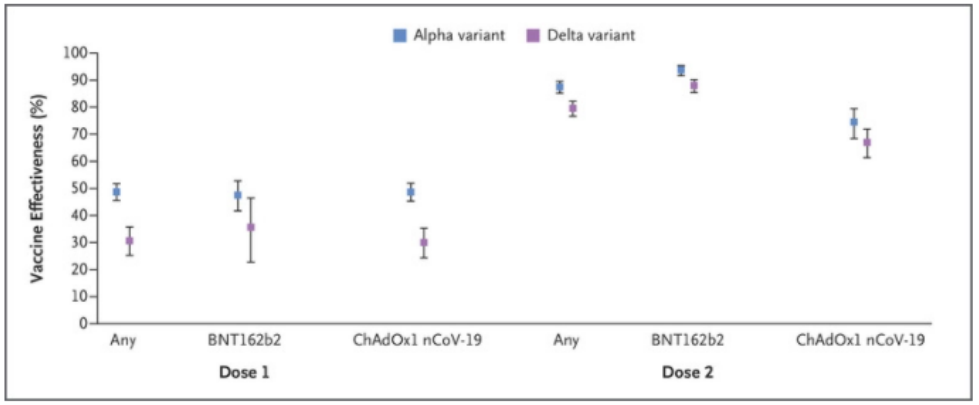
Immunisation AEFI 2021

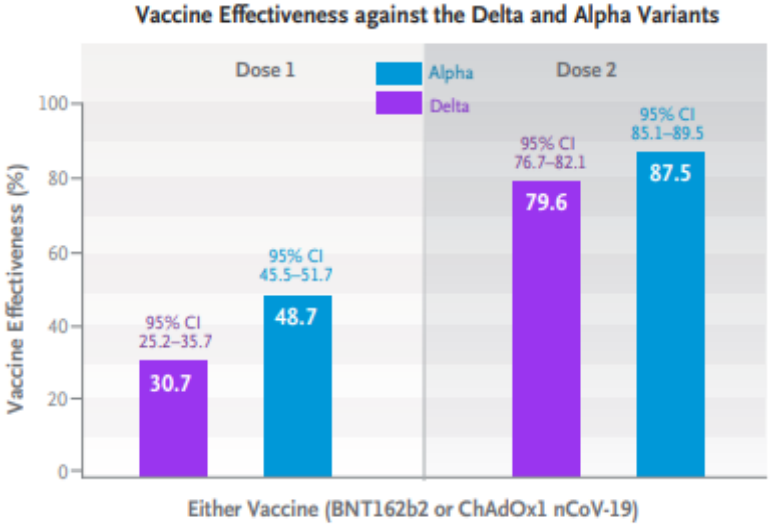
The NEW ENGLAND JOURNAL of MEDICINE

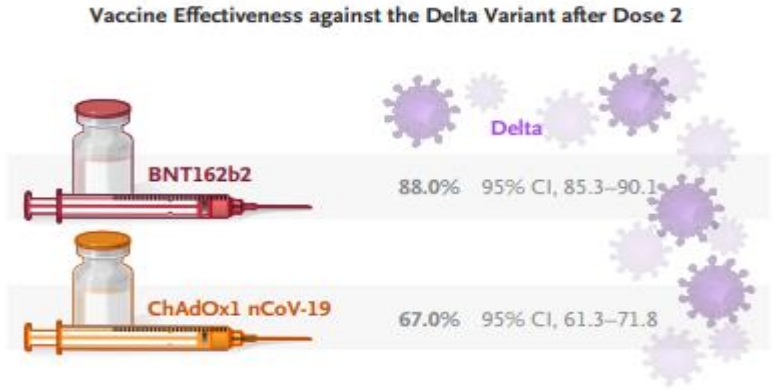
ORIGINAL ARTICLE

Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant



Shown is the effectiveness of one dose and two doses of the BNT162b2 and ChAdOx1 nCoV-19 vaccines, or either vaccine ("any"), against symptomatic disease with the B.1.1.7 (alpha) or B.1.617.2 (delta) variant of the severe acute respiratory syndrome coronavirus 2. I bars indicate 95% confidence intervals.





CONCLUSIONS

Two doses of the BNT162b2 or ChAdOx1 nCoV-19 vaccine were highly effective against the delta variant of SARS-CoV-2, although slightly less so than against the alpha variant.

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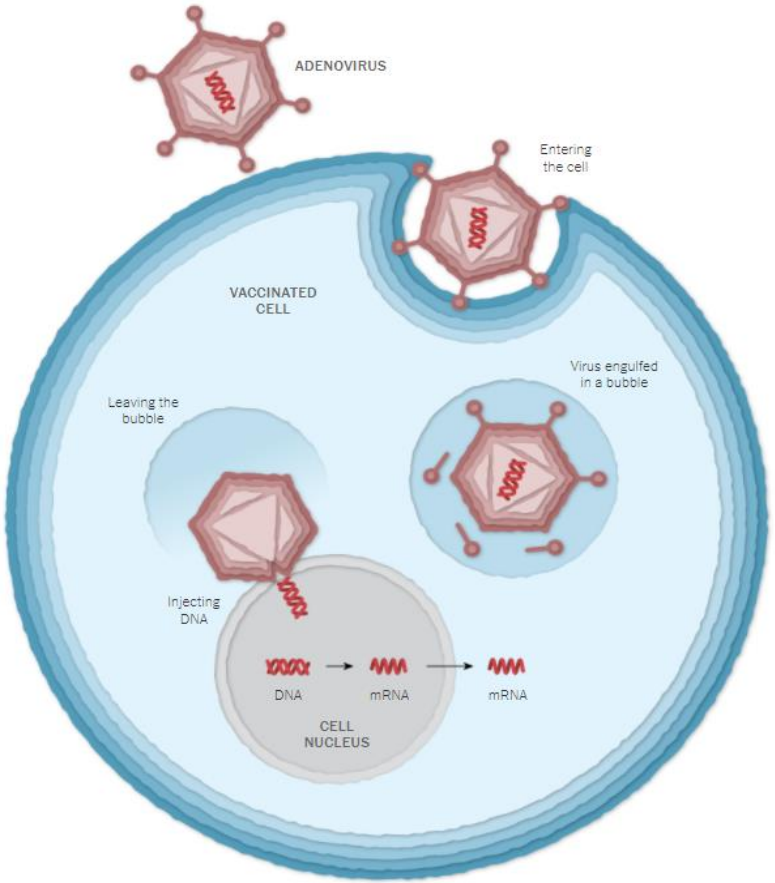
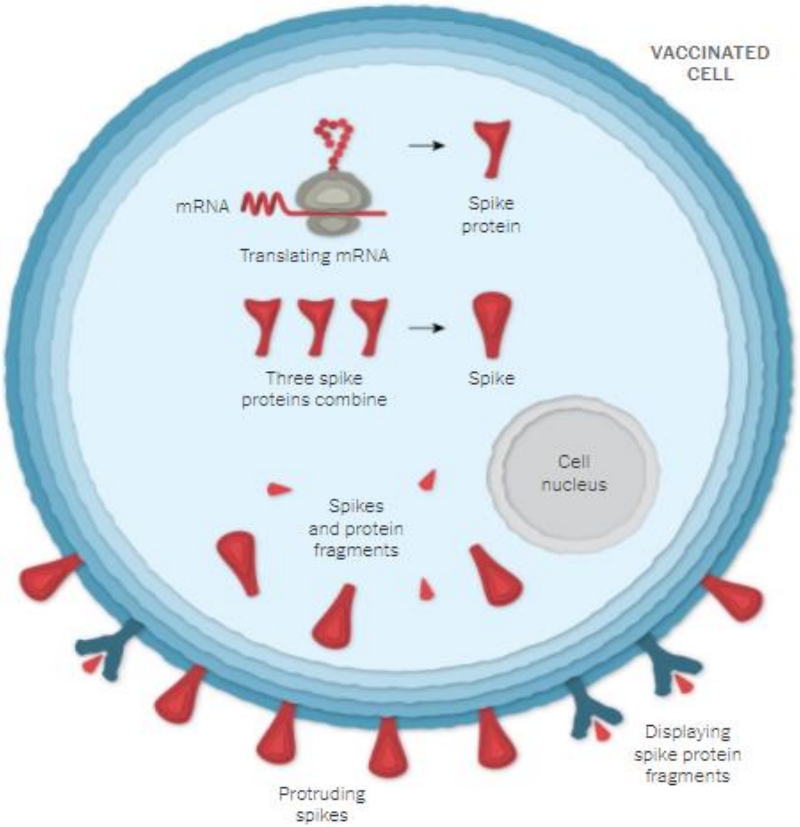
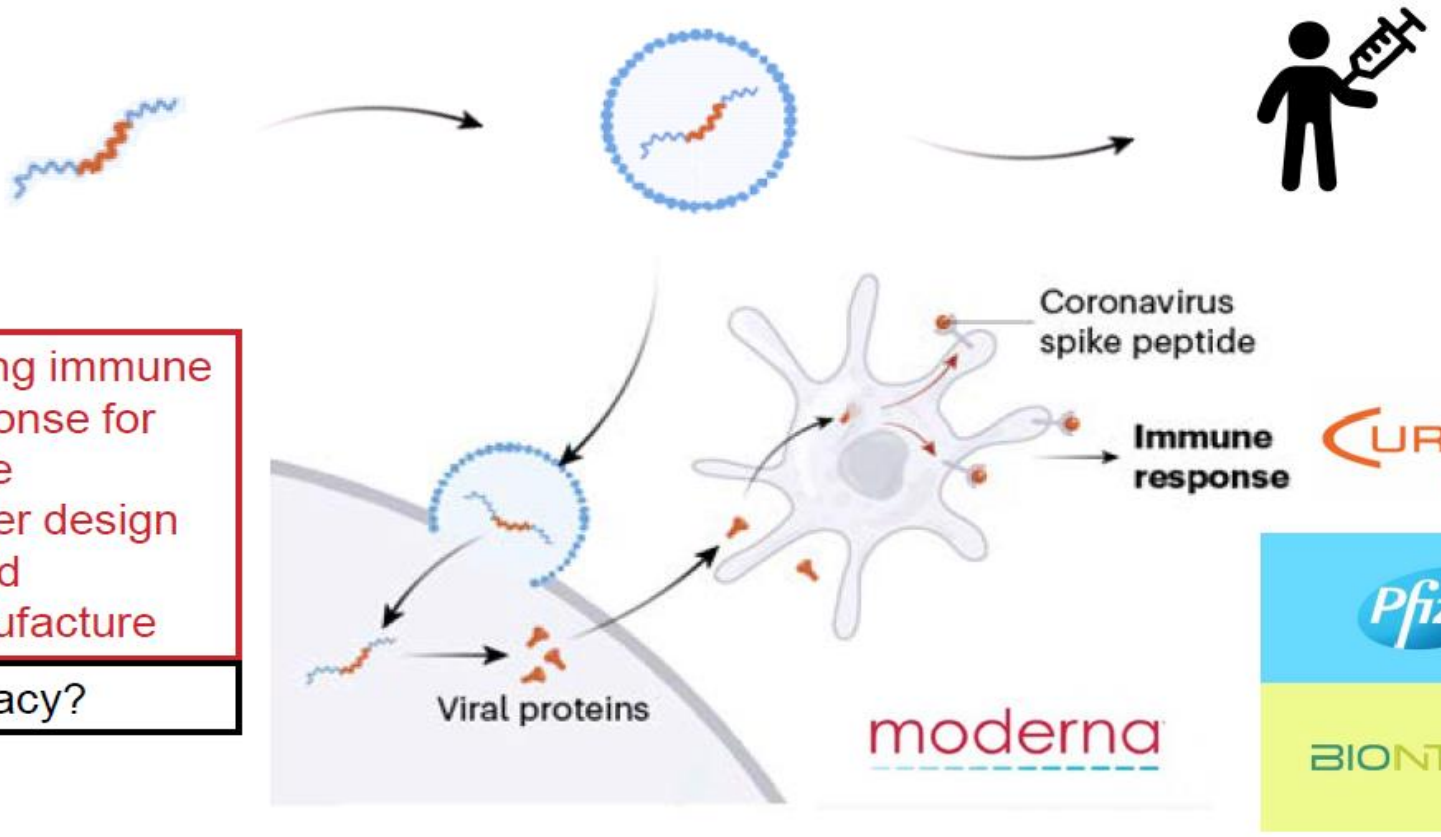
Chimp adenovirus (ChAdOx1 nCoV-19) S protein (now called AZD1222)





mRNA vaccines



Strong immune response for some
Easier design
Rapid manufacture

Efficacy?

Diagram: Callaway, E. (2020). The race for coronavirus vaccines: a graphical guide. *Nature*, https://www.nature.com/articles/d41586-020-01221-y
Image from the Noun Project

What's in the Pfizer jab?

- Nucleoside-modified messenger RNA — **active ingredient**
- ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate) (ALC-0315) — **lipid casing**
- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) — **lipid casing**
- Distearoylphosphatidylcholine (DSPC) — **lipid casing**
- Cholesterol — **lipid casing**
- Potassium chloride — **salt**
- Monobasic potassium phosphate — **salt**
- Sodium chloride — **salt**
- Dibasic sodium phosphate dihydrate — **salt**
- Sucrose — **sugar**
- Water for injections

What's in the AstraZeneca jab?

- Recombinant, replication-deficient chimpanzee adenovirus vector — **active ingredient**
- Histidine — **amino acid**
- Histidine hydrochloride monohydrate — **amino acid salt**
- Sodium chloride — **salt**
- Magnesium chloride hexahydrate — **salt**
- Disodium edetate (EDTA) — **salt**
- Sucrose — **sugar**
- Ethanol absolute — **alcohol**
- Polysorbate 80 — **surfactant**
- Water

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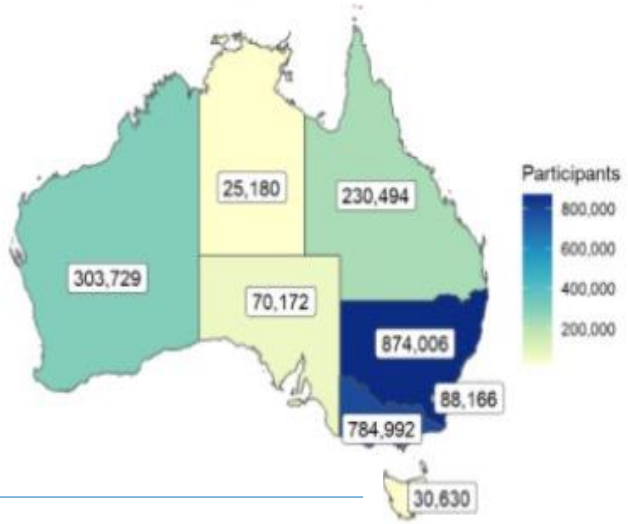
AusVaxSafety
An NCIRS led collaboration

As at 16 August 2021

All people

3,913,283 surveys sent Australia wide*
2,407,369 participants (61.5% response rate)



Aboriginal and Torres Strait Islander people

42,059 surveys sent Australia wide*
29,954 participants (71.2% response rate)

54.3% of participants reported no adverse event

45.7% of participants reported any adverse event

0.9% of participants reported visiting a doctor or emergency department

How does it work?

Day 0
You receive a COVID-19 vaccine at a participating immunisation clinic

Day 3
You will get the 1st survey from your state/territory health department or your immunisation provider

Day 8
You will get the 2nd survey from your state/territory health department or your immunisation provider

6 weeks
after your COVID-19 vaccine you will get the final survey*

*If your vaccine doses are less than 6 weeks apart, you'll only get one final survey after your second vaccine dose.

Vaxtracker
Monitoring Vaccine Safety

SmartVax

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Comirnaty dose 1 & 2

Comirnaty vaccine Dose 1 - All participants

Current as at 16 August 2021

1,007,479 people responded to an SMS/email about their health in the three days after their COVID-19 vaccinations.

62.8%
reported **no** adverse event

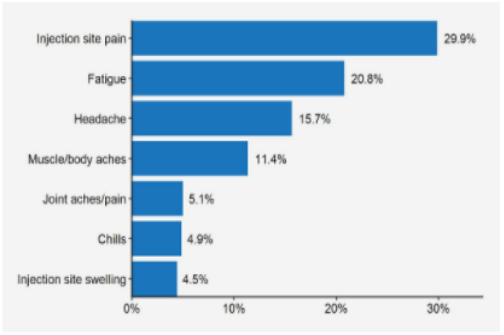
37.2%
reported any adverse event

6.7%
reported missing work, study or routine duties for a short period (<1 day missed by the majority).

0.5%
reported seeing a doctor or going to emergency department in the days after

374,832 people reported one or more adverse events.

The most commonly reported were (% of total participants):



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

Comirnaty vaccine Dose 2 - All participants

Current as at 16 August 2021

770,864 people responded to an SMS/email about their health in the three days after their COVID-19 vaccinations.

43.6%
reported **no** adverse event

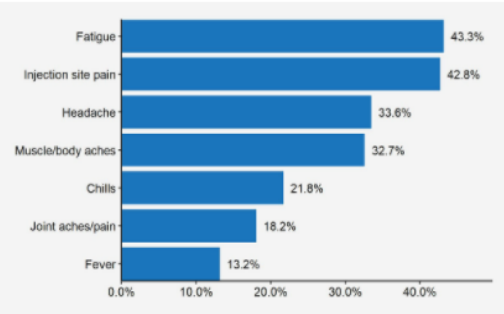
56.4%
reported any adverse event

21.2%
reported missing work, study or routine duties for a short period (<1 day missed by the majority).

1.3%
reported seeing a doctor or going to emergency department in the days after vaccination.

434,988 people reported one or more adverse events.

The most commonly reported were (% of total participants):



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**. Refer to Comirnaty Product Information on the TGA website for further details.

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Astra Zeneca dose 1 & 2

COVID-19 Vaccine AstraZeneca Dose 1 - All participants

Current as at 16 August 2021

429,723 people responded to an SMS/email about their health in the three days after their COVID-19 vaccinations.

44.4%
reported **no** adverse event

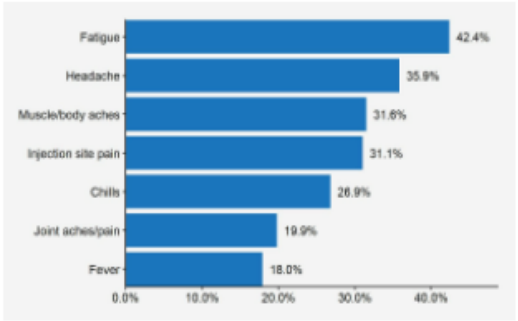
55.6%
reported any adverse event

17.6%
reported missing work, study or routine duties for a short period (<1 day missed by the majority).

1.0%
reported seeing a doctor or going to emergency department in the days after vaccination.

238,715 people reported one or more adverse events.

The most commonly reported were (% of total participants):



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.** Refer to COVID-19 Vaccine AstraZeneca Product Information on the TGA website for further details.

COVID-19 Vaccine AstraZeneca Dose 2 - All participants

Current as at 16 August 2021

199,174 people responded to an SMS/email about their health in the three days after their COVID-19 vaccinations.

73.6%
reported **no** adverse event

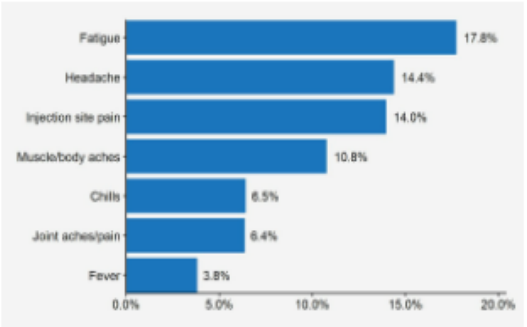
26.4%
reported any adverse event

5.3%
reported missing work, study or routine duties for a short period (<1 day missed by the majority).

0.5%
reported seeing a doctor or going to emergency department in the days after vaccination.

52,489 people reported one or more adverse events.

The most commonly reported were (% of total participants):



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.** Refer to COVID-19 Vaccine AstraZeneca Product Information on the TGA website for further details.

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Report Form

Australian Government
Department of Health
Therapeutic Goods Administration

Office use only
Date report received:
Notification ID:

National Adverse Events Following Immunisation (AEFI) reporting form

Vaccinated person's details	
Personal details	
Surname:	
First name:	
Gender:	☐ Male ☐ Female ☐ Unknown
Date of Birth:	**or**
Age:	Months **or** Years
Street address:	
Suburb:	
State:	
Postcode:	
Name of parent/guardian: (if relevant)	
Phone: Landline (inc. area code) or mobile	

AESI

- Suspected Thrombosis with Thrombocytopaenia Syndrome following AstraZeneca COVID-19 vaccination (within 4-42days following vaccination)
- Death that is unexpected/unexplained within 6 weeks following a vaccination
- Anaphylaxis following COVID-19 vaccination requiring hospital admission
- Suspected Guillain-Barré syndrome or new onset neurological event following COVID-19 vaccination requiring hospital admission
- Suspected vaccine-related myocarditis following COVID-19 vaccination
- Other unexpected, serious events requiring hospitalisation following COVID-19 vaccination

TGA weekly data

Total adverse event reports to 8 August 2021

3.5	48,143	13,723,146
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
30,795	17,034	326
Total reports for AZ vaccine	Total reports for Comirnaty	Total reports for brand not specified

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TGA Weekly Data

Table 1: Newly confirmed and probable TTS cases for the week of 6-12 August 2021‡

New confirmed TTS	New probable TTS
Two new cases: • 22-year-old woman from Victoria • 82-year-old man from Western Australia	Nine new cases: • 61, 77, 84 and 85-year-old women from NSW • Two 73-year-old men from NSW • 60 and 78-year-old men from NSW • 70-year-old man from Victoria

Age	Total cases	CDC classification†		
		Tier 1	Tier 2	Not classified
<30 years	2	1	1	-
30-39	2	2	-	-
40-49	6	6	-	-
50-59	23	11	7	5
60-69	24	9	6	9
70-79	33	9	8	16
80+	14	3	6	5
All ages	**104** **(48 men, 56 women)**	**41**	**28**	**35**

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) **and** a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) **and** a low platelet count **and** anti-PF4 antibodies
- Not classified = case does not meet the criteria for Tier 1 or Tier 2 (for example clots in common locations with **low** platelet count but no evidence of anti-PF4 antibodies).

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TGA TTS

Table 3: Time to onset, treatment and outcomes for TTS cases*

Time to onset/ diagnosis (days)	Median (range)	12 (1-83)
Treated in ICU	At any point	32
	Currently	6
Outcome	Discharged	86
	In hospital	12
	Fatal	6

*Data is based on the most recent medical information available to the TGA

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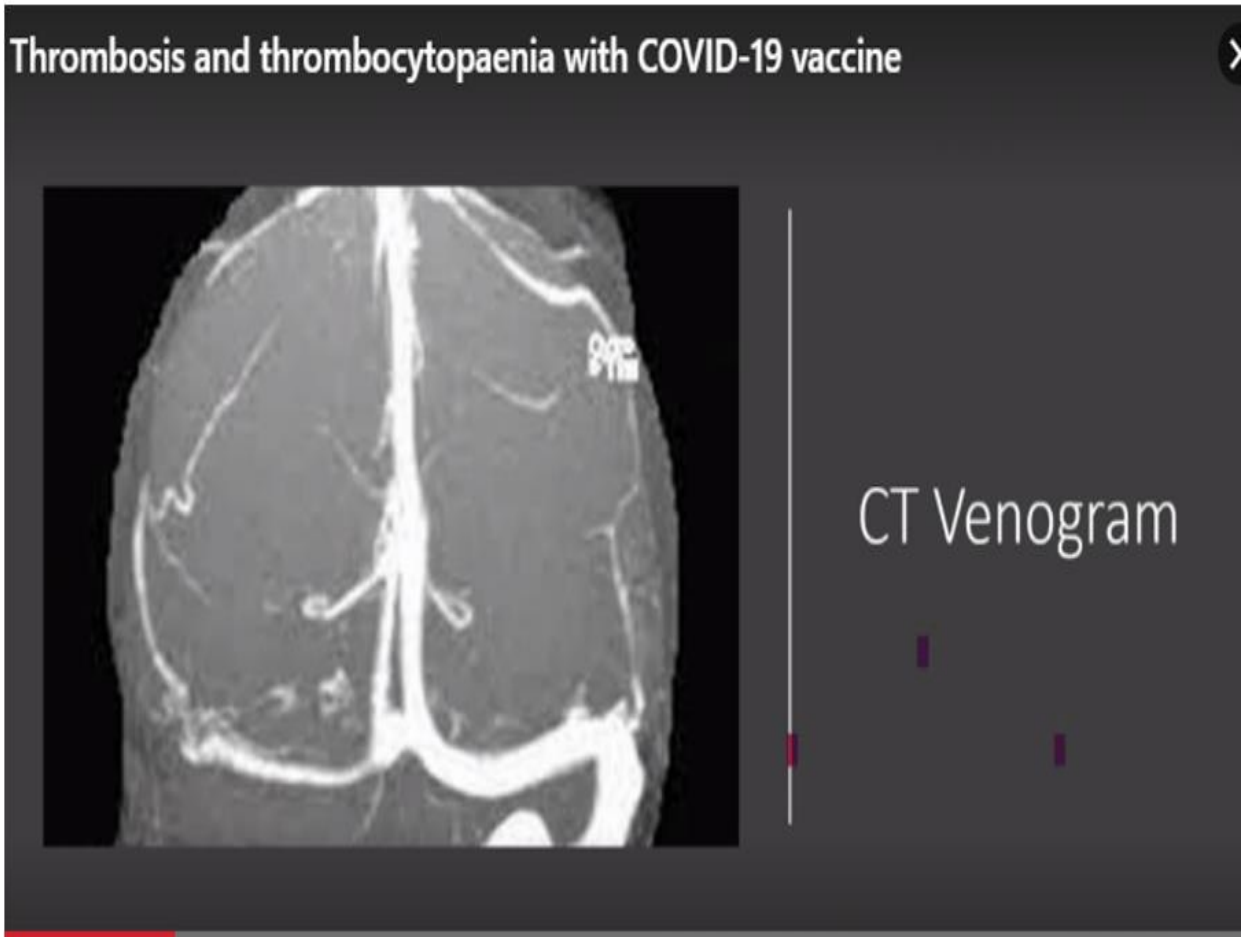
CVST



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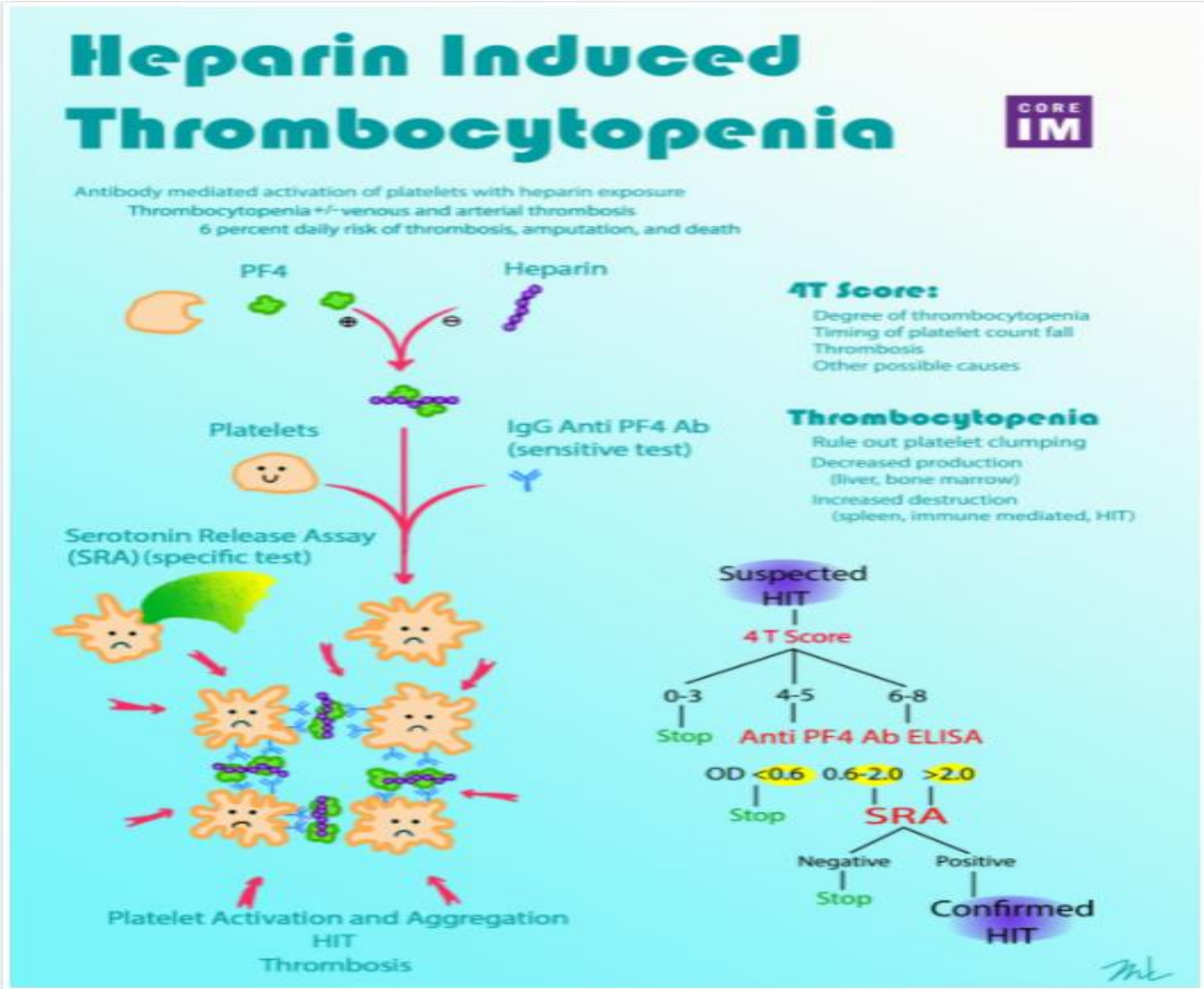


[5 Pearls on Heparin-Induced Thrombocytopenia | Core IM Podcast]

THANZ Multidisciplinary† VITT Guideline for Doctors

Background

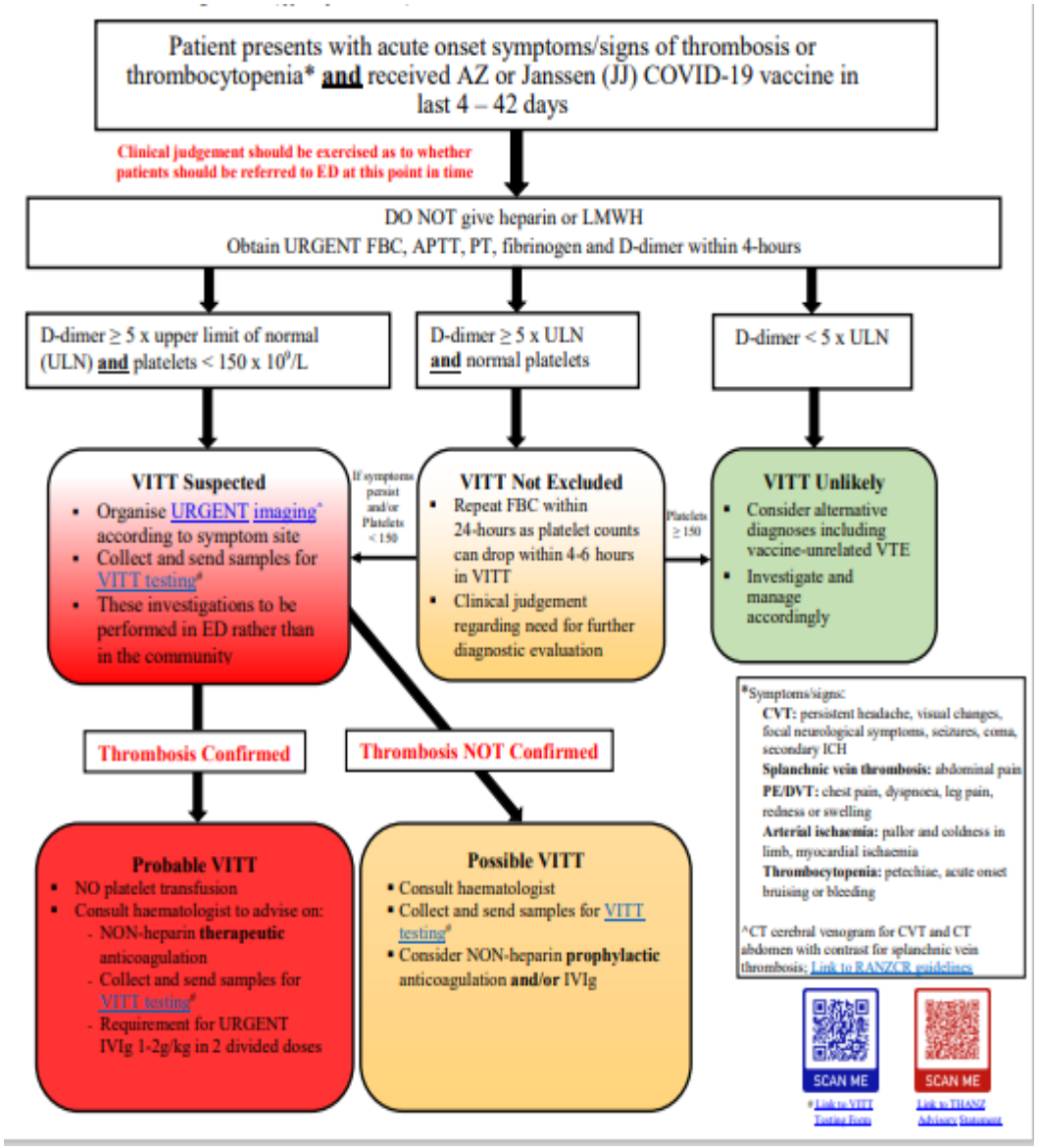
A severe prothrombotic syndrome associated with thrombocytopenia has been described in a small number of patients exposed to the COVID-19 AstraZeneca and Janssen (Johnson & Johnson) vaccines. This syndrome is currently being called several names: VITT (vaccine-induced immune thrombotic thrombocytopenia syndrome), TTS (thrombosis with thrombocytopenia syndrome), and VIPIT (vaccine-induced prothrombotic immunethrombocytopenia). For the purposes of this Thrombosis & Haemostasis society of Australia New Zealand (THANZ) Multidisciplinary guideline, the term VITT will be used. It has been observed in early reported cases that platelet transfusions and administration of heparin may lead to progressive thrombosis.

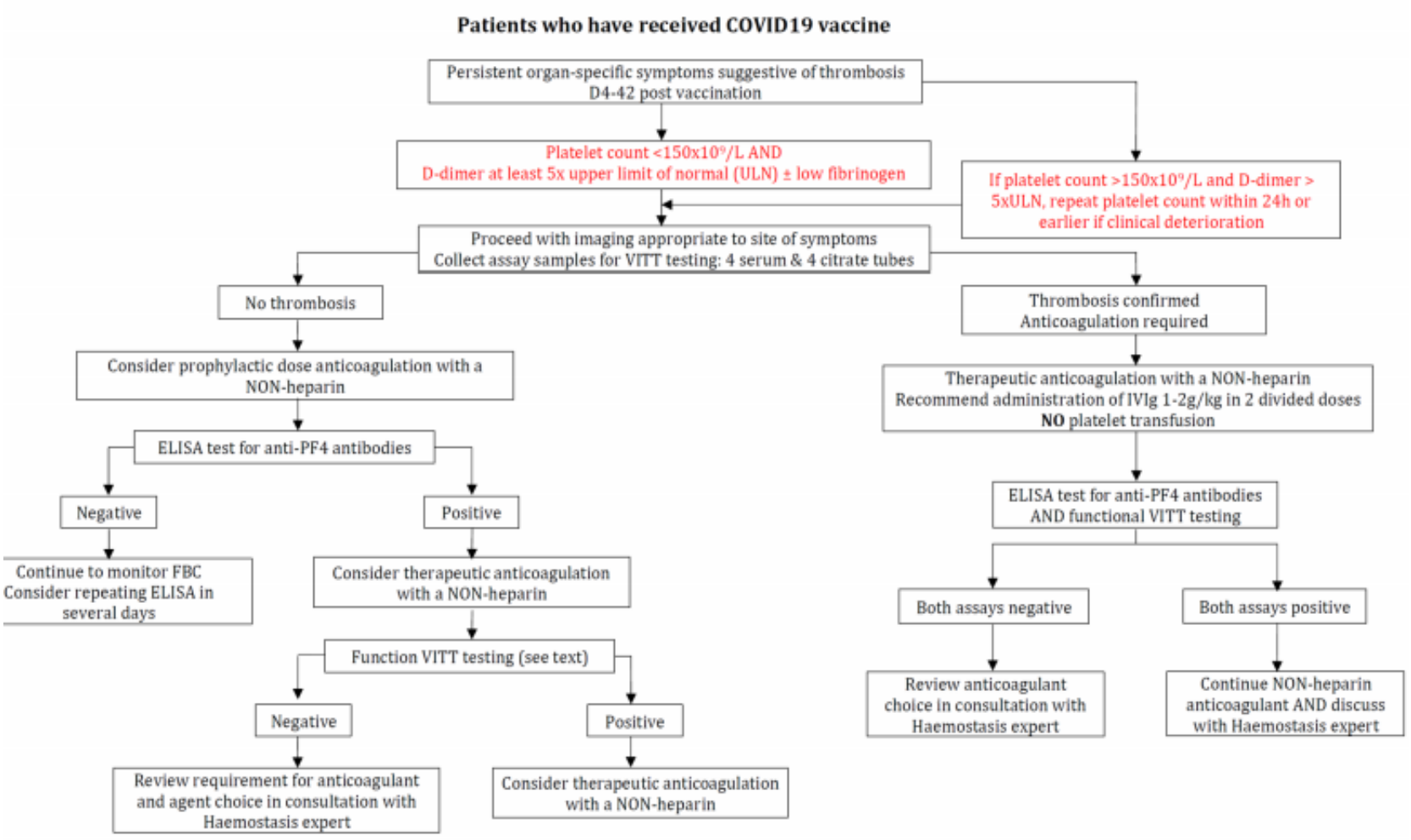
What causes this syndrome?

The exact pathophysiology of the syndrome is still unknown however, the majority of cases are associated with the presence of pathological antibodies against platelet factor 4 (PF4) or PF4/polyanion complexes. These antibodies are only detectable by specific ELISA methods in specialized laboratories.

When should I suspect VITT?

- Onset of symptoms 4 – 42 days after vaccination, AND
- Thrombosis – cerebral venous sinuses, splanchnic vein; DVT/PE or arterial thrombosis; AND
- Thrombocytopenia (<150 x 10^9), AND
- High d-dimer (typically > 5 x ULN)





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COVID-19 VACCINATION

Primary care approach to thrombosis with thrombocytopenia syndrome after COVID-19 AstraZeneca vaccine

Key Points

- Consider thrombosis with thrombocytopenia syndrome (TTS) in anyone presenting with possible thrombosis or thrombocytopenia, 4-42 days after having COVID-19 Vaccine AstraZeneca
- Refer suspected cases immediately to emergency if they are acutely unwell (e.g. neurological deficit)
- Initial investigations are a full blood count and D-dimer, which can be performed in the community if results are reviewed within **6 hours**
- Typical lab findings of TTS are thrombocytopenia (platelets < 150 x 10^9/L) and very high D-dimer (≥ 5 x ULN)

Background

Thrombosis with thrombocytopenia syndrome (TTS) is a serious, rare condition associated with COVID-19 Vaccine AstraZeneca, that can lead to long term disability or death. There is emerging evidence that early detection and management of cases, including referral to hospital can prevent the development of more serious complications.[1]

There is no association between Comirnaty (Pfizer) vaccine and TTS.

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Australian Government

COVID-19 VACCINATION

Patient Information on thrombosis with thrombocytopenia syndrome

30 June 2021 – Version 3.2

What has been updated:

Updated TTS time to onset.

AstraZeneca Vaccine and the COVID-19 vaccination program

The Australian Government receives advice and recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) about the AstraZeneca vaccine.

There has been a link between the AstraZeneca COVID-19 vaccine and a rare condition called thrombosis with thrombocytopenia syndrome (TTS). This condition appears to be more common in younger adults.

Comirnaty is the preferred COVID-19 vaccine for adults under 60 years of age at this time. However, adults under 60 years of age may still choose to receive the AstraZeneca COVID-19 vaccine if they have weighed up the benefits and the risks. Talk to your doctor or immunisation provider to help inform your decision.

All adults are recommended to be vaccinated against COVID-19. The risk of severe illness and death from COVID-19 progressively increases with age in older adults. This means that older adults will have a higher benefit from vaccination.

More information on what this means can be found at **www.health.gov.au/covid19-vaccines**

Medium exposure risk in the Australian context

Scenario 2: Infection rate similar to second wave of COVID-19 in Victoria
(275 infections per 100,000 people in a 16-week period)

For every 100,000 AstraZeneca vaccinations