COVID-19 Vaccines Safety

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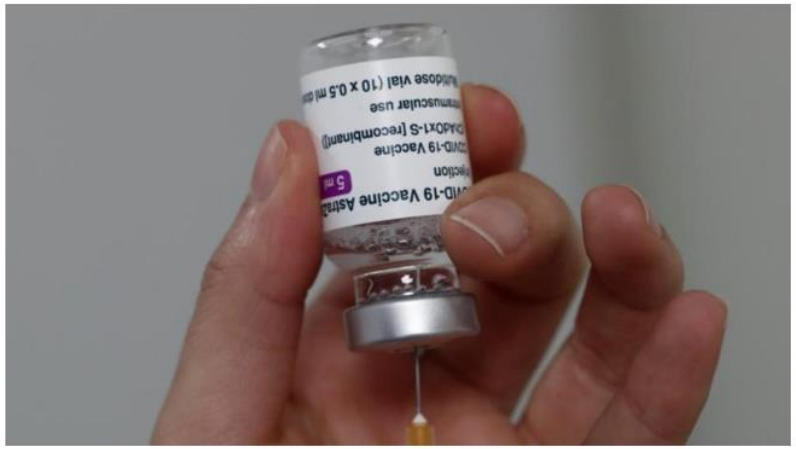
The West Australian

Health

Austria halts AZ vaccine batch after death

Michael Shields and Ludwig Burger AAP
Sun, 7 March 2021 9:06PM



Austria has suspended inoculations with a batch of AstraZeneca's COVID-19 vaccine after a death.

Austrian authorities have suspended inoculations with a batch of AstraZeneca's COVID-19 vaccine as a precaution while investigating the death of one person and the illness of another after the shots.

One 49-year-old woman died as a result of severe coagulation disorders, while a 35-year-old woman developed a pulmonary embolism and is recovering, Austria's Federal Office for Safety in Health Care (BASG) said on Sunday.

Coronavirus

Queensland revises AstraZeneca COVID-19 vaccine advice for those with history of anaphylaxis

Queensland Premier Annastacia Palaszczuk Source: AAP

Eligible people with a history of severe allergic reactions are now advised they can be vaccinated but should be monitored for 30 minutes after receiving the AstraZeneca jab.

Primary concerns raised for AZ: Blood Clots and Allergic reactions

- Recent media from Europe relating to incidence of thrombotic (clotting) events following the AstraZeneca COVID-19 vaccine

- Recent concerns raised by Queensland Health following a small number of Allergic Reactions in a short time frame during the initial roll out

Adverse events from Pfizer and AstraZeneca Vaccines

AstraZeneca

Common
- pain, swelling, tenderness, redness or itching at the injection site
- tiredness
- headache
- muscle pain
- nausea
- chills
- fever
- feeling unwell
- joint pain

Less Common
- enlarged lymph nodes
- pain in limb
- dizziness
- decreased appetite
- stomach pain

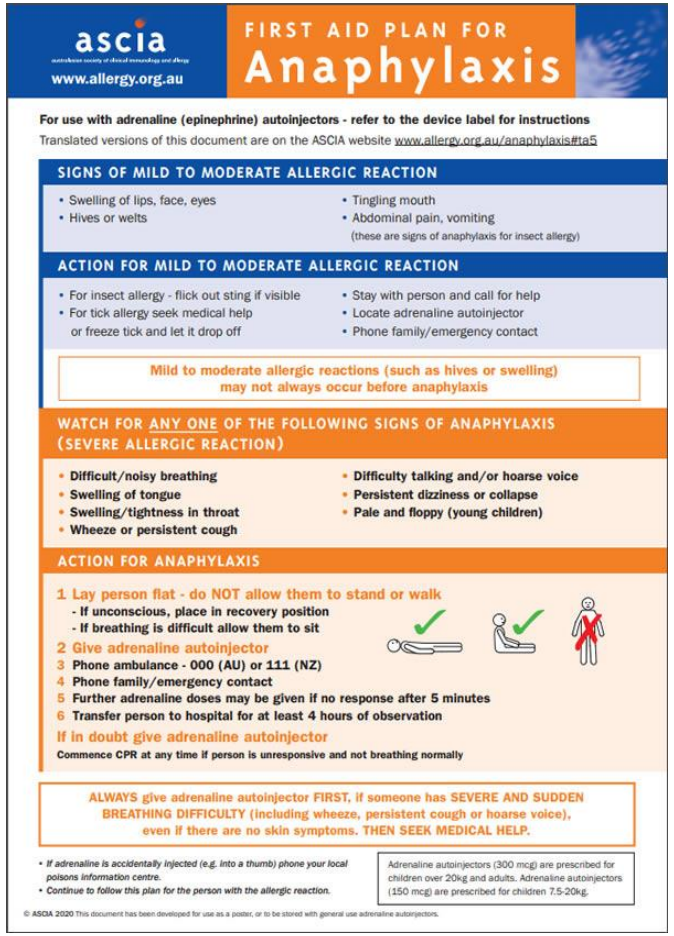
Rare
- severe allergic reaction (anaphylaxis)

Pfizer

Common
- pain or swelling at the injection site
- tiredness
- headache
- muscle pain
- chills
- fever
- joint pain

Less Common
- redness at the injection site
- nausea
- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- itching at the injection site

Rare
- severe allergic reaction (anaphylaxis)



ascia
www.allergy.org.au

FIRST AID PLAN FOR
Anaphylaxis

For use with adrenaline (epinephrine) autoinjectors - refer to the device label for instructions

Translated versions of this document are on the ASCIA website www.allergy.org.au/anaphylaxis#ta5

SIGNS OF MILD TO MODERATE ALLERGIC REACTION

- Swelling of lips, face, eyes
- Hives or welts
- Tingling mouth
- Abdominal pain, vomiting

(these are signs of anaphylaxis for insect allergy)

ACTION FOR MILD TO MODERATE ALLERGIC REACTION

- For insect allergy - flick out sting if visible
- For tick allergy seek medical help or freeze tick and let it drop off
- Stay with person and call for help
- Locate adrenaline autoinjector
- Phone family/emergency contact

Mild to moderate allergic reactions (such as hives or swelling) may not always occur before anaphylaxis

WATCH FOR ANY ONE OF THE FOLLOWING SIGNS OF ANAPHYLAXIS (SEVERE ALLERGIC REACTION)

- **Difficult/noisy breathing**
- **Swelling of tongue**
- **Swelling/tightness in throat**
- **Wheeze or persistent cough**
- **Difficulty talking and/or hoarse voice**
- **Persistent dizziness or collapse**
- **Pale and floppy (young children)**

ACTION FOR ANAPHYLAXIS

1 Lay person flat - do NOT allow them to stand or walk
- If unconscious, place in recovery position
- If breathing is difficult allow them to sit

2 Give adrenaline autoinjector
3 Phone ambulance - 000 (AU) or 111 (NZ)
4 Phone family/emergency contact
5 Further adrenaline doses may be given if no response after 5 minutes
6 Transfer person to hospital for at least 4 hours of observation

If in doubt give adrenaline autoinjector

Commence CPR at any time if person is unresponsive and not breathing normally

ALWAYS give adrenaline autoinjector FIRST, if someone has SEVERE AND SUDDEN BREATHING DIFFICULTY (including wheeze, persistent cough or hoarse voice), even if there are no skin symptoms. THEN SEEK MEDICAL HELP.

- *If adrenaline is accidentally injected (e.g. into a thumb) phone your local poisons information centre.*
- *Continue to follow this plan for the person with the allergic reaction.*

Adrenaline autoinjectors (300 mcg) are prescribed for children over 20kg and adults. Adrenaline autoinjectors (150 mcg) are prescribed for children 7.5-20kg.

- > 180,000 COVID-19 Vax doses administered
  - Of this > 20,000 doses of AZ vaccine administered in Australia @ 18th March 2021
  - **14 cases** of anaphylaxis from Pfizer
  - **5 cases** of anaphylaxis reported to AZ
- TGA r/v 5 cases (4 from QLD) and 1x NSW and VIC
  - Only 1 considered a meeting criteria for anaphylaxis (Brighton collaboration)
- ***Pfizer vaccine**: 8.3 million first doses
  - 0.3% total adverse event rate.
  - For anaphylaxis, 1: 49,000 doses (i.e. 168/8.3M)
- ***AstraZeneca vaccine**: 6.9 million first doses
  - 0.45% total adverse event rate.
  - For anaphylaxis, 1:66,000 doses (i.e. 105/6.9M)
- **Influenza Vaccine Anaphylaxis Rate**
  - 1-2 / 1 Million doses

* UK Medicines and Healthcare Regulatory Agency (MHRA)

Individuals who should be assessed for their suitability for vaccine dose

- people with immediate (within 4 hours) and generalised symptoms of a possible allergic reaction (e.g. urticaria/hives) to a previous dose of a COVID-19 vaccine
- people with a generalised allergic reaction (without anaphylaxis) to any component of the COVID-19 vaccine to be administered (e.g. PEG in Pfizer or polysorbate 80 in AstraZeneca)
- people with a prior history of anaphylaxis to previous vaccines and/or multiple drugs (injectable and/or oral) where ingredients such as PEG or polysorbate 80 may conceivably be the cause
- people with a known systemic mast cell activation disorder with raised mast cell tryptase that requires treatment
- MAY REQUIRE VACCINATION WHERE MEDICAL STAFF IN ATTENDANCE
- **OBSERVE FOR 30min**

Other types of allergies?

- Where there is a history of allergy; anaphylaxis to food, drugs, venom or latex; or allergic conditions, including asthma, atopic dermatitis (eczema) or allergic rhinitis (hay fever), should be observed for at **least 15 minutes** following administration of the vaccine

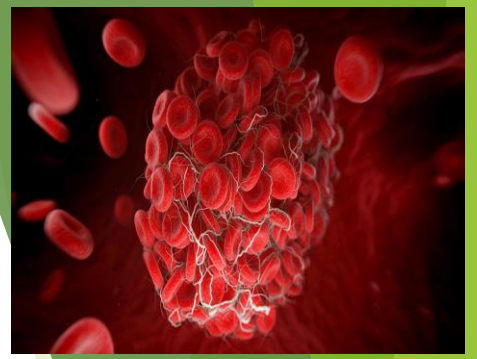
Response from TGA REVIEW of Reported Anaphylaxis cases

"some of these cases may have represented allergic reactions or immediate stress responses to vaccination that may appear similar to an anaphylactic reaction, with symptoms such as nausea, throat tightness or rapid heart rate. Although they might not meet the criteria for anaphylaxis, they still need to be monitored and taken seriously."

- All 4 cases in QLD had a history of allergic reactions to a variety of agents
- Some foods and other chemicals
- Some drugs / vaccines
- Appropriately managed at the time at the clinical sites

Adult specialist immunisation service for Queensland (ASISQ)

- Queensland Health setting up service to provide assistance with specialist consultation and review for AEFI and potential support and contraindications to vaccination
- Allergy testing and supervised immunisation
- Education and research activities
- Telehealth and outreach services
- Located in MNHHS and MSHHS



- **European Medical Agency (EMA)**
  - > 20 Million doses of AZ vaccine administered in Europe
  - 7 cases of DIC, 18 CVST
  - 469 total thromboembolic events (23 per 1,000,000)
- Concluded that the vaccine **may** be associated with these very rare cases
- Causal link was not proven but could be possible and needs more investigation
- The **overall rate reports** of thromboembolic events reported after vaccination both before and after AZ roll out are lower than would be expected in the general population.
  - No increase in overall risk of blood clots

Table 1. Risk of VTE in women at various life stages[5,6]

Population	Risk of VTE per 10,000 women per year
Women of childbearing age non-OC users	4
Women taking COC	7–10
Pregnant and postpartum women	20–30*

*Postpartum rates for the first 12 weeks postpartum have been quoted as 40–65 per 10,000 women per year,[35] and approximately 300–400 per 10,000 women per year during the two days before and the day after delivery[36]

COC, combined oral contraceptive; OC, oral contraceptive; VTE, venous thromboembolism

Risk of venous thromboembolism in women taking the combined oral contraceptive: A systematic review and meta-analysis. Volume 45, No.1, January/February 2016 Pages 59-64

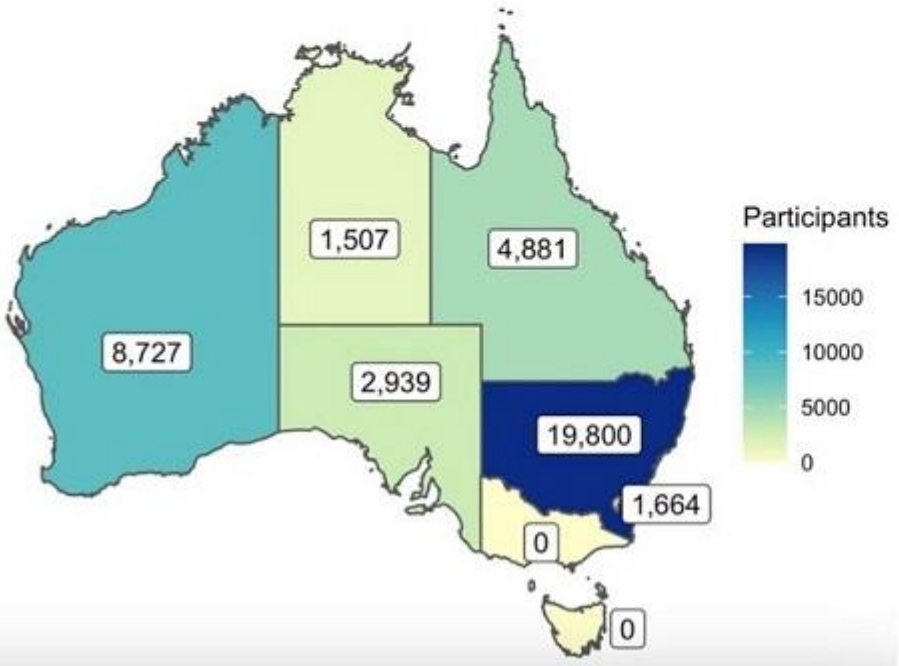
AuVaxSafety System – monitoring AE

As at 14 March 2021

NO SAFETY SIGNAL DETECTED

59,793 surveys sent Australia-wide

39,518 participants (66.1% response rate)

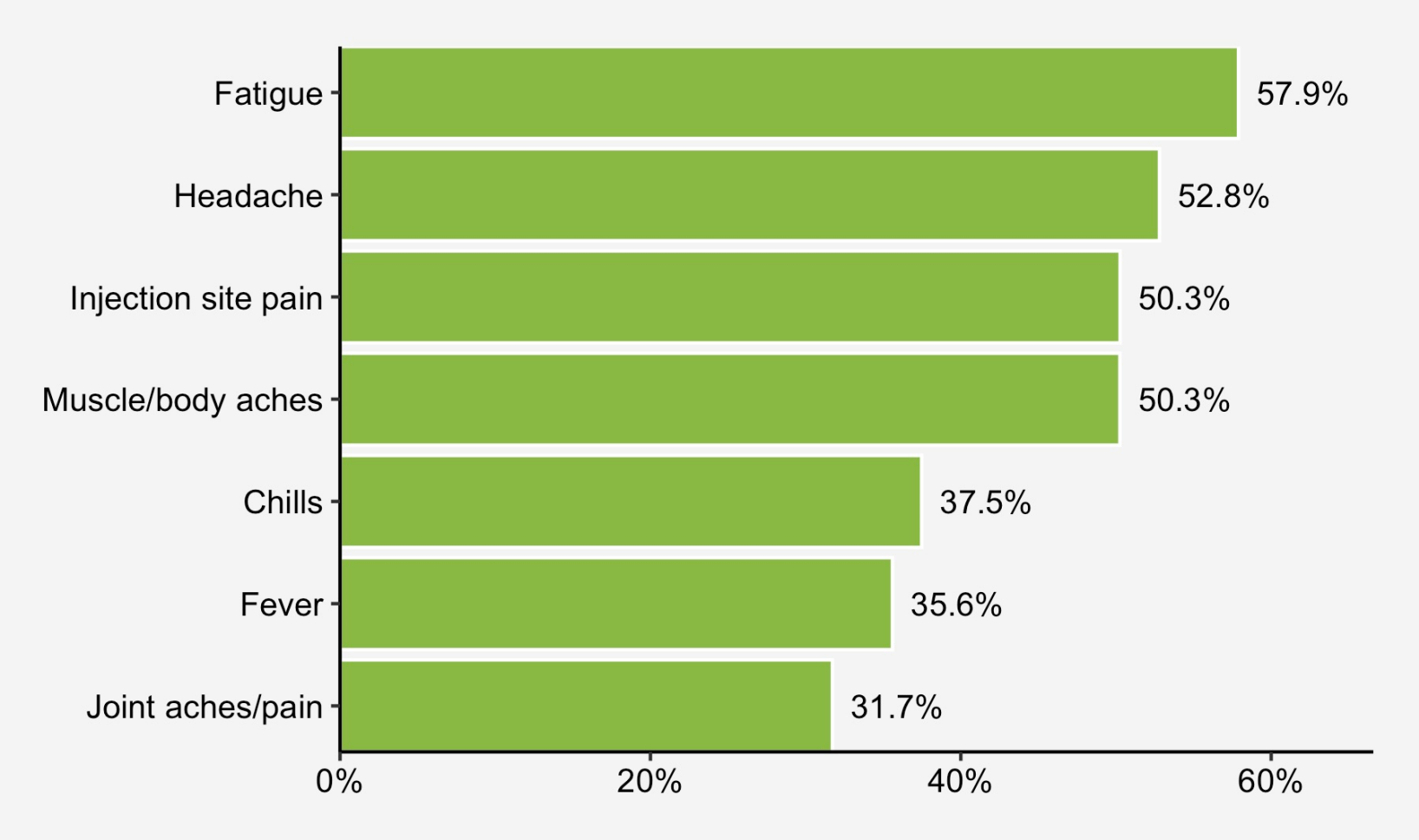


60.1% of participants reported no adverse event

39.9% of participants reported any adverse event

0.8% of participants reported visiting a doctor or emergency department

AstraZeneca – 3,000 people 1 or more AE Most commonly reported



Pfizer – 12,800 people 1 or more AE most commonly reported