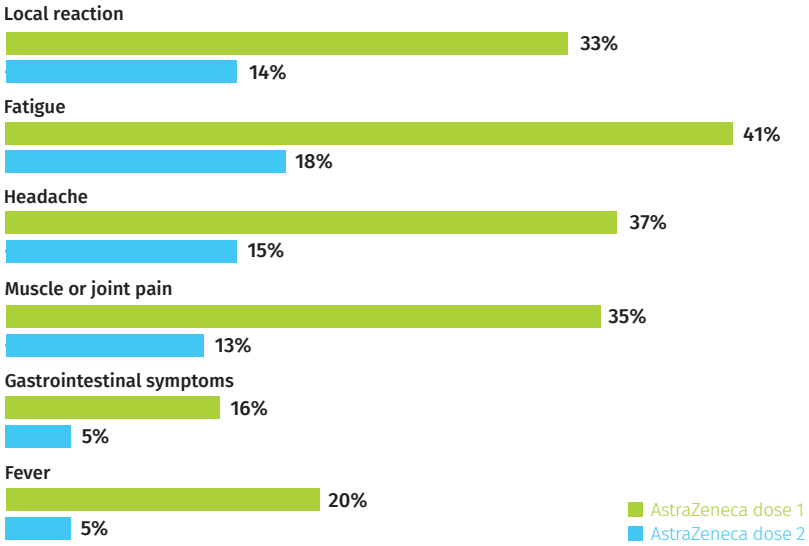


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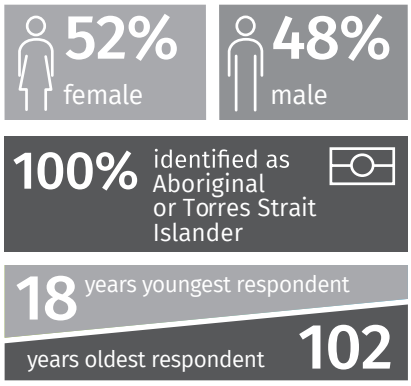


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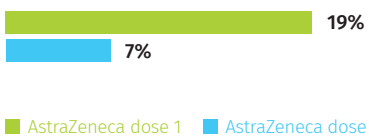


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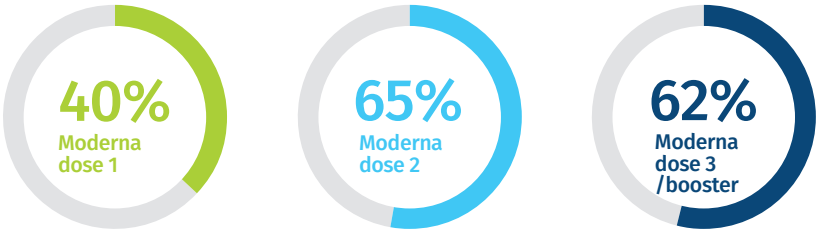
**Data on this page show the responses of all individuals aged 12 years and older who received the Moderna COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination.**

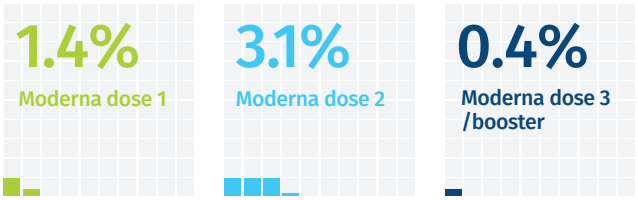
## Safety surveys completed

**41,557**

## Reported at least one adverse event




## Medical attendance

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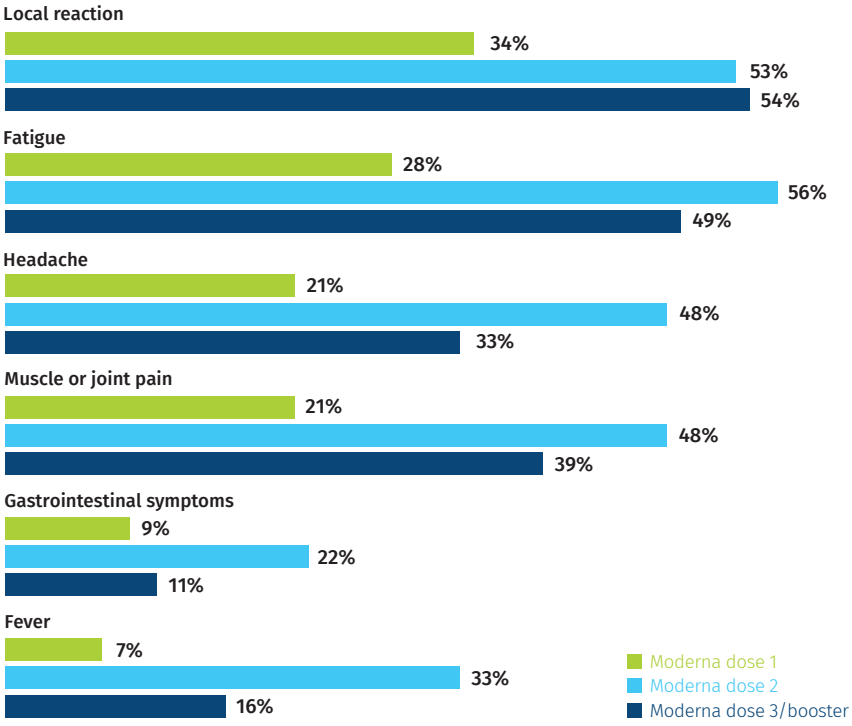
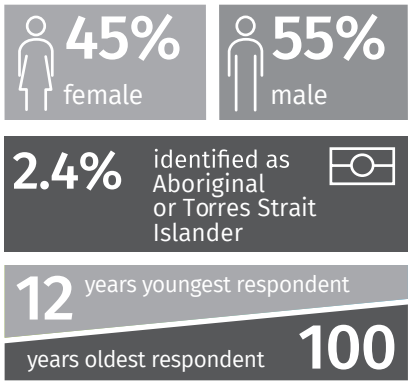



## Respondent demographics

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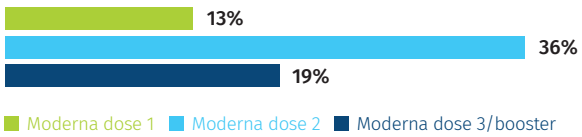


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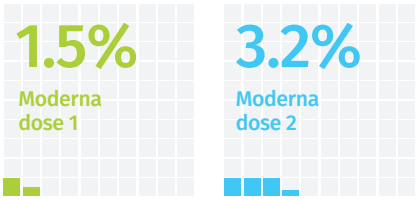
**Data on this page show the responses of Aboriginal and Torres Strait Islander people aged 12 years and older who received the Moderna COVID-19 vaccine and completed an AusVaxSafety survey sent on day 3 after vaccination.**

## Safety surveys completed

**1,068**

## Reported at least one adverse event


## Medical attendance

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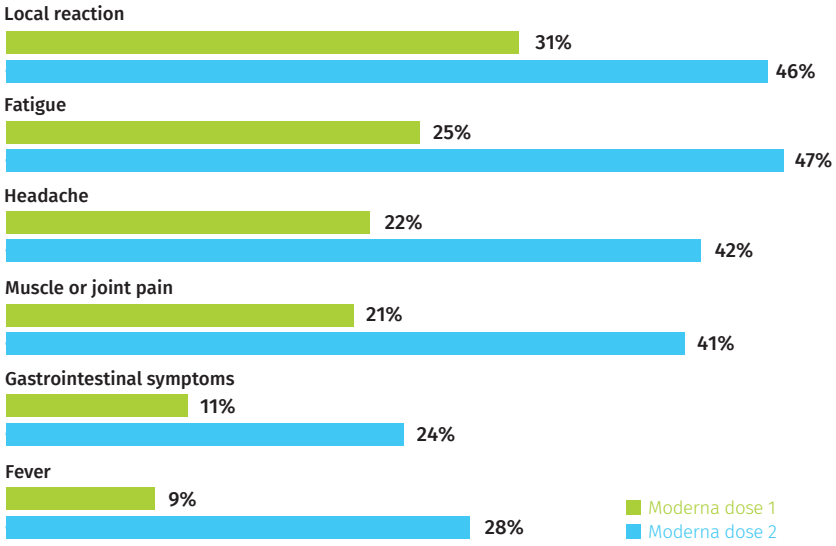


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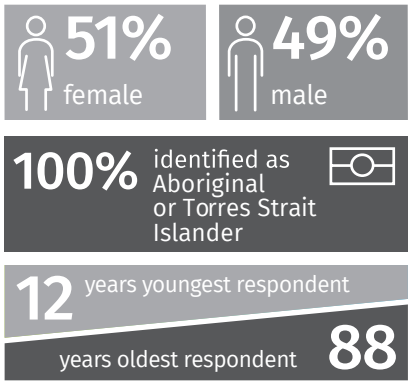


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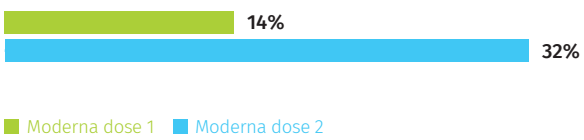


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