

COVID-19 Vaccinations & the fight against Delta

**Nepean Blue Mountains PHN with
Associate Professor Nicholas Wood, NCIRS**

19 August 2021

7.00pm – 8.30pm

Acknowledgement of Country

**I would like to acknowledge the
traditional owners of the land in which
we all meet today and to pay my respects to
Aboriginal elders past, present and emerging.**

**I would also like to extend my respect
to all Aboriginal people present today.**

Introductions

Facilitator / Q&A Moderator

- **Dr Michael Crampton**
GP Clinical Lead, Wentworth Healthcare. GP, Myhealth Windsor and Windsor COVID-19 Respiratory Clinic

Key Speaker

- **Associate Professor Nicholas Wood**
Associate Director, Clinical Research and Services, National Centre for Immunisation Research and Surveillance

Introductions

The Panel

- **Kate Tye** - Snr. Mgr. Primary Care Support and Development, Wentworth Healthcare
- **Katie Taylor** - Practice Manager, Myhealth North Richmond
- **Dr Louise McDonnell** - GP, Hazelbrook General Practice. Clinical Lead for HealthPathways and GP Lead at the Hazelbrook Commonwealth Vaccination Centre

Agenda

- **Nepean Blue Mountains Vaccination program update** – *Kate Tye*
- **COVID-19 vaccines update** – *Associate Professor Nicholas Wood*
- **Vaccine program considerations** – *Dr Michael Crampton*
- **A practice perspective**
 - Katie Taylor, Practice Manager
 - Dr Louise McDonnell, General Practitioner
- **Q & A – facilitated questions with the Panel** – *Dr Michael Crampton*
- **Close**

Nepean Blue Mountains COVID-19 Vaccination Roll-Out Update

Kate Tye

Senior Manager Primary Care Support and Development

COVID-19 Vaccination Roll-Out Nepean Blue Mountains Region

Feb	<ul style="list-style-type: none"> • 22/2 Phase 1a commenced with RACF rollout and vaccination of frontline workers
March	<ul style="list-style-type: none"> • 22/3 Phase 1b commenced with week 1 general practice COVID-19 vaccine roll-out - practices commenced in phases across four weeks
April	<ul style="list-style-type: none"> • 8/4 ATAGI announced Pfizer as preferred vaccine over AstraZeneca for adults aged under 50 years of age • 12/4 Week 4 of general practice on-boarding to the COVID-19 vaccination program • 30/4 Residential Aged Care Facility resident vaccination program complete in the NBM region
May	<ul style="list-style-type: none"> • 3/5 GPRCs and State Hubs can commence vaccination of people 50 years and over for AZ vaccine • 3/5 Nepean Vaccination Hub opened to frontline workers and general practice staff • 5/5 Participating general practices had their dose allocation increased • 12/5 Commenced disability supported living accommodation vaccination • 17/5 People 50 years and over eligible for vaccine through general practice • 22/5 Notification to practices with high throughput of an additional increase in AZ dose allocation • 24/5 Nepean Vaccination Hub opened to the public for those under 50 years of age
June	<ul style="list-style-type: none"> • 8/6 All adults over the age of 40 years eligible for the COVID-19 vaccine • 17/6 ATAGI announces Pfizer is the preferred vaccine for those aged 50-59 years of age • 21/6 Week 18 of the general practice roll-out - general practice from EOI 2 commence • 27/6 Stay at Home orders announced for greater Sydney • 28/6 Week 19 of general practice roll-out - additional practices from EOI 2 commence • 30/6 AstraZeneca eligibility extended to anyone over 18 years of age
July	<ul style="list-style-type: none"> • 5/7 Pfizer roll-out commences in selected general practices in the region • 5/7 announcement of mandatory vaccination for Residential Aged Care Facility Workers • 14/7 Lockdown in greater Sydney is extended to 30 July 2021 due to the increasing cases infectious in the community • 22/7 Immunisation Nurse Recruitment Drive commenced - 165 EOIs received • 23/7 ATAGI approves Pfizer vaccine for use in 12-15 year olds • 28/7 Lockdown in greater Sydney extended till 27th August 2021
August	<ul style="list-style-type: none"> • 16/8 NBMLHD Vaccination Hub Caddens opens for AZ vaccine • 23/8 NBMLHD Nepean Vaccination Hub moves to Panthers for Pfizer Vaccine open to people 16-39 years of age



Registered Nurses Needed

for local COVID-19 Vaccination effort

Are you a registered nurse with a day per week or more to spare?

Would you like to support the community response to this pandemic?

More nurses are needed to help with the immunisation effort at GP clinics in the Blue Mountains area.

Your community NEEDS you!

Flexible days and hours. Work close to home.

Visit www.nbmphn.com.au/RNsWanted to express your interest.

NBM Vaccination Program

Primary Care Vaccination Sites - Nepean Blue Mountains Region

Vaccination Type	NBM Region	Penrith LGA	Blue Mountains LGA	Hawkesbury LGA	Lithgow LGA
AstraZeneca	92	52	14	20	6
Pfizer	37	16	8	9	4
Commonwealth Vaccination Centres - AZ & PF	3	1	1	1	0
Pharmacy -AZ	1				1
Total	96	53	15	21	7

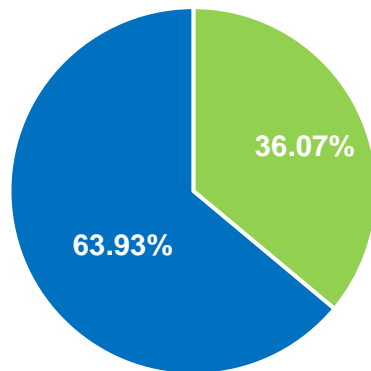
State Vaccination Hubs – Delivered by the Local Health District

Nepean Vaccination Hub – Sommerset St moving to Panthers from Monday 23rd August 2021

Caddens AstraZeneca Hub – Baptist Church Caddens

Nepean Blue Mountains Population

Estimated proportion of doses administered to NBMPHN residents*



- Estimated proportion of total required doses administered
- Estimated proportion of doses still to be administered

304,128 residents estimated over age of 15yrs

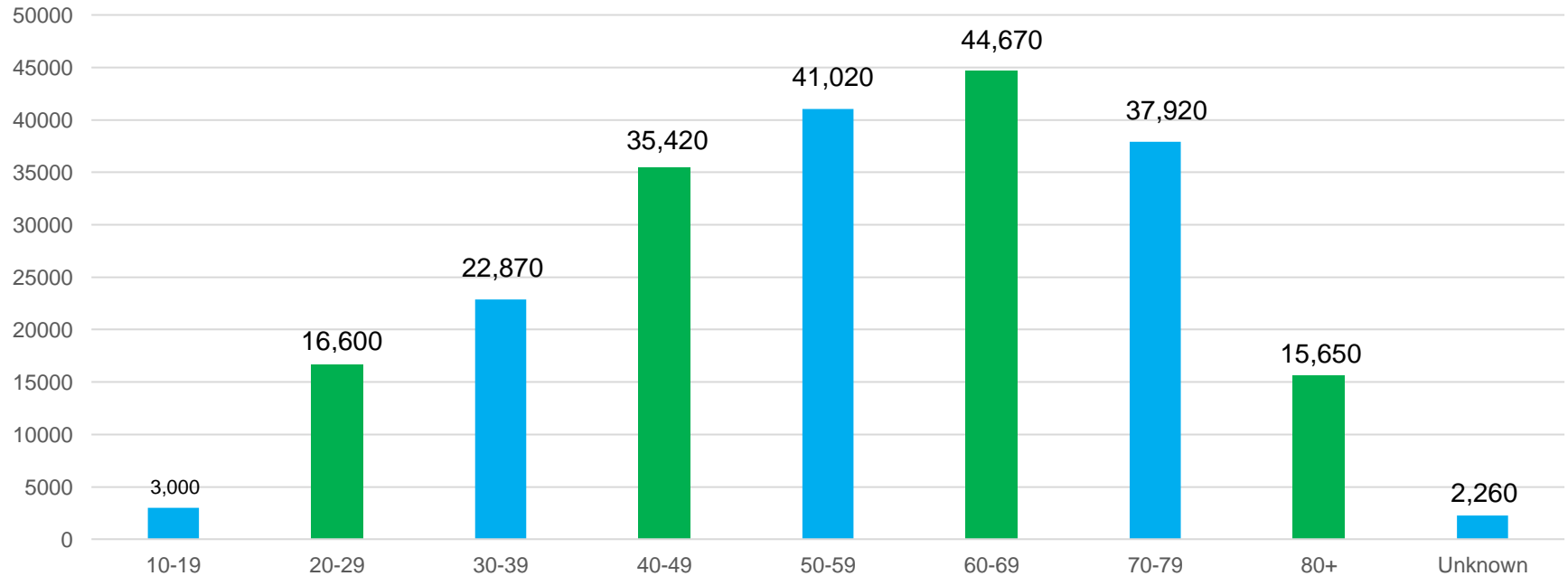
608,256 doses required to fully vaccinate this population

219,410 doses have been delivered to people who reside in NBM region between

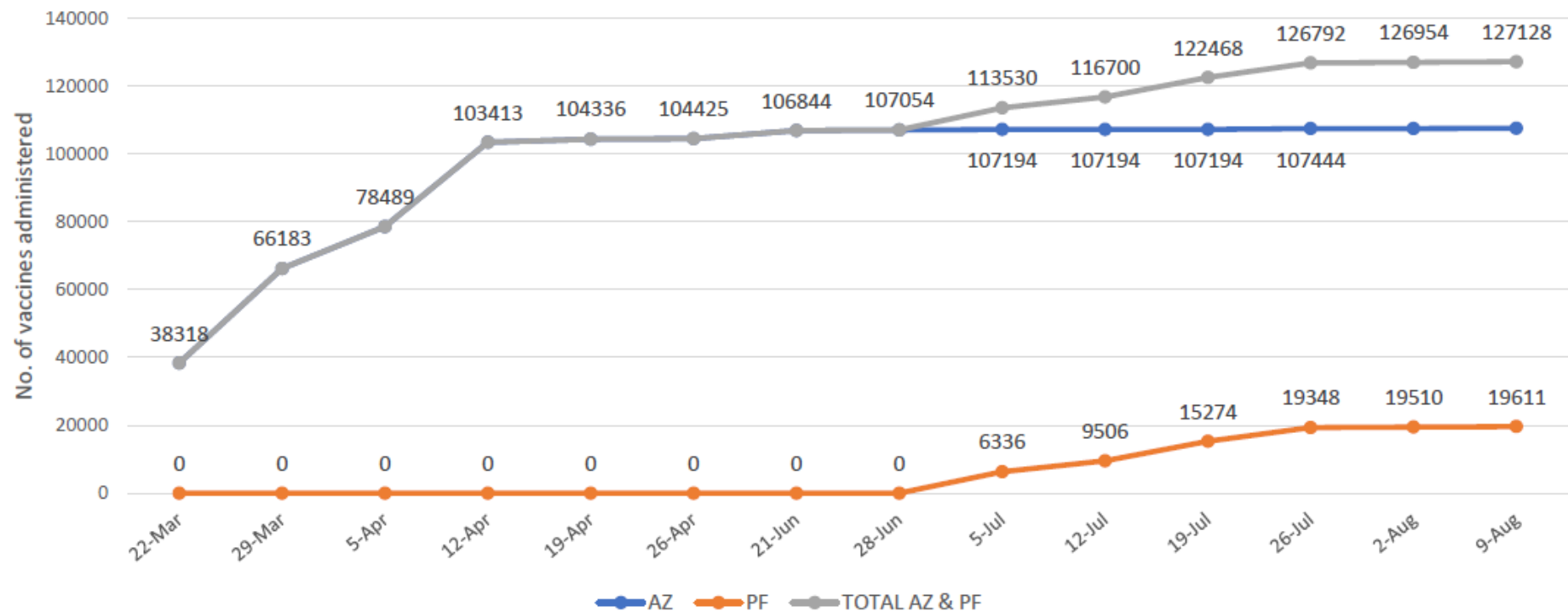
22nd March -15th August

**Please note that this information is based on data obtained from the Australian Immunisation Register (AIR) and should be used as an estimate only and interpreted with caution. AIR data does not distinguish between first and second doses, it includes data from state hubs and may also underestimate administration counts with some data being excluded due to inability to be accurately mapped to a clinic.*

219,400 doses Administered by Age – NBM Region

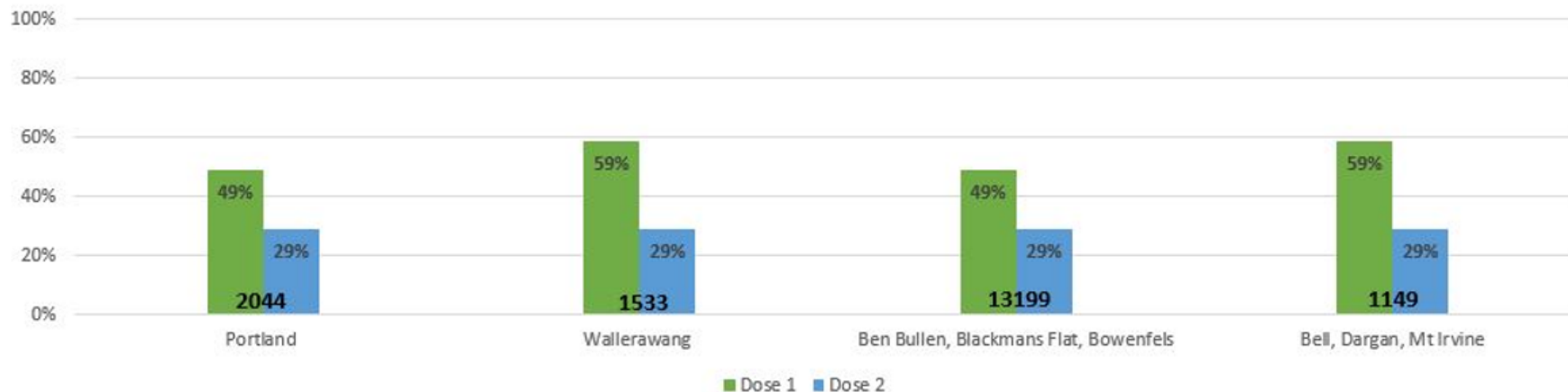


Estimated number of doses administered (cumulative)
NBMPHN, all practices
22 Mar - 9 Aug 2021



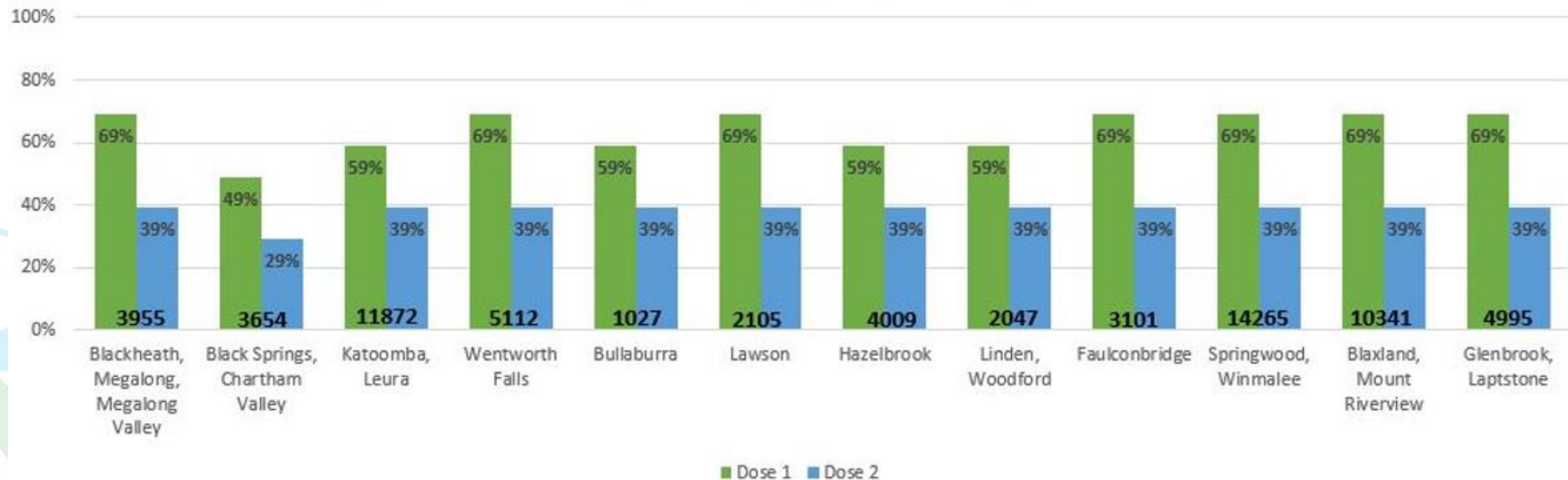
Lithgow LGA – Population Vaccinated by Postcode

% of Population Vaccinated by Suburb (Grouped by Postcode) in Lithgow LGA



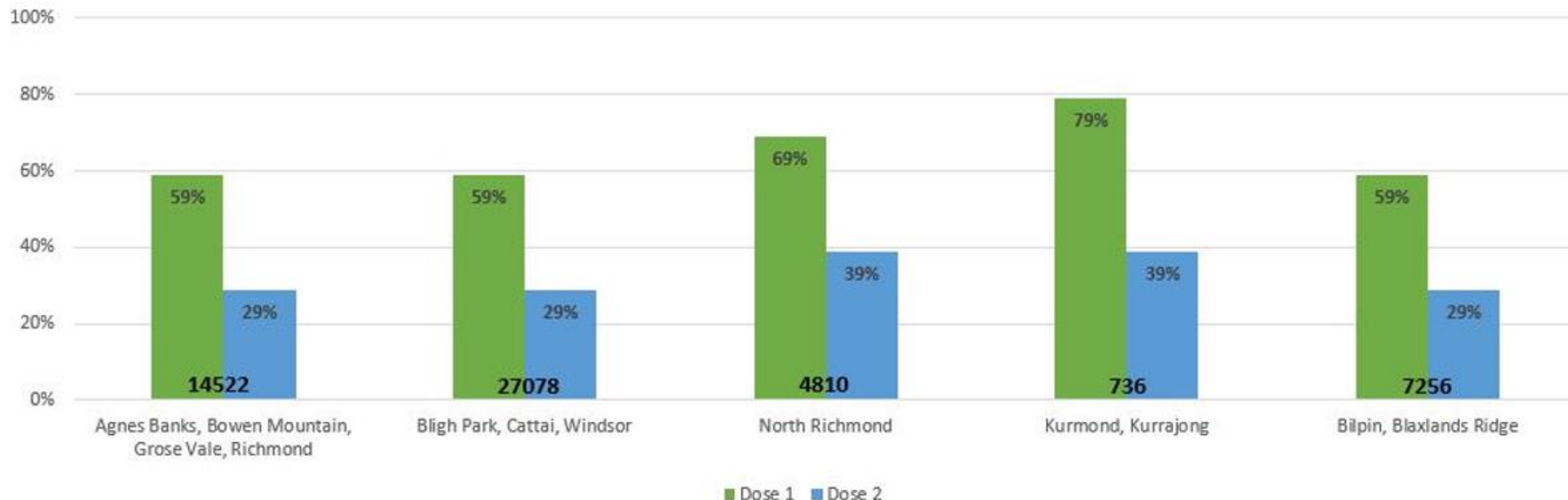
Blue Mountains LGA – Population Vaccinated by Postcode

% of Population Vaccinated by Suburb (Grouped by Postcode) in Blue Mountains LGA



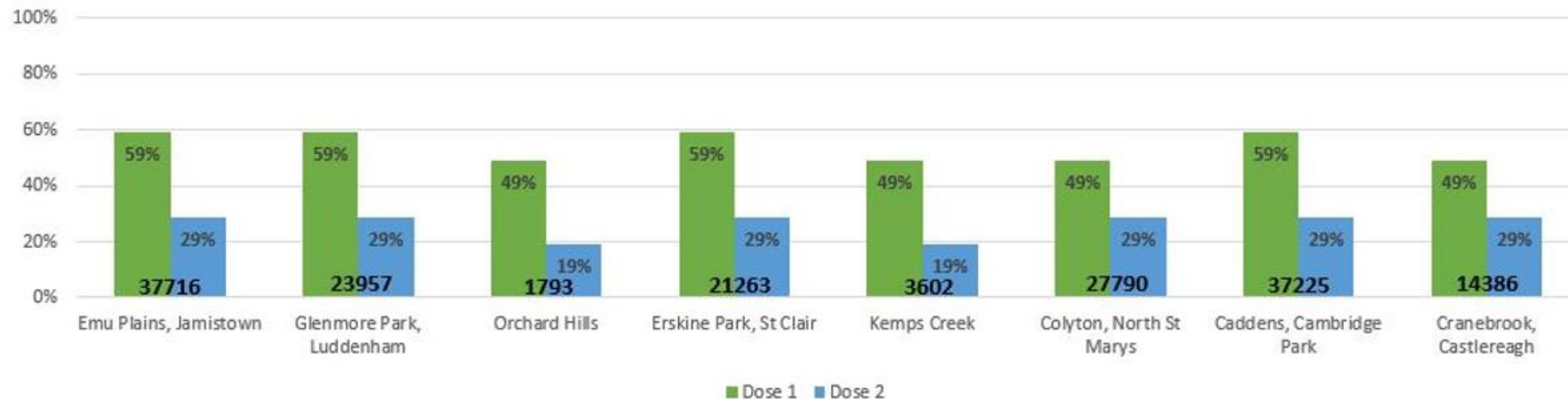
Hawkesbury LGA – Population Vaccinated by Postcode

% of Population Vaccinated by Suburb (Grouped by Postcode) in Hawkesbury LGA



Penrith LGA – Population Vaccinated by Postcode

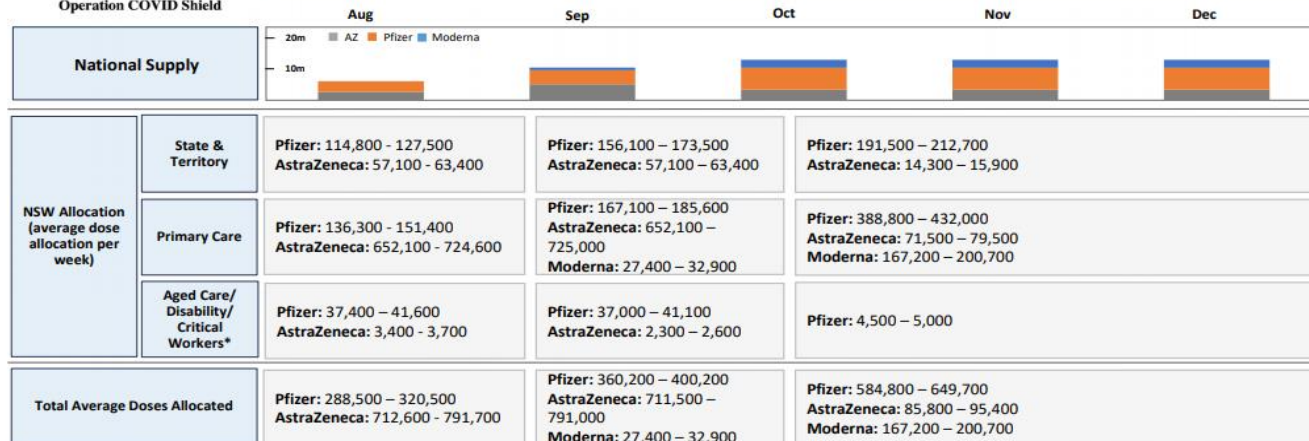
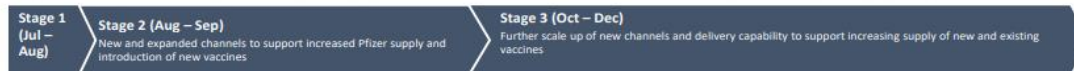
% of Population Vaccinated by Suburb (Grouped by Postcode) in Penrith LGA



New South Wales – Allocation Summary by Stage



Australian Government
Operation COVID Shield



*As defined by the Australian Technical Advisory Group on Immunisation.



Additional Considerations

- August allocations reflects actual doses allocated
- Average banded allocations provided have been provided to support forward planning and **are subject to change**
- Confirmed allocations will be provided **4 weeks in advance**, once supply has been confirmed with vaccine manufacturers
- Given the size of the Australian population over 60, it is assumed that demand for AZ doses will reduce in Stage 2 and be met by Stage 3. However, AZ doses will be available if demand continues through Stages 2 & 3, also taking into consideration that AstraZeneca can be administered to the <60 cohort where medical advice is sought
- Novavax will be included once indicative supply schedules have been provided.

Where to from here?

- Commencing the 16th September additional general practices will receive the Pfizer vaccine onboarded across three weeks
- General practices will then be delivering both AZ and Pfizer vaccine
- Working closely with practices to assist them to plan how they will deliver the two vaccines
- 165 RN – Nurse Immunisers have expressed interest to undertake casual shifts at a practice – contact our workforce team
- Additional pharmacies will commence over the coming weeks



Associate Professor Nicholas Wood

**Associate Director, Clinical Research
and Services**

**National Centre for Immunisation
Research and Surveillance**



NBMPHN

Update COVID-19 vaccines

A/Professor Nicholas Wood





- NSW Ministry of Health and AEFI reporting
- Latest information on the use of AstraZeneca vaccine
- Infectivity of Delta variant
- Vaccine safety
 - TTS
 - ITP after AstraZeneca vaccine
- Mixed schedules and Booster doses
- Vaccination in children



- Reports coming in from GP, Specialist, Public
- Processed by MoH team
- Expert panel process
 - Ad hoc serious AESI case review
 - Weekly meeting with haematology experts
 - 3 weekly meeting with cardiology experts
 - 3 weekly meeting with neurology experts
 - Fortnighly meeting with allergy experts
- NSWISS able to provide advice
 - EMAIL: schn-nswiss@health.nsw.gov.au

What should you tell your patients about the AZ vaccine?

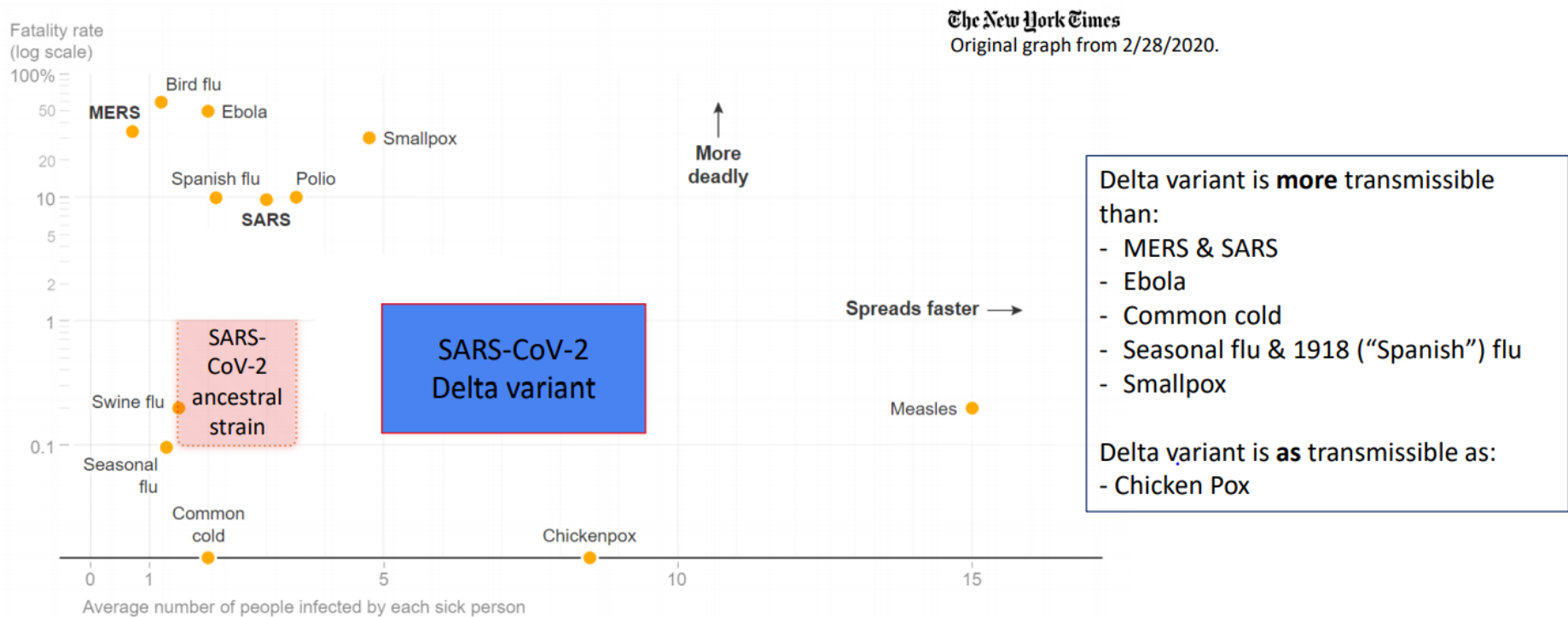


- Explain efficacy
 - Risk of infection
 - Need 2 doses
- Explain safety
 - AusVaxSafety www.ausvaxsafety.org.au
 - TTS risk – noting lack of data in under 40yr olds
- How to monitor for symptoms that might be related to an adverse event including TTS
- What action should be taken by individuals in the event of such symptoms arising

Australia's active vaccine safety system



Transmission of Delta variant vs. ancestral strain and other infectious diseases



Note: Average case-fatality rates and transmission numbers are shown. Estimates of case-fatality rates can vary, and numbers for the new coronavirus are preliminary estimates.

Vaccine efficacy against Delta

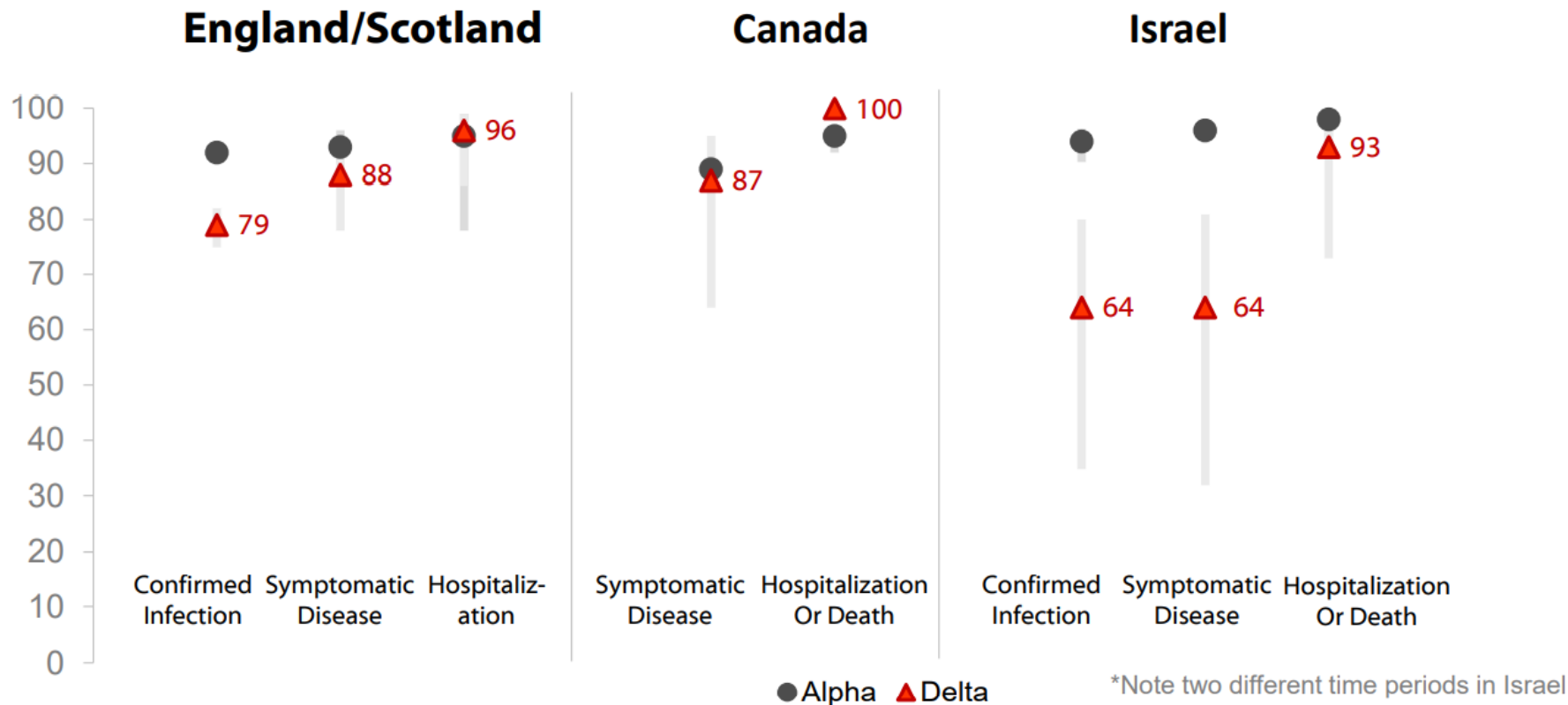


Vaccine Efficacy/Effectiveness against Delta VOC

VACCINE	LAB STUDIES	VACCINE EFFICACY/EFFECTIVENESS	
		ANY INFECTION*	HOSPITALISATION AND DEATH*
AstraZeneca	✓	Effectiveness: Single dose 33-67% ^{49,50} 2 doses: 60% ^{50,51}	Effectiveness: Single dose: 71-88% ^{49,52} 2 doses: 92% ⁵²
Johnson & Johnson	✓	-	-
Moderna	✓	Effectiveness: Single dose: 72% ⁴⁹	Effectiveness: Single dose: 96% ⁴⁹
Pfizer/BioNTech	✓	Effectiveness: Single dose: 33-56% ^{49,50} 2 doses: 79-88% ⁴⁹⁻⁵¹	Effectiveness: Single dose: 78-94% ^{49,52} 2 doses: 96% ⁵²
Bharat Biotech	✓	Efficacy: 65.2% ²⁶	-

*This table provides a summary; details are available in the Vaccine Efficacy/Effectiveness Against Variants table on Page 7

Pfizer 2-Dose Vaccine Effectiveness for Alpha vs. Delta



Sheikh et al. Lancet (2021): [https://doi.org/10.1016/S0140-6736\(21\)01358-1](https://doi.org/10.1016/S0140-6736(21)01358-1); Lopez Bernal et al. medRxiv preprint; <https://doi.org/10.1101/2021.05.22.21257658>; Stowe et al. PHE preprint: https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZIEig/view/479607266; Nasreen et al. medRxiv preprint: <https://doi.org/10.1101/2021.06.28.21259420>; <https://www.gov.il/en/departments/news/06072021-04>



How many people in hospital with COVID-19 are vaccinated?

Of the 538 people hospitalised as a result of COVID-19 in the current outbreak, 95 (18%) people were in ICU. Of the people in ICU 87 (91.6%) were unvaccinated and 8 (8.4%) were partially vaccinated or had a single dose within 14 days. There have been no fully vaccinated cases in ICU.

Table 9. Hospitalisations and ICU admissions due to COVID-19, by vaccination status, NSW, from 16 June to 31 July 2021

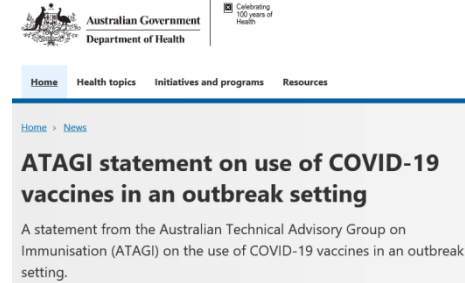
Vaccination status	Hospitalised (%)	Hospitalised and in ICU (%)
Fully Vaccinated	9 (1.7%)	0 (0.0%)
Partially Vaccinated	46 (8.6 %)	8 (8.4%)
None	475 (88.3%)	87 (91.6%)
Unknown/Missing	8 (1.5%)	0 (0.0%)
Total	538 (100.0%)	95 (100.0%)

Interpretation: Of the 538 people hospitalised, 9 (1.7%) were fully vaccinated, 46 (8.6%) were partially vaccinated and 475 (88.3%) were not vaccinated.

Has advice changed now with outbreaks?



- Patients are now advised:
 - If 60 years of age or older and unvaccinated book an appointment for COVID-19 vaccine now
 - If first dose of AstraZeneca has been received, second dose can be given 6-8 weeks after dose 1 (previously 12 week interval between dose 1 and 2)
 - For those aged 40-59 years and not yet been vaccinated and are unable to obtain an appointment for the Cominarty (Pfizer) vaccine, encouraged to speak to GP about AstraZeneca risks and likely benefits
 - Anyone aged 18-39 years wishing to get the AstraZeneca vaccine, is encouraged to talk to their GP



<https://www.nsw.gov.au/covid-19/health-and-wellbeing/covid-19-vaccination-nsw/about-vaccine-rollout>

Risk of TTS



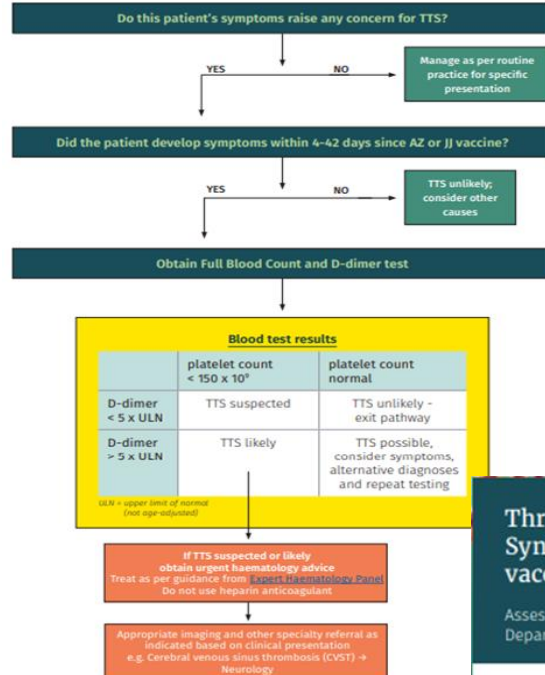
Age bracket (years)	Estimated rate (per 100,000 AZ vaccinations)
<50	3.4
50-59	2.4
60-69	1.5
70-79	2.0
≥80	1.6

(Keep in mind, the risk estimates in the under-50s are based on a much smaller number of people who received the AstraZeneca vaccine compared to those over 50.)

TTS after AstraZeneca



Guideline for Suspected TTS in the Emergency Department



People should seek immediate medical attention if they develop any of the following symptoms after vaccination:

- severe or persistent headache, blurred vision, confusion or seizures
- shortness of breath, chest pain, leg swelling or persistent abdominal pain
- unusual skin bruising and/or pinpoint round spots beyond the site of vaccination.

The most common time period for onset of TTS symptoms is 4–30 days after vaccination.

Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination

Assessment of patients presenting to the Emergency Department with TTS symptoms

June 2021 v2.0



Home Health topics Initiatives and programs Resources

Home > News

Joint statement from ATAGI and THANZ on Thrombosis with Thrombocytopenia Syndrome (TTS) and the use of COVID-19 Vaccine AstraZeneca

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

cytopenia (platelets < 150 x 10⁹/L) and very high D-dimer (TTS) is a serious, rare condition associated with lead to long term disability or death. There is a management of cases, including referral to hospital and complications.¹

by (Pfizer) vaccine and TTS.



Immune thrombocytopenia (ITP)

- The TGA is closely monitoring reports of ITP and investigating whether there may be a link with the AstraZeneca vaccine. This is in light of cases reported to the TGA and a recent Scottish study suggesting a small increase in the risk of ITP (1 in 100,000 vaccinated people).
- **TGA has received** To 8 August 2021, the TGA has received 46 reports of suspected ITP following vaccination..

<https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-12-08-2021>

ARTICLES

<https://doi.org/10.1038/s41591-021-01408-4>

Check for updates

OPEN

First-dose ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic and hemorrhagic events in Scotland

C. R. Simpson^{1,2}, T. Shi², E. Vasileiou², S. V. Katikireddi³, S. Kerr², E. Moore⁴, C. McCowan⁵, U. Agrawal⁶, S. A. Shah², L. D. Ritchie⁶, J. Murray⁴, J. Pan⁷, D. T. Bradley^{8,9}, S. J. Stock², R. Wood^{2,4}, A. Chuter¹⁰, J. Beggs¹⁰, H. R. Staggs², M. Joy¹¹, R. S. M. Tsang¹¹, S. de Lusignan¹¹, R. Hobbs¹¹, R. A. Lyons¹², F. Torabi¹², S. Redden¹², M. O'Leary¹², A. Akhbari¹², J. McMennamin⁴, C. Robertson^{4,7} and A. Sheikh^{2,10}

Other TGA reports post AstraZeneca vaccine



- Reports of suspected GBS
 - GBS is currently being accessed by the Pharmacovigilance Risk Assessment Committee in Europe
 - TGA will report on this investigation when more information is available
- Capillary Leak syndrome- cases have been reported following immunisation with the AstraZeneca Vaccine overseas



**Statement of the WHO
Global Advisory
Committee on Vaccine
Safety (GACVS) COVID-19
subcommittee on reports
of Guillain-Barré
Syndrome (GBS)
following adenovirus
vector COVID-19 vaccines**

<https://www.tga.gov.au/resource/covid-19-vaccine-safety-monitoring-plan>





- All adults in greater Sydney should strongly consider the benefits of earlier protection with COVID-19 Vaccine AstraZeneca rather than waiting for alternative vaccines
- Astra Zencea - recommend a shorter interval of 6-8 weeks between doses in an outbreak (versus the routine 12 week interval)
- Spacing Comirnaty (Pfizer) to a routine interval of 6 weeks would allow limited vaccine supplies to be redirected to obtain first dose protection in outbreak areas of greatest need.
- **BASICALLY = get at least one dose as soon as you can**



- Combined or mixed COVID-19 vaccine schedules are currently not routinely recommended in Australia (except for where AEFI after dose 1).
- More information relating to safety and efficacy, as well as information on appropriate intervals between doses is required.
- Several European countries are giving Pfizer or Moderna as second doses to AstraZeneca recipients
- ATAGI Advice on “vaccine switch” – in special circumstances just released



ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances

Medical contraindication or serious adverse event



The medical contraindications to the administration of a COVID-19 vaccine in the [ATAGI Clinical Guidance on COVID-19 vaccine in Australia in 2021](#) are:

- anaphylaxis after a previous dose of the same vaccine
- anaphylaxis to any component of the vaccine, including:
 - polyethylene glycol (PEG) for Comirnaty
 - polysorbate 80 for COVID-19 Vaccine AstraZeneca
- thrombosis with thrombocytopenia syndrome (TTS) occurring after the first dose of COVID-19 Vaccine AstraZeneca
- past experience of capillary leak syndrome (contraindication to vaccination with COVID-19 Vaccine AstraZeneca)
- any other serious adverse event attributed to the first dose of a COVID-19 vaccine (and without another cause identified) following expert review (typically by a jurisdictional immunisation specialist service or a relevant medical specialist)*, including:
 - Myocarditis following an mRNA vaccine*.
 - Immune thrombocytopenia (ITP) following dose 1 of any COVID-19 vaccine*.

*Consultation with a specialist is required to assess for potential vaccine-induced adverse events and to inform future vaccination options. Suitable specialists include immunologists or immunisation specialist services.

Precautionary conditions for dose 2



- If a person has had dose 1 of Astra Zeneca and has the following
 - History of Heparin induced thrombocytopenia
 - History of CVST
 - History of idiopathic splanchnic vein thrombosis
 - History of antiphospholipid syndrome with thrombosis
- Then move to Pfizer for dose 2 to complete the primary course

AstraZeneca Vaccine medical contraindication



The patient noted above has a history of the following medical condition/s and it is recommended they receive the Pfizer (COMIRNATY™) COVID-19 vaccine according to current ATAGI advice.

- ☐ Cerebral venous sinus thrombosis (CVST)
- ☐ Heparin-induced thrombocytopenia (HIT)
- ☐ Idiopathic splanchnic (mesenteric, portal, splenic) vein thrombosis
- ☐ Antiphospholipid syndrome (APLS) with thrombosis and/or miscarriage
- ☐ Capillary leak syndrome
- ☐ Anaphylaxis, thrombosis with thrombocytopenia syndrome (TTS) or other serious adverse event attributed to the first dose of the AstraZeneca COVID-19 vaccine
- ☐ History of anaphylaxis to a component of the AstraZeneca COVID-19 vaccine

Medical
Practitioner
signature

Print and Sign

Medical Practitioner
name

Date:

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number

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**RECOMMENDATION TO RECEIVE THE PFIZER
(COMIRNATY™) COVID-19 VACCINE**



Process for requesting an alternative COVID-19 vaccine



People with a medical contraindication to the AstraZeneca COVID-19 vaccine need to discuss their medical condition with a general practitioner (GP) or treating specialist. If an alternative vaccine is recommended, the individual can book an appointment via one of the following options:

1. A GP who administers the Pfizer COVID-19 vaccine (COMIRNATY™):

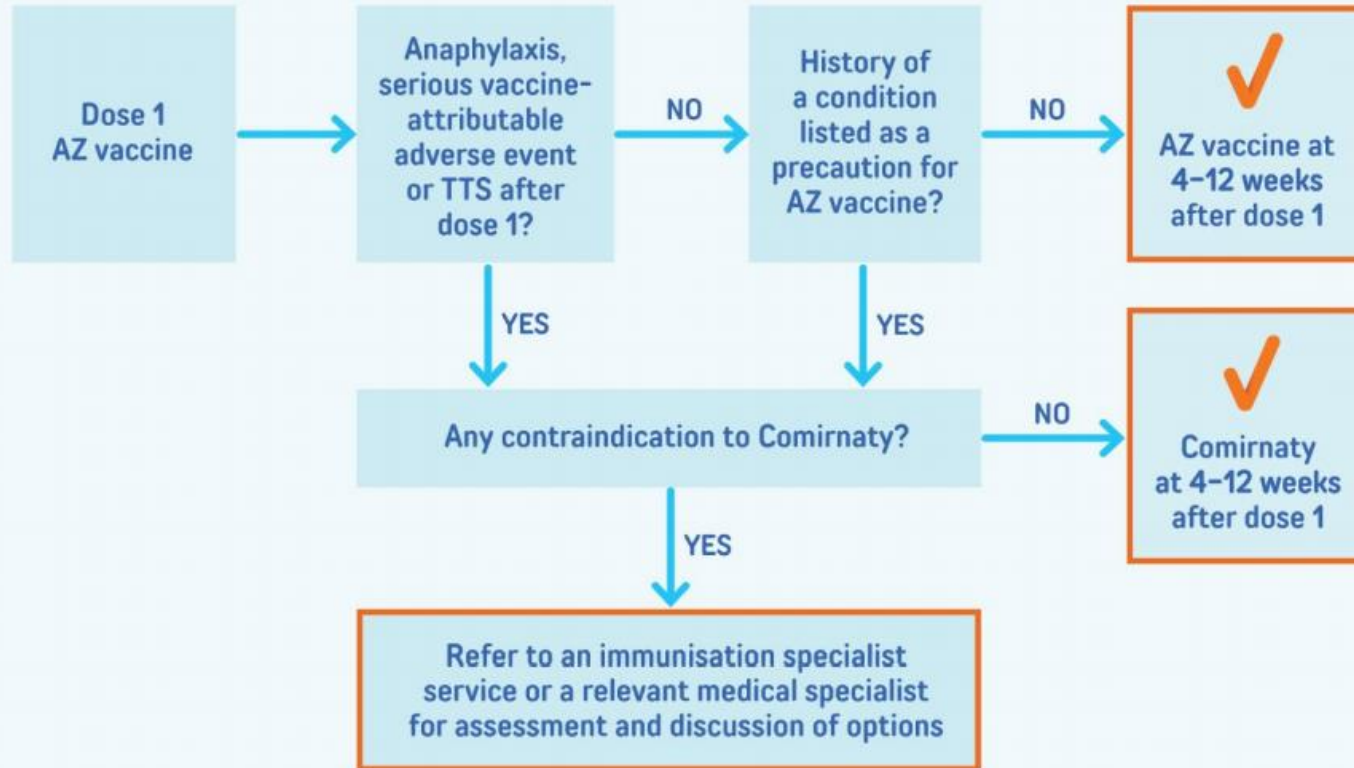
- People will be able to access and book an appointment with a GP who can administer the Pfizer COVID-19 vaccine (COMIRNATY™). A list of GPs with Pfizer COVID-19 vaccine (COMIRNATY™) is available via [HotDoc](#).

or

2. A NSW Health vaccination clinic

- GPs/treating specialists will be required to:
 - Complete a '[Recommendation for Alternate Vaccination](#)' form and provide this to the patient. The form is to be completed to align with the medical contraindications identified by ATAGI
 - Make a direct referral to a NSW Health vaccination clinic via the relevant email contact located on [COVID-19 HealthPathways](#)
 - Email the patient's name, contact number, email address and residential address to the NSW Health Clinic contact and they will arrange an appointment directly with the patient.
- GPs are advised the NSW Health vaccination clinic will assess the request for vaccination. A referral does not guarantee an appointment or priority appointment
- LHD/SHNs are to establish local processes to manage the GP requests for alternative vaccinations.

First dose of COVID-19 Vaccine AstraZeneca received in Australia or overseas



Safety of Astra Zeneca and Pfizer mixed vaccine schedule



Side effect	Frequency of side effect after dose 1 AZ/dose 2 AZ ⁶	Frequency of side effect after dose 1 AZ/dose 2 Pfizer ⁶
Injection site pain	47%	77%
Fever	0%	6%
Myalgia	19%	59%
Malaise	17%	54%
Headache	32%	65%
Fatigue	50%	77%

There are no data on comparative protective efficacy or effectiveness between homologous and heterologous COVID-19 vaccine schedules.

[COVID-19 vaccination – Clinical advice on the use of a different COVID-19 vaccine as the second dose \(health.gov.au\)](#)

Pfizer COVID-19 vaccine

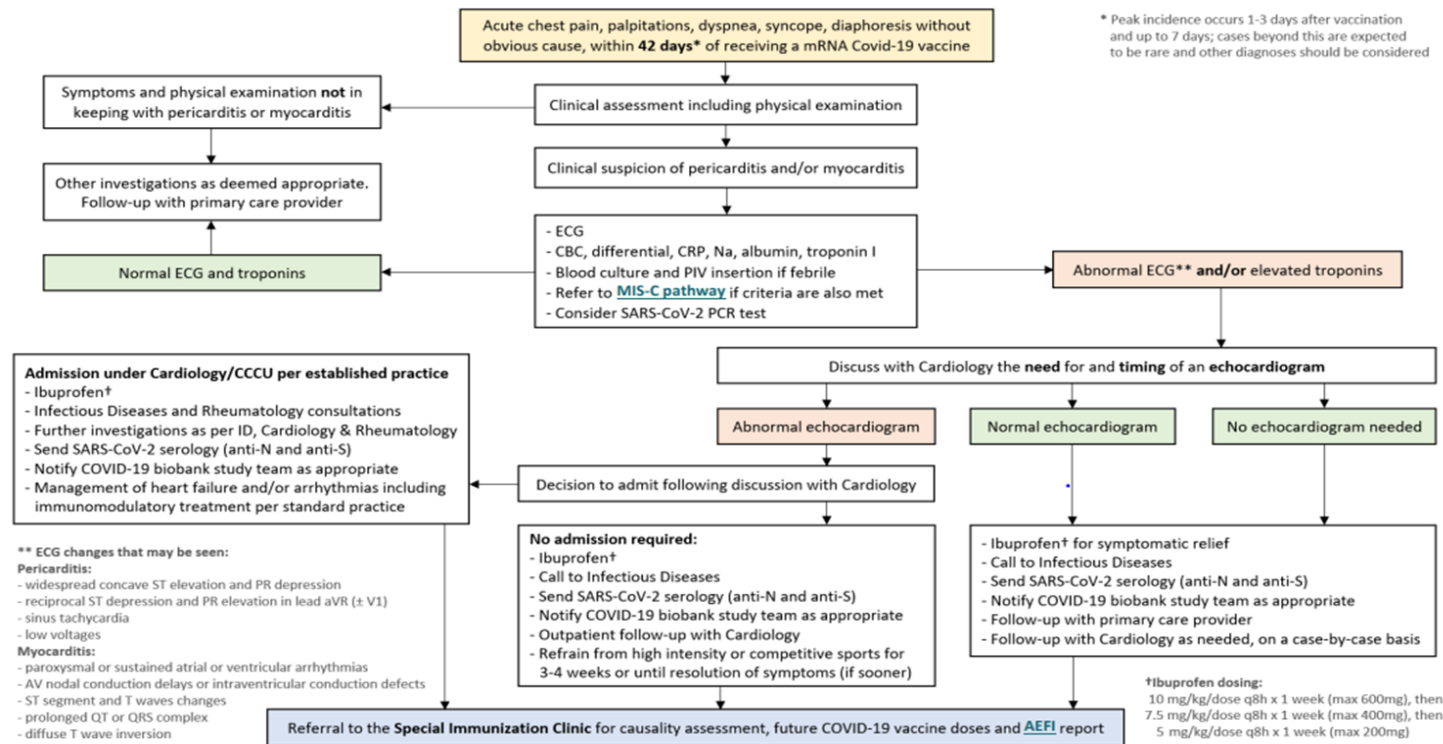
Comirnaty





- Post-market safety surveillance of mRNA COVID-19 vaccines has found an increased frequency of myocarditis and pericarditis most frequently
 - in adolescents and younger adults under 30 years of age,
 - more frequently in males compared to females, and
 - more frequently after the second dose.
- Need Investigation with ECG, CXR, Troponin, potentially ECHO or Cardiac MRI
- Majority of cases have been mild and have resolved.
- Mild cases may be treated with non-steroidal anti-inflammatory drugs (NSAIDS) for symptomatic relief.

Algorithm for the management of patients with myocarditis or pericarditis after mRNA COVID-19 Vaccination





Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines

The following guidance has been developed jointly by the Australian Technical Advisory Group on Immunisation (ATAGI) and the Cardiac Society of Australia and New Zealand (CSANZ).

Version 1.0 – 30 July 2021

Underlying cardiac conditions and Pfizer COVID vaccine



- Most pre-existing cardiac conditions are **not** regarded as contraindications to vaccination. Comirnaty is a recommended vaccine for people with a history of heart conditions: this includes coronary artery disease, myocardial infarction, stable heart failure, arrhythmias, rheumatic fever, rheumatic heart disease (RHD), Kawasaki Disease, most congenital heart disease and people with implantable cardiac devices
- People with a history of any of the following conditions can receive an mRNA vaccine (e.g. Comirnaty) but should consult a cardiologist about the best timing of vaccination and whether any additional precautions are recommended:
 - Inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis
 - Current acute rheumatic fever
 - People aged 12-29 years with dilated cardiomyopathy
 - Complex or severe congenital heart disease including single ventricle (Fontan) circulation
 - Acute decompensated heart failure
 - Cardiac transplant recipients.

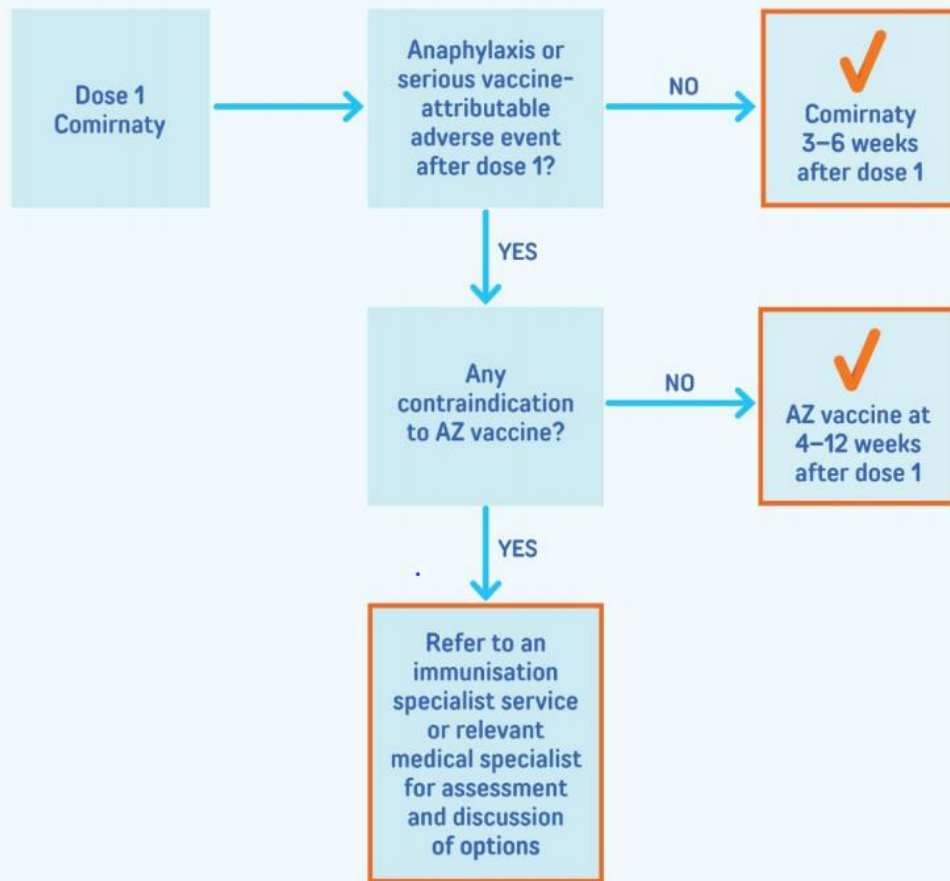


Advice for people who experience myocarditis/pericarditis attributed to an mRNA COVID-19 vaccine

People who experience myocarditis and/or pericarditis after an mRNA COVID-19 vaccine should be referred to a cardiologist for further assessment and management, to investigate for possible causes other than vaccination, and for follow-up.

Currently, ATAGI advises people who have had myocarditis or pericarditis attributed to an mRNA COVID-19 vaccine where other causes have been excluded, to defer future doses of mRNA COVID-19 vaccine, and to discuss this with their treating doctor. It should be noted that Spikevax (Moderna) is also an mRNA vaccine and therefore not recommended for people who have experienced myocarditis and/or pericarditis after Comirnaty.

Additional advice on second dose vaccination in this context will be provided in the near future.



Any other serious adverse event attributed to the first dose of a COVID-19 vaccine includes:

- o Myocarditis following an mRNA vaccine – discuss with specialist.
- o Immune thrombocytopenia (ITP) following dose 1 of any COVID-19 vaccine*


Myocarditis and pericarditis after Pfizer vaccine



- Should be seen by a cardiologist for ongoing review
 - Often need serial ECG and ECHO
- Patients with established myocarditis should be admitted to hospital for cardiac monitoring (ideally continuous ECG monitoring), until the cardiac biomarker levels have peaked and symptoms have resolved
- Avoid high intensity exercise or competitive sports until resolution of symptoms and ECG changes and normalisation of cardiac function
- Not for 2nd dose of mRNA vaccine,
- Discuss with vaccine or medical specialist re “vaccine switch”

TGA approves Pfizer vaccine in 12-15 year olds





Australian Government
Department of Health
Therapeutic Goods Administration

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TGA Provisional Approval of Pfizer-BioNTech COVID-19 vaccine to include 12-15 years age group

23 July 2021

The Therapeutic Goods Administration (TGA) has provisionally approved the use of the Pfizer BNT162b2 COVID-19 vaccine (COMIRNATY) in individuals 12 years and older. Previously, the Pfizer COVID-19 vaccine was provisionally approved for use in individuals 16 years or older.

Provisional approval for use in the 12-15 years age group has been made following careful evaluation of the available data supporting safety and efficacy, including clinical studies with adolescents 12 to 15 years of age. Use in this age group was supported by the independent expert Advisory Committee on Vaccines.

Further details of the data supporting this approval and TGA's evaluation are included in the [Product Information \(PI\) \(pdf,454kb\)](#) and the [Australian Public Assessment Report \(AusPAR\)](#).



ORIGINAL ARTICLE

Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents

Robert W. Frenck, Jr., M.D., Nicola P. Klein, M.D., Ph.D., Nicholas Kitchin, M.D., Alejandra Gurtman, M.D., Judith Absalon, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Emmanuel B. Walter, M.D., Shelly Senders, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Hua Ma, Ph.D., Xia Xu, Ph.D., Kenneth Koury, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Timothy Jennings, D.O., Donald M. Brandon, M.D., Stephen J. Thomas, M.D., Özlem Türeci, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

July 15, 2021

N Engl J Med 2021; 385:239-250

DOI: 10.1056/NEJMoa2107456

Table 2. SARS-CoV-2 Serum Neutralization Assay Results 1 Month after Dose 2 of BNT162b2 among Participants without Evidence of Infection.*

Age Group	No. of Participants	Geometric Mean 50% Neutralizing Titer (95% CI)†	Geometric Mean Ratio (95% CI), 12 to 15 Yr vs. 16 to 25 Yr‡
12–15 yr	190	1239.5 (1095.5–1402.5)	1.76 (1.47–2.10)
16–25 yr	170	705.1 (621.4–800.2)	—

Children aged 12-15 years now approved for Pfizer



- ATAGI recommends priorities for Comirnaty (Pfizer) vaccine:
- children with specified medical conditions that increase their risk of severe COVID-19 – see **Appendix A** for more details
- Aboriginal and Torres Strait Islander children aged 12–15 years
- all children aged 12–15 years in remote communities, as part of broader community outreach vaccination programs that provide vaccines for all ages (≥ 12 years).

[ATAGI statement regarding vaccination of adolescents aged 12–15 years](#) | Australian Government Department of Health

ATAGI statement regarding vaccination of adolescents aged 12–15 years

A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding vaccination of adolescents aged 12-15 years



Morbidity and Mortality Weekly Report

Early Release / Vol. 70

July 30, 2021

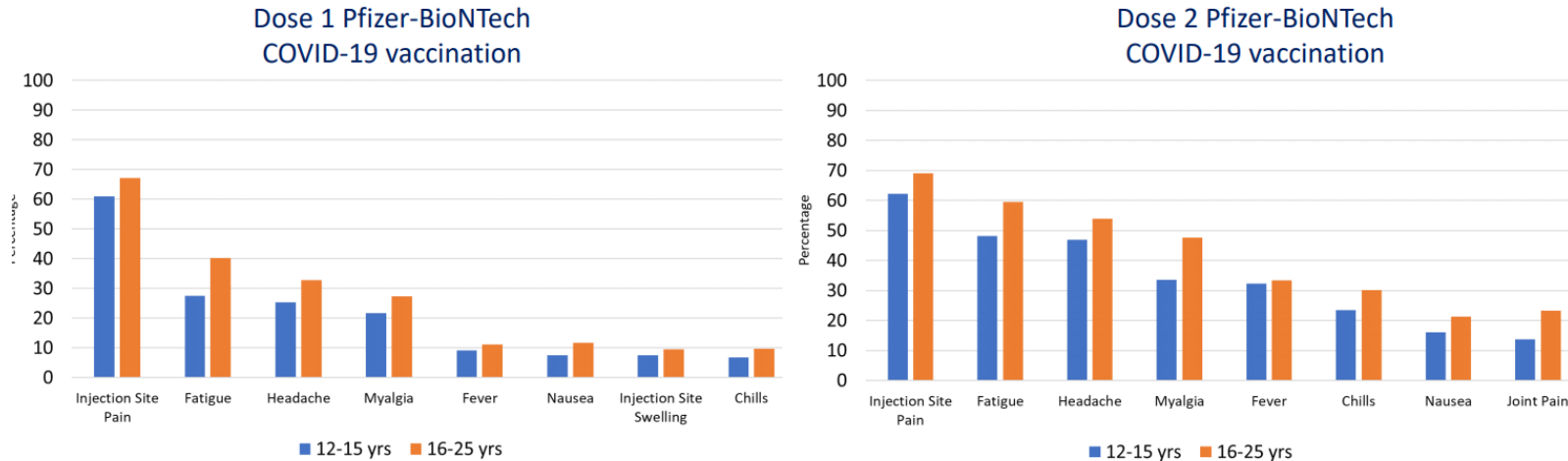
COVID-19 Vaccine Safety in Adolescents Aged 12–17 Years — United States, December 14, 2020–July 16, 2021

Anne M. Hause, PhD¹; Julianne Gee, MPH¹; James Baggs, PhD¹; Winston E. Abara, MD¹; Paige Marquez, MSPH¹; Deborah Thompson, MD²; John R. Su, MD, PhD¹; Charles Licata, PhD¹; Hannah G. Rosenblum, MD^{1,3}; Tanya R. Myers, PhD¹; Tom T. Shimabukuro, MD¹; David K. Shay, MD¹

Vaccination in children and adolescents



V-safe: Top solicited reactions reported at least once in days 0–7 after vaccination with Pfizer-BioNTech in 12–15-year-olds vs. 16–25-year-olds* (data thru Jun 13, 2021)



* Includes participants who completed at least one survey in the first week after dose 1 of Pfizer-BioNTech COVID-19 vaccine



Q. Can you administer the COVID-19 vaccine less than 7 days after a live vaccination?

A. Yes in special circumstances e.g. outbreak, imminent travel

Q. Do patients need to wait 7 days after a COVID-19 vaccine to receive other vaccinations?

A. No, a shorter interval (<7 days, including co-administration) is acceptable in the following settings:

- Increased risk of COVID-19 or another vaccine-preventable disease (e.g., COVID-19 outbreak, influenza outbreak, tetanus-prone wound)
- Logistical issues e.g., difficulty scheduling visits to maintain the 7-day interval (ATAGI Clinical Guidance)

Q. Can someone have a COVID-19 vaccine if it has been <6 months since having the virus?

A. Yes, Evidence suggests that past infection reduces the risk of reinfection for at least 6 months”. This allows discretion e.g. for early vaccination in outbreak setting (ATAGI clinical guidance)

Vaccine boosters including variants are under study



Pfizer commenced studies for boosters

- A third dose of the Pfizer COVID-19 vaccine as a booster
- A variant-specific booster candidate, based on the B.1.351 variant

Moderna commenced studies for:


- A variant-specific booster candidate, based on the B.1.351 variant (mRNA-1273.351)
- A multivalent booster candidate, mRNA-1273.211, which combines Moderna's authorized vaccine and variant-specific booster in a single vaccine.
- A third dose of the Moderna COVID-19 Vaccine as a booster.



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Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots

Media Statement

For Immediate Release: Wednesday, August 18, 2021

Contact: [Media Relations](#)

(404) 639-3286

Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released the following statement on the Administration's plan for COVID-19 booster shots for the American people.

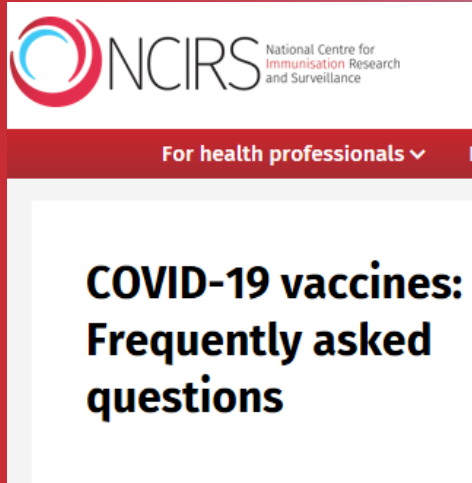
Take home message



- Vaccines are the best way to protect people from COVID-19
- Everyone should continue to get their vaccination when asked to do so unless specifically advised otherwise.
- As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.
- Cases of an extremely rare specific type of blood clot with low blood platelets continue to be investigated.
- TGA encourage people to report symptoms that could suggest myocarditis particularly after the second dose of Comirnaty (Pfizer)

THANK YOU

Questions?



<https://www.ncirs.org.au/covid-19/covid-19-vaccines-frequently-asked-questions>



COVID-19

Glossary of Medical Terminology for
Immunisation and Vaccine development

Supporting communication for the
COVID-19 vaccination program.

English

Produced by Health and Social Policy Branch NSW Ministry of Health, NSW Aboriginal Health Communication Service, NSW Refugee Health Service and School of Population Health, University of New South Wales.



Vaccine program considerations

Dr Michael Crampton

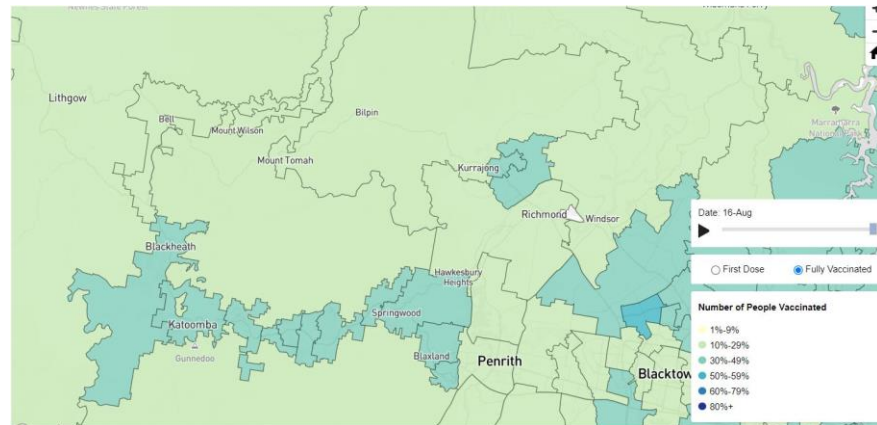
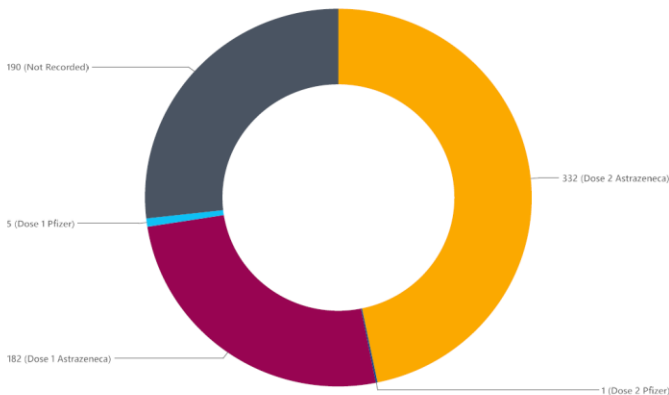
Vaccine program considerations

1. Local data:

<https://www.nsw.gov.au/covid-19/find-the-facts-about-covid-19#map-of-nsw-vaccinations-by-home-postcode>

2. Practice Data: CAT4

COVID-19 Vaccination Status [Population = 710]



3. Vaccine delivery

- **Commonwealth Plan** – broaden then increase supply to busiest practices
- **Practice Plan** – Clinics, Opportunistic, Outreach

	Opened Vial	Opened Vial	Drawn Up Syringe	Drawn Up Syringe
	Refrigerated	Room	Refrigerated	Room
AZ	48 hours	6 hours	6 hours	1 hour
Pfizer	6 hours	1 hour	6 hours	1 hour

4. Protecting Vaccinators and Staff

- Vaccination session = Medium Contact risk event
 - So contact with +ve case -> shutdown
- If vaccinators wear - N95, gloves, eye protection = low exposure risk
 - So contact with +ve case -> continued practice

NB: All exposure category decisions are based on a local risk assessment

Case = confirmed positive case in a patient, staff member or other

Given current evidence, the risk assessment remains unchanged regardless of vaccination status

CONTACT TYPE – See page 2 for more detailed assessment for a breach						
		No contact	Transient Contact – Low Risk Transient, not face-to-face, limited contact that does not meet the definition of face-to-face contact OR In general, less than 30 minutes in a closed space *Note: always subject to local documented risk assessment, including assessments of occupational exposures and of the closed space		Medium Risk Scenarios Any face-to-face contact within 1.5 metres and less than 15 minutes OR In general, greater than 30 mins in a closed space OR Based on agreed documented risk assessment including assessments of occupational exposures and of the physical environment	Highest Risk Scenarios Prolonged face-to-face contact within 1.5 metres and greater than 15 minutes OR Aerosol generating behaviours (AGBs e.g. coughing) OR Aerosol generating procedures (AGPs) OR Contact with <u>multiple</u> COVID-19 cases/suspected cases/probable cases
PPE worn during contact between health care worker and case	1. No effective PPE worn by staff member or case e.g. no PPE or PPE with major breaches such as mask below nose	Low Risk	Moderate Risk	OR	High Risk	High Risk
	2. Surgical mask only worn by staff member i.e. no eye protection ➢ Case no PPE	Low Risk	Low to Moderate Risk	OR	Moderate Risk	High Risk
	3. Surgical mask only worn by staff member i.e. no eye protection ➢ Case wearing surgical mask	Low Risk	Low to Moderate Risk	OR	Moderate Risk	High Risk
	4. Staff member in surgical mask and eye protection* with no concerns or breaches ➢ Case no PPE *Use of gown/apron and gloves should be risk assessed based on individual incident, exposure to body substance and chances of environmental contamination	Low Risk	Low Risk		Low to Moderate Risk	High Risk
	5. Staff member in surgical mask and eye protection* with no concerns or breaches ➢ Case wearing surgical mask * See note in Category 4 box	Low Risk	Low Risk		Low to Moderate Risk	Moderate Risk OR High Risk
	6. Staff member in P2/N95 and eye protection; no breaches ➢ Case either with or without PPE * See note in Category 4 box		Low Risk			

LOW RISK Continue to work HCW alert to mild symptoms Test if symptomatic	LOW TO MODERATE RISK Initial test usually not earlier than day 2 post exposure, but can work while result is pending Retest day 5 Monitor for symptoms, test if symptomatic Wear a mask at all times on site including staff only spaces	MODERATE RISK Leave workplace immediately and isolate Test as soon as possible, but not before day 2; isolate until day 5 and retest. If both negative, can return to work with repeat testing every 72 hours Clearance/exit test on day 13 Monitor for symptoms, test if symptomatic Wear a mask at all times on site, including staff only spaces	HIGH RISK Leave workplace immediately and isolate for 14 days from last exposure Initial test usually not earlier than day 2 post exposure Monitor for symptoms, test if symptomatic Retest day 7 post last exposure Retest day 13 (clearance test) Proof of negative day 13 test is needed to return to work
--	---	--	--

5. Patient Vaccine Eligibility

- **Commonwealth/State ‘eligibility divide’**
 - Active campaign to broaden GP eligibility to equal local rules
 - Dr de Toca: “Use clinical judgement in all situations” as long as TGA approved
 - Dr de Toca: “Excess Dose Policy exists” (must be TGA approved)

6. Drive thru delivery of vaccines

- ATAGI (and Commonwealth) guidelines recently published to assist practices who may wish to consider delivering by a drive thru option

Katie Taylor

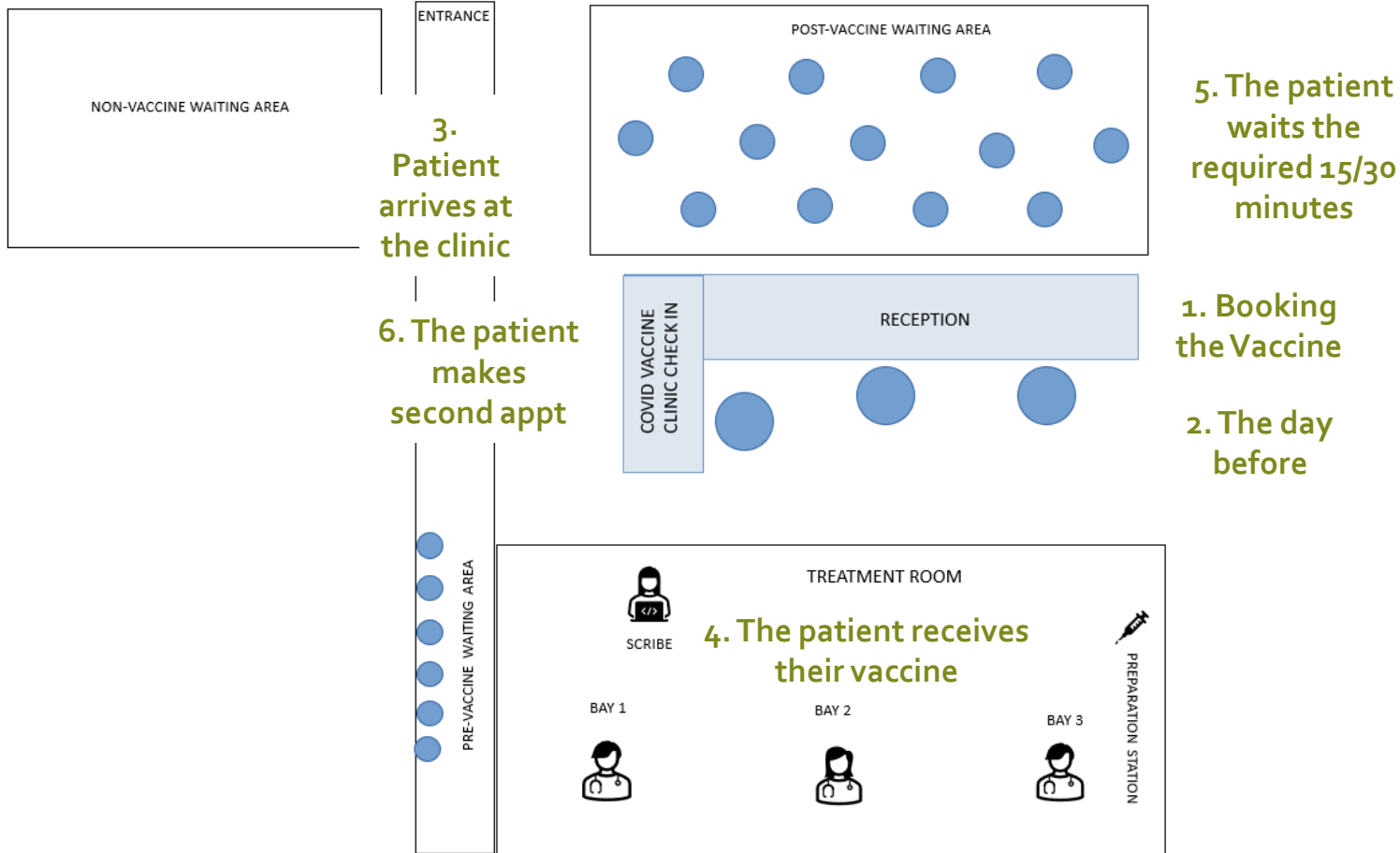
Practice Manager
Myhealth North Richmond

MYHEALTH NORTH RICHMOND

COVID-19 Vaccination Clinic Workflow

MYHEALTH NORTH RICHMOND

- 7 GPs
 - 5 Nurses (3 Practice Nurses & 2 Vaccination Only Nurses)
 - 1 AIN
 - 6 Administration Staff
-
- Delivering both Astra Zeneca and Pfizer.
-
- 20 x 1 hour clinics Monday – Friday.
 - 10 clinics per vaccine.
 - 1 morning & 1 afternoon session per vaccine.
-
- Recently introduced Saturday afternoon clinics.



CHALLENGES

- Ever changing vaccine eligibility requirements
- Managing requirements around two vaccines
- Managing patient expectations
- Balancing GP/Nurse time between vaccines and regular duties
- Spatial limitations
- Minimising risk of staff burn out

LEARNINGS

- Utilise entire team
- Streamline as many steps as possible
- Standing Order allows for Nurse led clinics
- Vaccine clinic is just that
- Onus on the patient to prepare themselves
- Do not over commit

More information

Our website

<https://www.nbmphn.com.au/Health-Professionals/Coronavirus/Immunisation>

HealthPathways

<https://nbm.communityhealthpathways.org/835663.htm>

Subscribe to our COVID-19 updates

<https://www.nbmphn.com.au/Contact/Subscribe-to-receive-NBMPHN-news>



Any further questions?

Email covid@nbmphn.com.au

or contact your Practice Support Officer

