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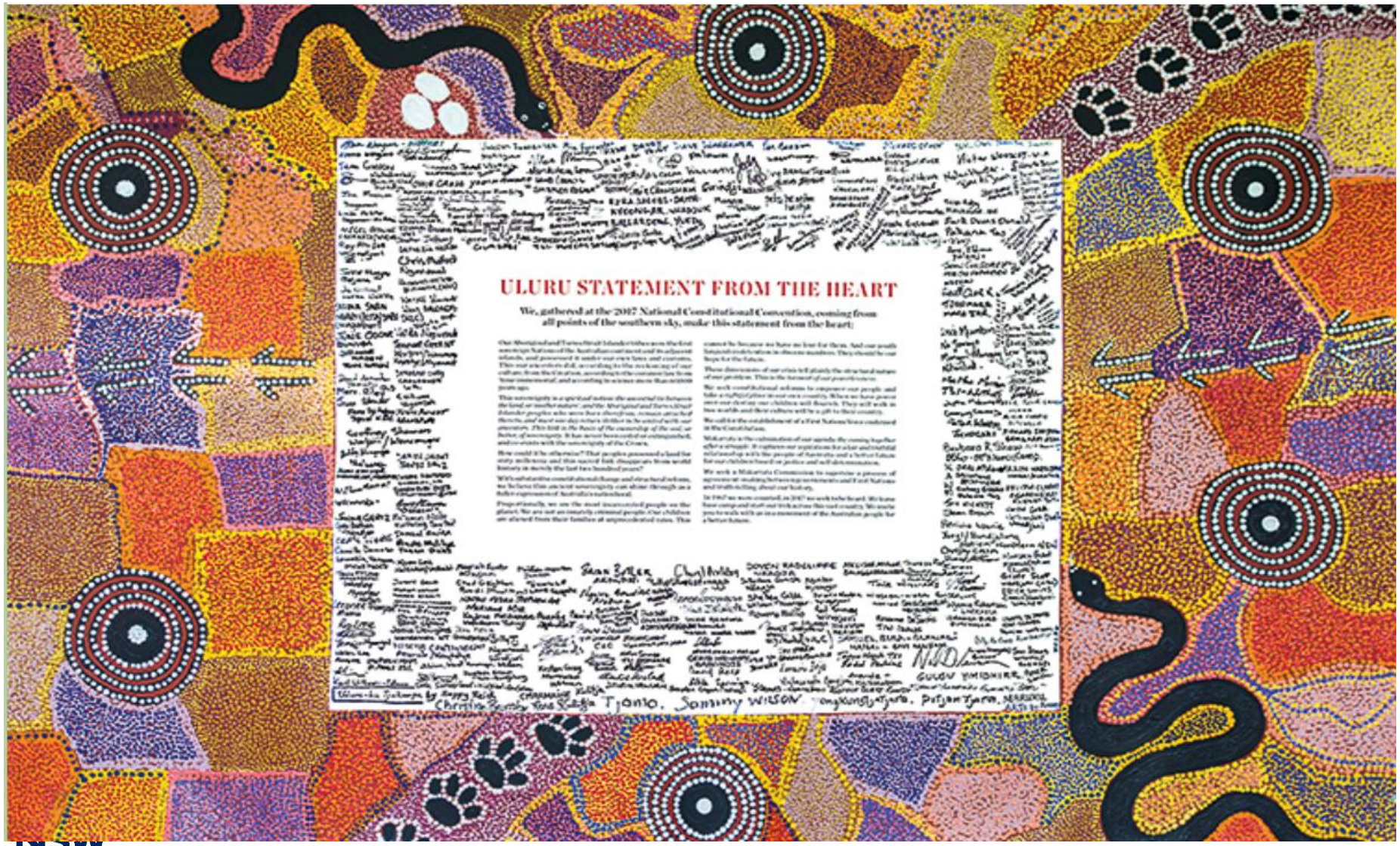
“In 1967 we were counted, in 2017 we seek to be heard”



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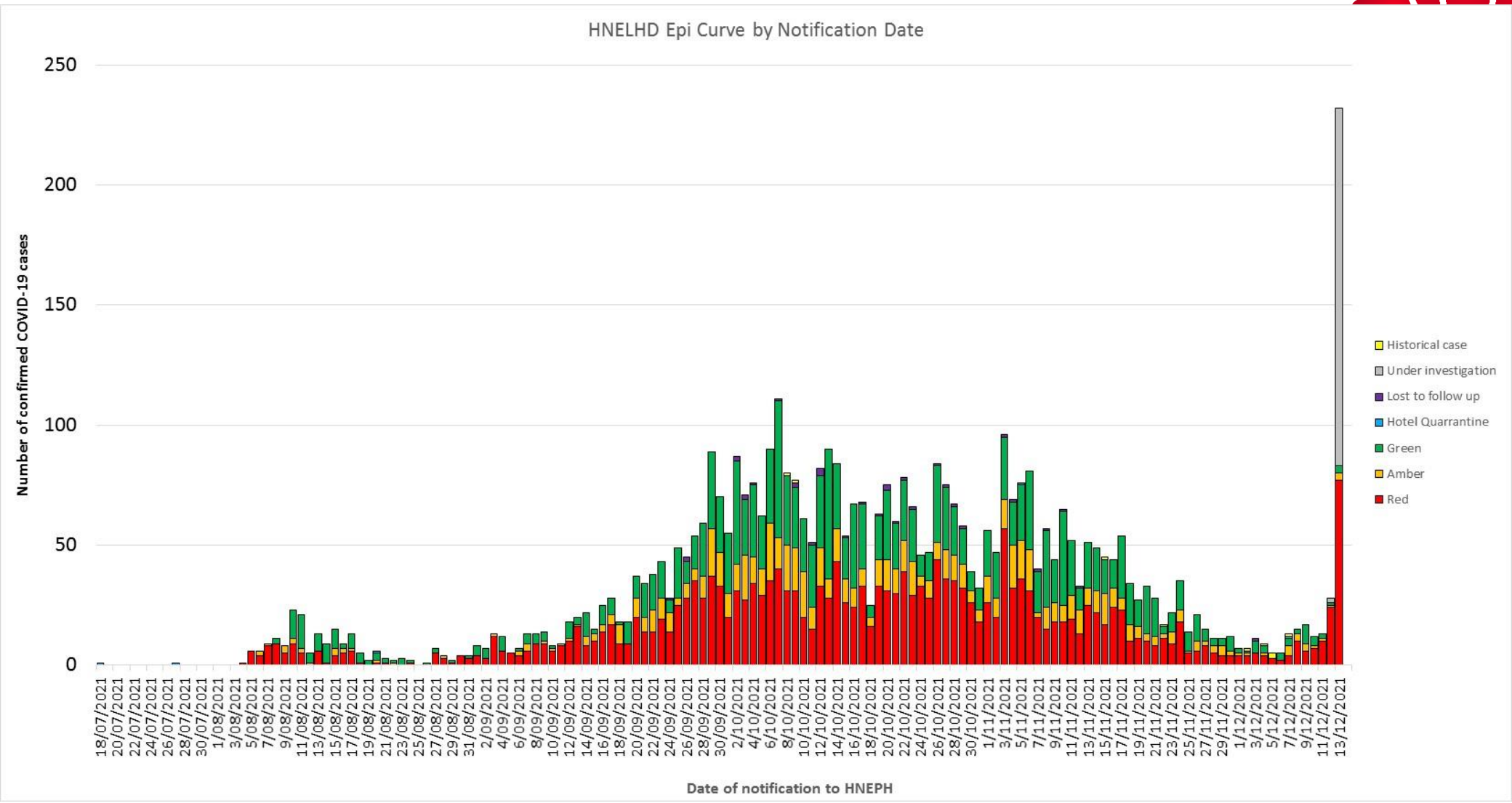
HNELHD Epi Curve by Notification Date
Number of confirmed COVID-19 cases
250
200
150
100
50
0
Historical case
Under investigation
Lost to follow up
Hotel Quarrantine
Green
Amber
Red
18/07/2021
20/07/2021
22/07/2021
24/07/2021
26/07/2021
28/07/2021
30/07/2021
1/08/2021
3/08/2021
5/08/2021
7/08/2021
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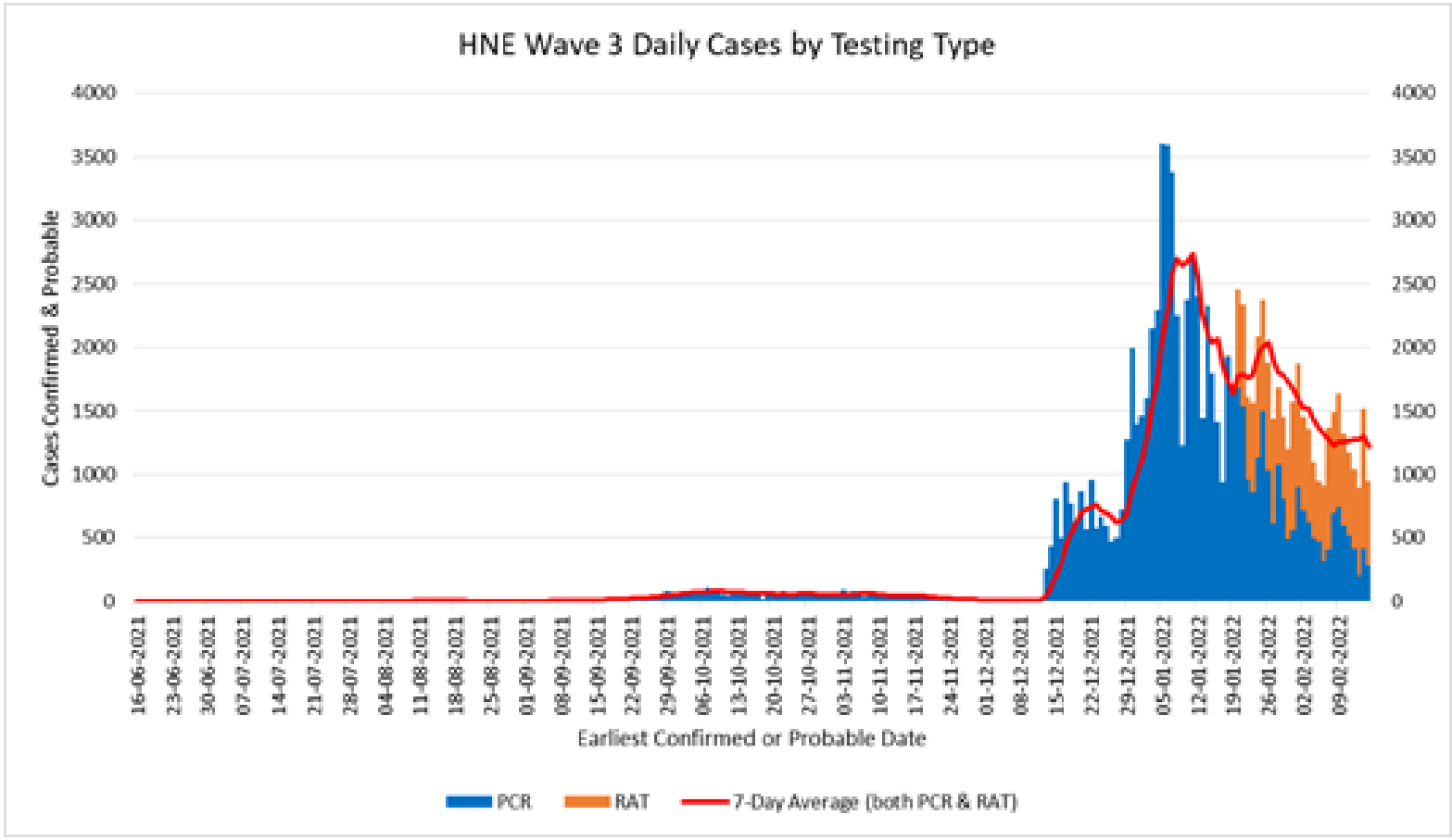
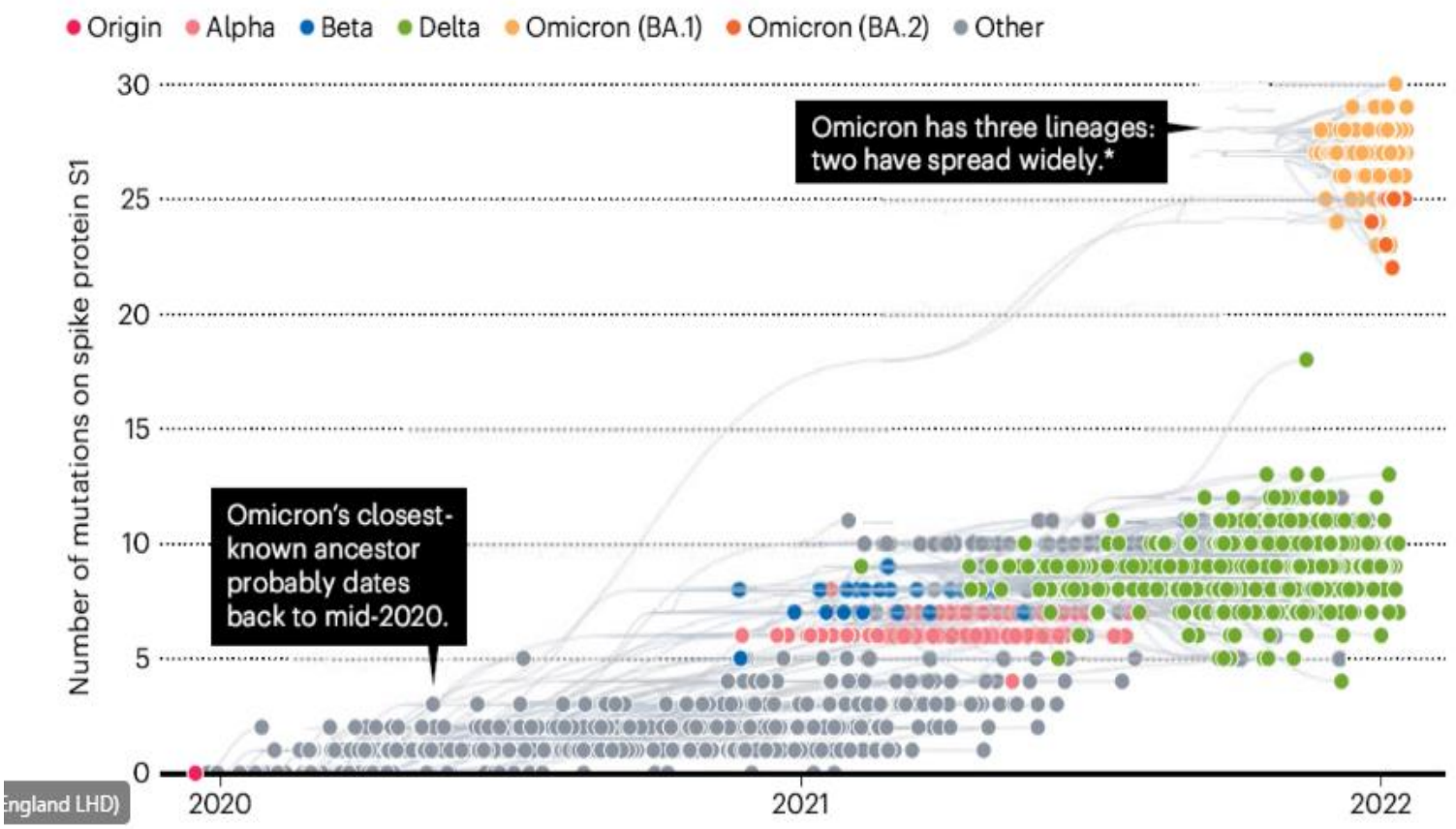
13/12/2021
Date of notification to HNEPH

HNE Wave 3 Daily cases



MOST MUTATED

The Omicron variant of the SARS-CoV-2 coronavirus has more mutations than any known predecessor. This chart shows mutations in the S1 subunit of the spike protein, which attaches to host cells.



O Macron

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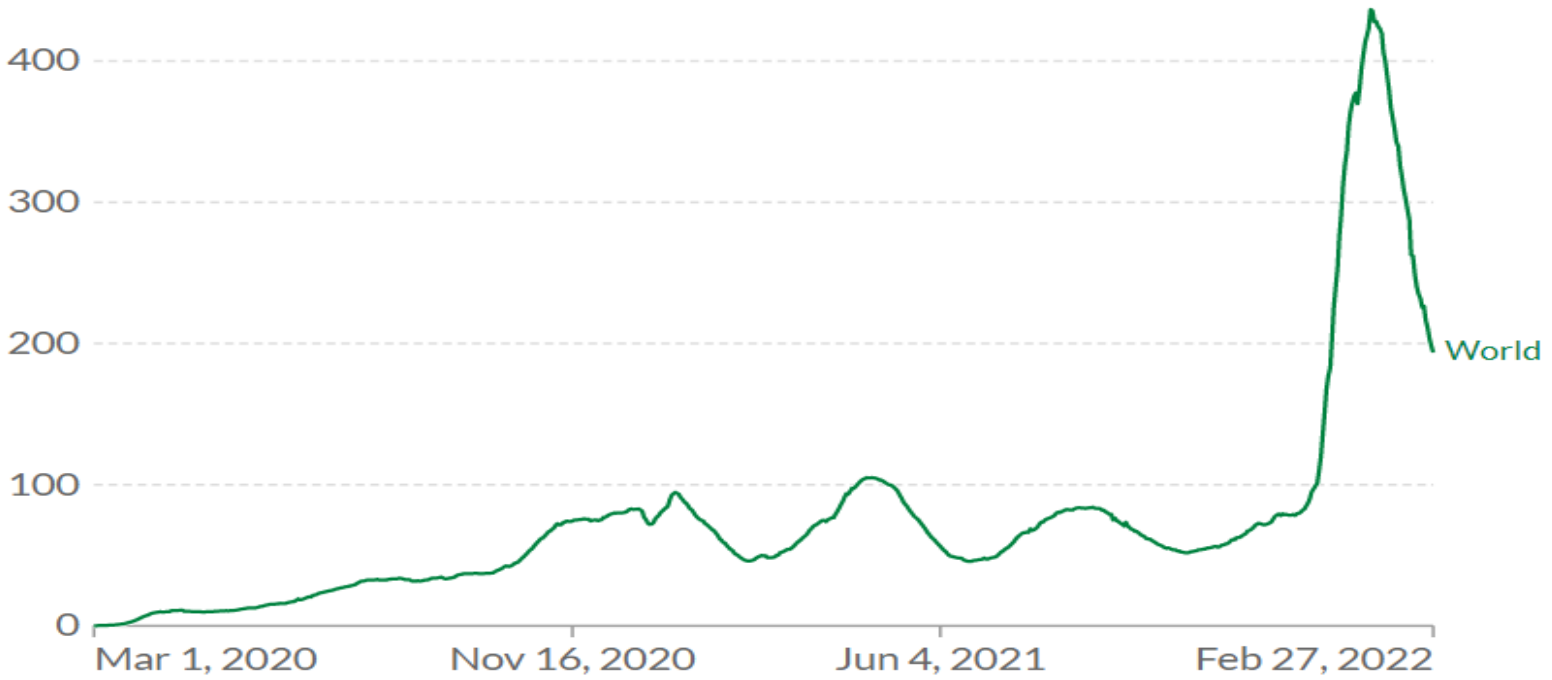
Daily new confirmed COVID-19 cases per million people

Our World in Data

7-day rolling average. Due to limited testing, the number of confirmed cases is lower than the true number of infections.

LINEAR | LOG



Source: Johns Hopkins University CSSE COVID-19 Data

NSW GOVERNMENT

Daily new confirmed COVID-19 cases per million people

Our World in Data

7-day rolling average. Due to limited testing, the number of confirmed cases is lower than the true number of infections.

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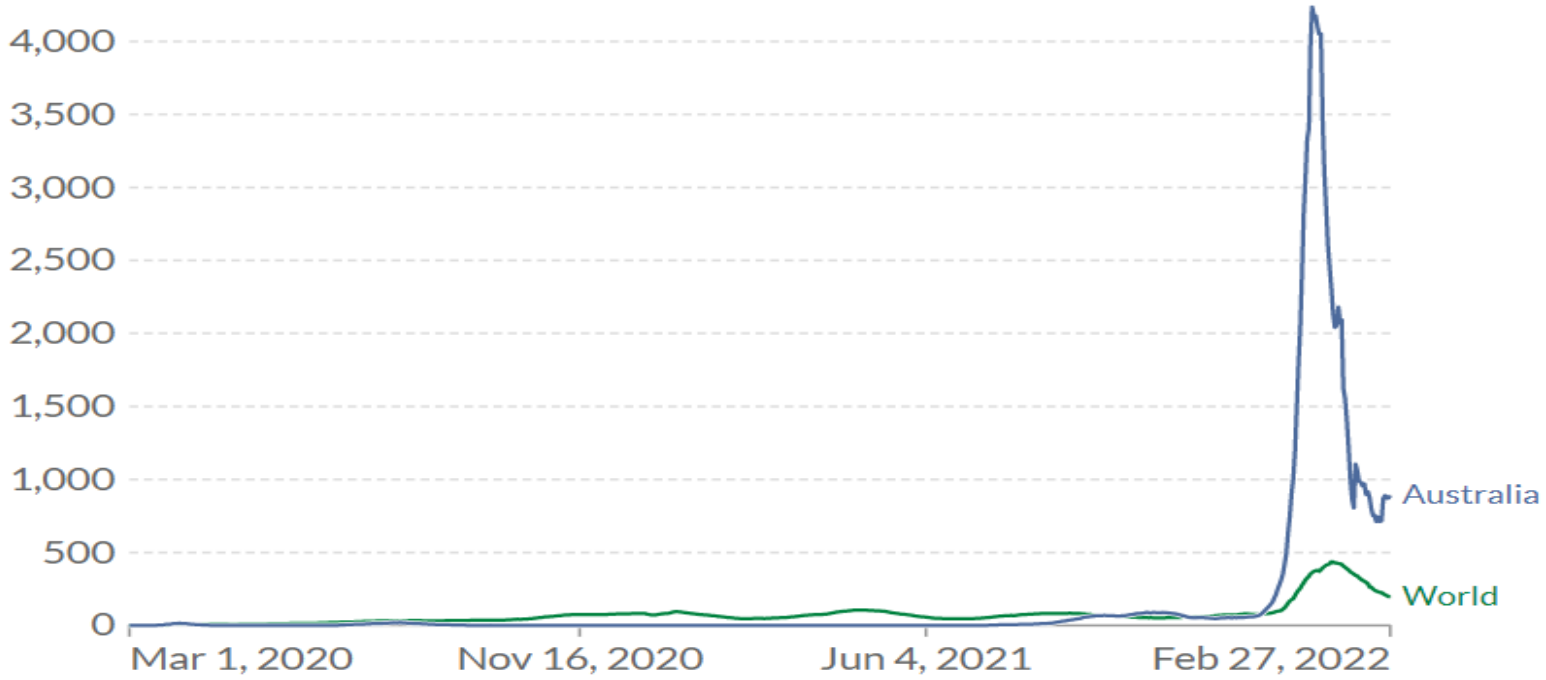

Source: Johns Hopkins University CSSE COVID-19 Data

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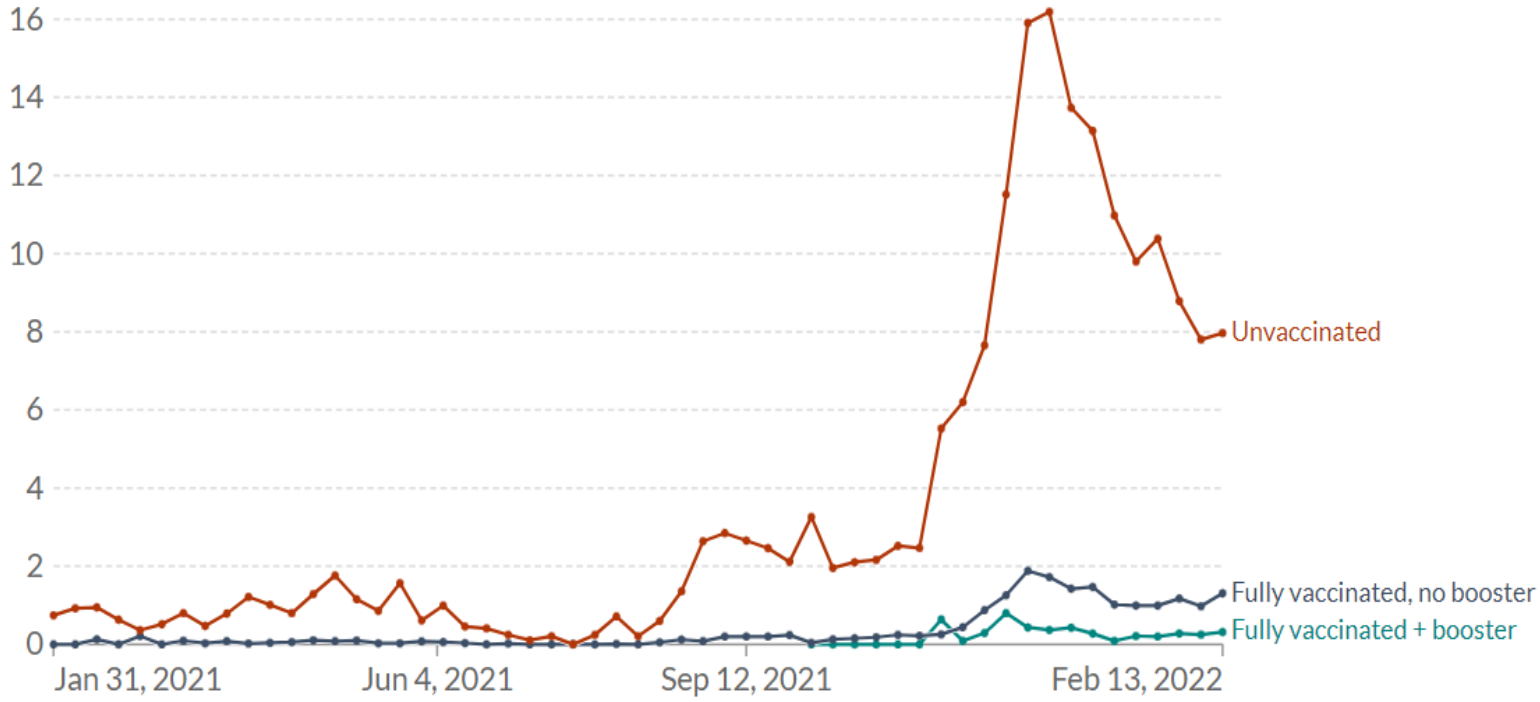
Switzerland: COVID-19 weekly death rate by vaccination status, All ages

Death rates are calculated as the number of deaths in each group, divided by the total number of people in this group. This is given per 100,000 people.

Our World in Data

LINEAR | LOG

Change age group



Source: Federal Office of Public Health

OurWorldInData.org/coronavirus • CC BY

Note: Data coverage includes both Switzerland and Liechtenstein. Unvaccinated people have not received any dose. Partially-vaccinated people are excluded. Fully-vaccinated people have received all doses prescribed by the initial vaccination protocol. The mortality rate for the 'All ages' group is age-standardized to account for the different vaccination rates of older and younger people.

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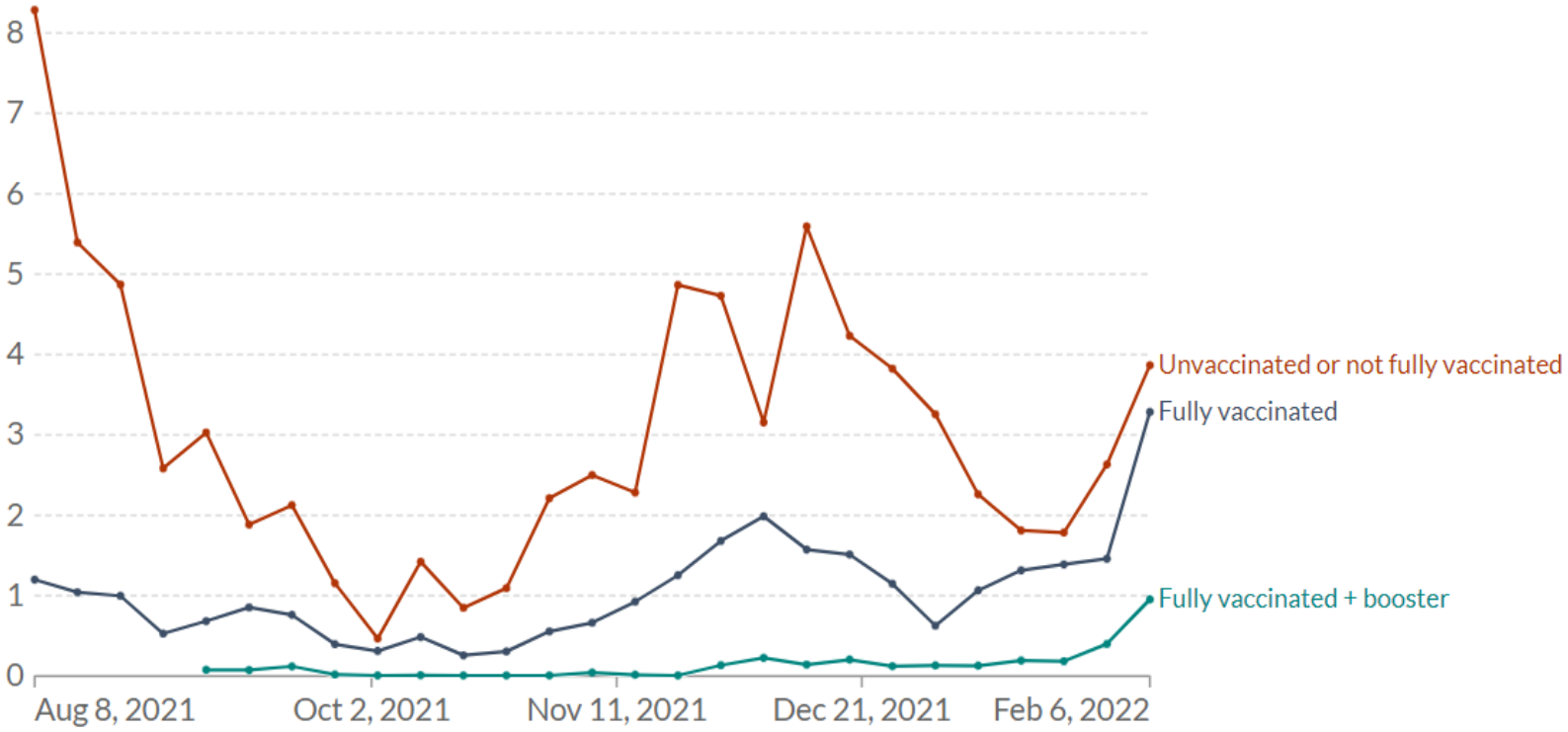
Chile: COVID-19 weekly death rate by vaccination status, All ages

Our World in Data

Death rates are calculated as the number of deaths in each group, divided by the total number of people in this group. This is given per 100,000 people.

LINEAR | LOG ⇄ Change age group



Source: Department of Epidemiology, Ministry of Health, via Ministry of Science GitHub repository

Note: The mortality rate for the 'All ages' group is age-standardized to account for the different vaccination rates of older and younger people.

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Case outcome comparison – delta vs omicron

Hunter New England	18 July 2021 - 07 Dec 2021 (Delta variant)	08 Dec 2021 - 15 Feb 2022 (Omicron variant)
Total cases	4,405	95,464
Hospitalised*	493 (11.2%)	1,785 (1.9%)
Admitted to ICU*	45 (10.2/1,000)	89 (0.9/1,000)
Deaths*	16 (3.6/1,000)	83 (0.9/1,000)

** Note, these categories are not mutually exclusive. Hospitalised includes cases admitted to ICU; deaths may occur with or without being admitted to hospital or ICU.*

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Deaths - delta vs omicron

Deaths 18 July 2021 - 07 Dec 2021 (Delta variant)			Deaths 08 Dec 2021 - 15 Feb 2022 (Omicron emergence)		
Age Group	**Frequency**	**Percent**	**Age Group**	**Frequency**	**Percent**
30-39	1	6.2%	30-39	0	-
40-49	3	18.75%	40-49	0	-
50-59	3	18.75%	50-59	1	1.2%
60-69	3	18.75%	60-69	11	13.3%
70-79	2	12.5%	70-79	21	25.3%
80-89	3	18.75%	80-89	31	37.3%
90+	1	6.2%	90+	19	22.9%
Gender	**Frequency**	**Percent**	**Gender**	**Frequency**	**Percent**
Female	4	25.0%	Female	27	32.5%
Male	12	75.0%	Male	56	67.5%

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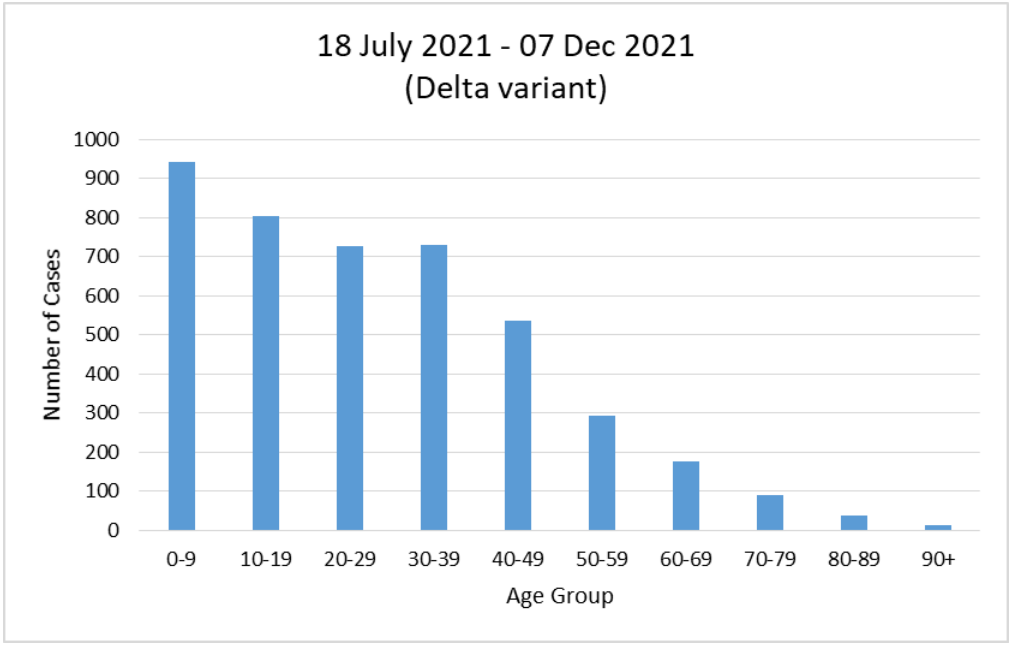
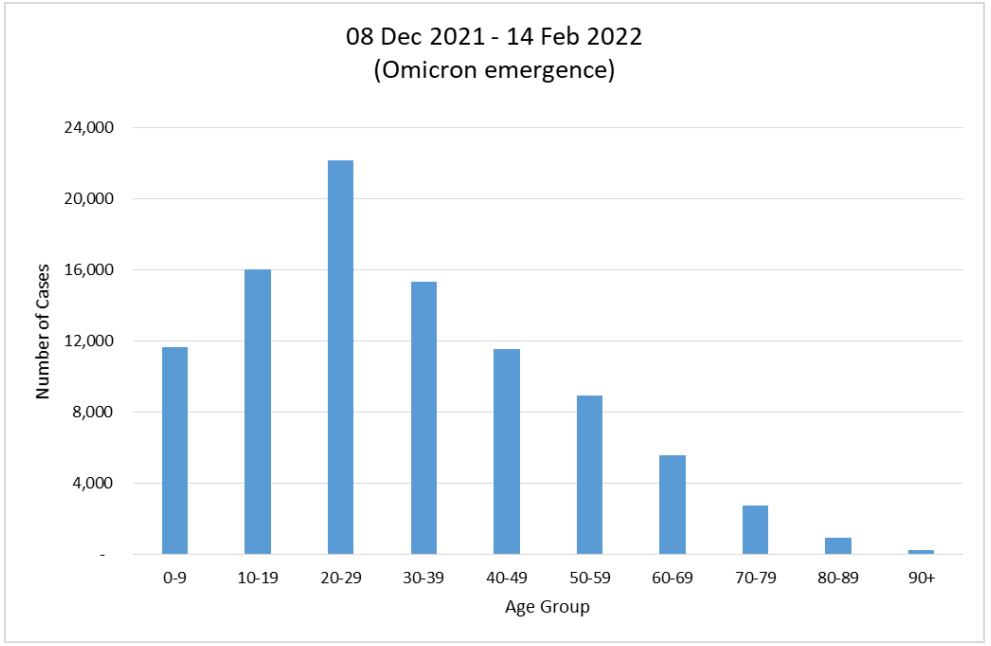
Age-distribution of cases – delta vs omicron





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The Sydney Morning Herald

By **Mary Ward** and **Lucy Carroll**

February 24, 2022 — 11.30am

Data reported by the *Herald* earlier this week showed only one in five people in their 20s who were eligible for a booster dose had received one, although significant numbers only became eligible this week. The age group has had the highest rate of infection since December.

Two COVID cases led to 295 infections within the walls of Argyle House nightclub in Newcastle. DARREN PATEMAN

> Hunter New England Local Health District health protection director Professor David Durrheim said evidence from Britain and South Africa indicated that, while two doses of a COVID-19 vaccine provided "moderate" protection against hospitalisation with Omicron, vaccine protection clearly waned after two to three months.

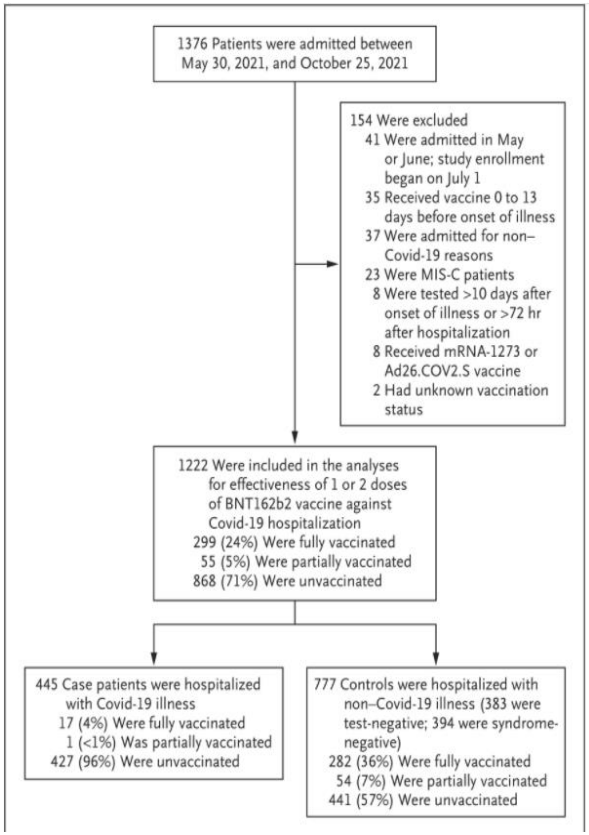
NSW GOVERNMENT

Effectiveness of BNT162b2 Vaccine against Critical Covid-19 in Adolescents

Samantha M. Olson, M.P.H., Margaret M. Newhams, M.P.H., Natasha B. Halasa, M.D., Ashley M. Price, M.P.H., Julie A. Boom, M.D., Leila C. Sahni, Ph.D., M.P.H., Pia S. Pannaraj, M.D., M.P.H., Katherine Irby, M.D., Tracie C. Walker, M.D., Stephanie P. Schwartz, M.D., Aline B. Maddux, M.D., Elizabeth H. Mack, M.D., et al., for the Overcoming Covid-19 Investigators*

Vaccine Efficacy = How well vaccine works in trial
Vaccine Effectiveness = How well vaccine works in real world

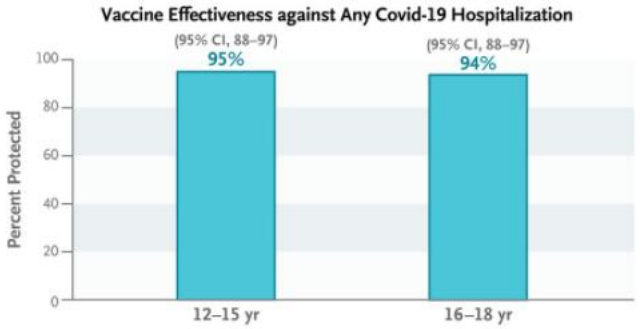
The NEW ENGLAND JOURNAL of MEDICINE

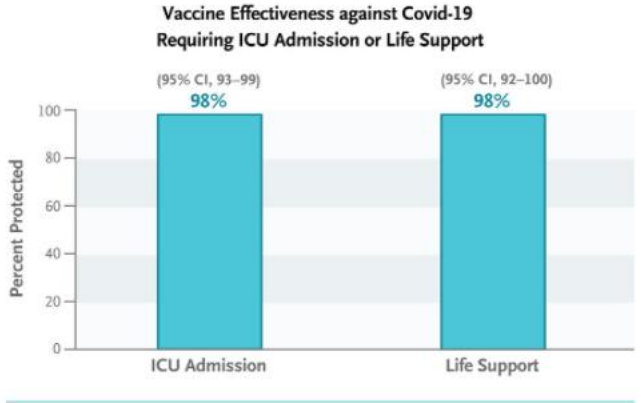


445 Case patients were hospitalized with Covid-19 illness
17 (4%) Were fully vaccinated
1 (<1%) Was partially vaccinated
427 (96%) Were unvaccinated

Figure 1. Study Enrollment and Outcomes (July 1–October 25, 2021).

Among the case patients between 12 and 18 years of age who were hospitalized with coronavirus disease





All 7 deaths occurred in patients who were unvaccinated.

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Protection against SARS-CoV-2 after Covid-19 Vaccination and Previous Infection

Victoria Hall, F.F.P.H., Sarah Foulkes, M.Sc., Ferdinando Insalata, M.Sc., Peter Kirwan, B.Sc., Ayoub Saei, Ph.D., Ana Atti, M.Sc., Edgar Wellington, M.Sc., Jameel Khawam, M.Sc., Katie Munro, M.Sc., Michelle Cole, D.B.M.S., Caio Tranquillini, M.D., Andrew Taylor-Kerr, M.P.P., et al., for the SIREN Study Group*

The NEW ENGLAND JOURNAL of MEDICINE

35,768 participants

Between December 7, 2020, and September 21, 2021

Among previously uninfected participants who received BNT162b2 vaccine, adjusted vaccine effectiveness decreased from 85% 14 to 73 days after the second dose to 51% at a median of 201 days

Infection-acquired immunity waned after 1 year in unvaccinated participants but remained consistently higher than 90% in those who were subsequently vaccinated, even in persons infected more than 18 months previously.

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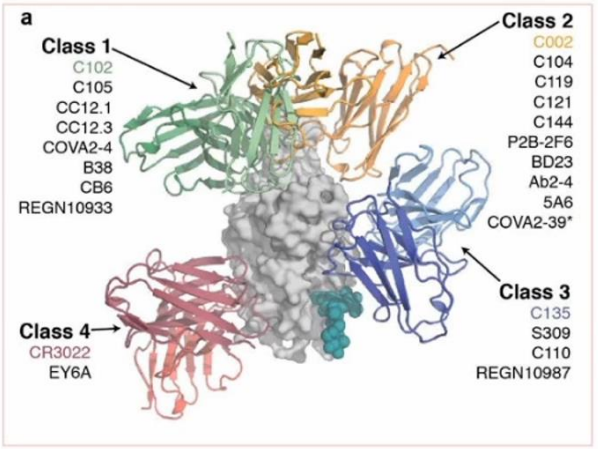
Need 3rd dose

Human mAbs to SARS-Cov-2: Multiple B cell targets



COVID-19 human neutralising antibodies in complex with the SARS-CoV-2 spike RBD

Classes 1 – 3 are neutralising; class 1 & 2 block ACE2 binding

Grey is Receptor Binding Domain

Multiple sites on the protein are targets for Ab

Not all sites are equally targeted – dominance of some and they may not be protective

Multiple B cells target the same site

The targets that provide immunity is unknown to the system - so use neutralising ones in vaccine, if known

A single aa change in the target can negate a class of Ab

Barnes et al. Nature 2020

Doherty Institute

A joint venture between The University of Melbourne and The Royal Melbourne Hospital

Institute for Infectious Diseases

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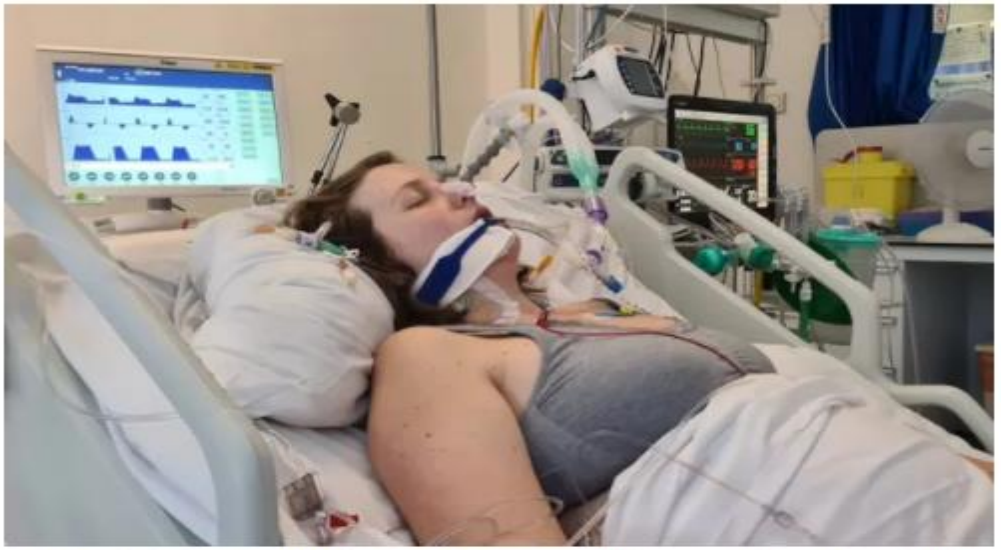
Search
The Guardian
For 200 years
Australian edition

One in six most critically ill NHS Covid patients are unvaccinated pregnant women

NHS England release statistics after evidence Covid can cause serious problems for mothers-to-be and their babies

- Coronavirus - latest updates
- See all our coronavirus coverage



NHS England is keen to persuade pregnant women to get fully vaccinated to minimise health risks. Photograph: NHS England/PA

One in six Covid patients requiring the NHS's highest form of life-saving care are unvaccinated pregnant women, new figures reveal.

Twenty of the 118 patients with Covid who received extra corporeal membrane oxygenation (Ecmo) between July and September were mothers-to-be, NHS England said.

Of these, 19 had not had a jab and the other had only had one dose of a vaccine.

Vaccination requirements for workers

Some workers are required to have a COVID-19 vaccination to go to work. Check the rules below.

Last updated: 25 February 2022

Education and care workers

Aged care workers and others who work in or enter aged care facilities

Health care workers

In-home and community aged care workers and anyone providing disability services

Airport workers

Quarantine workers

Transport workers

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Education and care workers

The following education and care workers must not enter or remain on the premises of schools, early education and family/day care facilities unless they are fully vaccinated for COVID-19 or have a medical contraindication certificate:

- Anyone who carries out work or works at a government or non-government school, including teachers, administration staff, and maintenance workers.
- Anyone who carries out work or works at an early education and care facility, for example, early childhood educators at a pre-school, day care facility, or family day care premises, administration staff and maintenance workers.
- Contractors, volunteers or students on student placement performing work at schools or early education and care facilities
- Workers who provide a disability support service at a government or non-government school or early education and care facility, if a working with children check is required
- Authorised persons carrying out work in relation to the registration of children for home schooling
- Adjudicators and staff working as part of the Higher School Certificate examinations.

Family day care residences **must not open** unless all adult residents of the premises are fully vaccinated for COVID-19.

Evidence of vaccination or exemption

A person who works in a school, early education or family/day care facility may be asked to produce evidence of their vaccination status by their employer or the occupier of a premise or the approved provider of education and care service.

Evidence of vaccination includes your:

- online **immunisation history statement**
- COVID-19 digital certificate via the Service NSW app
- COVID-19 digital certificate via the **Australian Immunisation Register**
- medical contraindication certificate
- medical clearance form.

Evidence of your **medical exemption** must be from a medical practitioner in the form approved by the NSW Chief Health Officer.

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Australian Government
Department of Health

ATAGI

Australian Technical Advisory Group on Immunisation

ATAGI expanded guidance on acute major medical conditions that warrant a temporary medical exemption relevant for COVID-19 vaccines

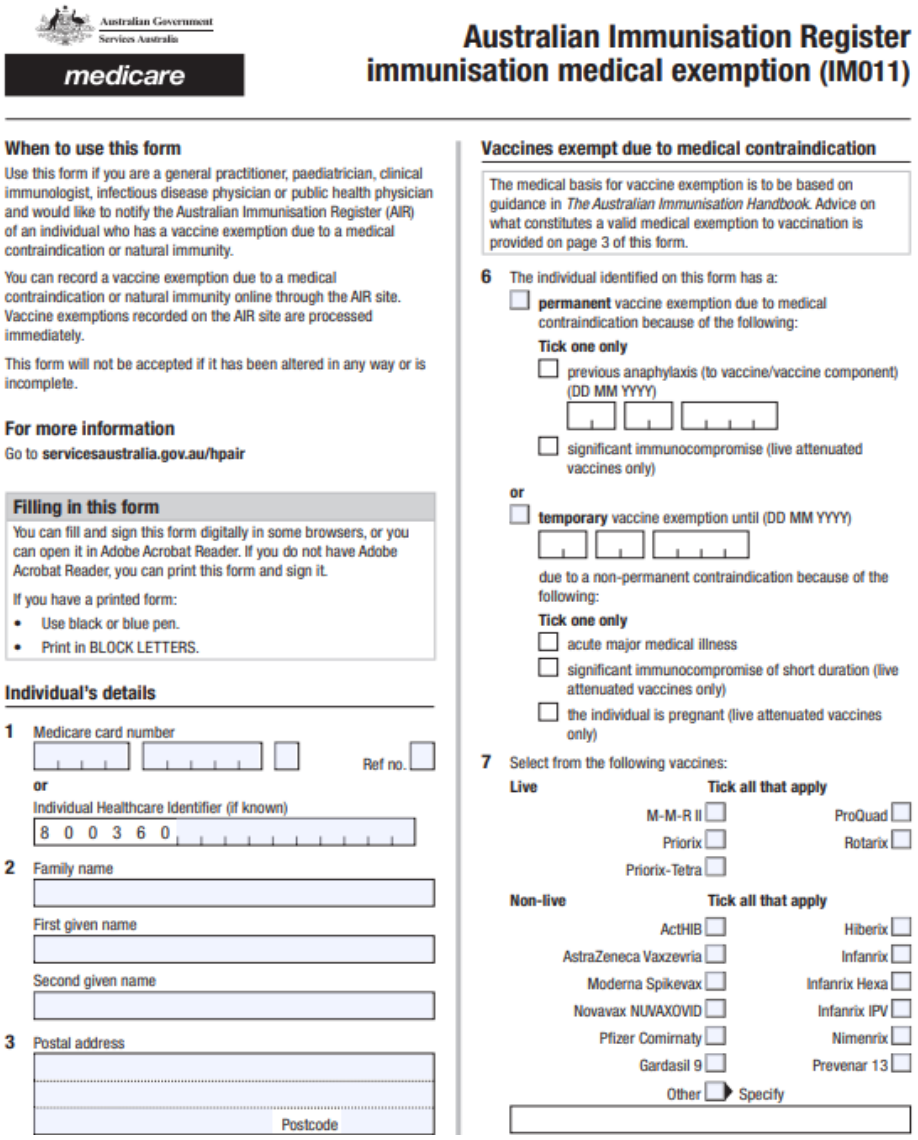
Updated: 25 February 2022

What's changed:

Rapid antigen tests (that where possible have been reported to the relevant State or Territory reporting system) are now considered acceptable proof of infection for the purposes of a temporary medical exemption to delay vaccination.

The time frame for temporary deferral of vaccination following SARS-CoV-2 infection has been updated from 6 months to 4 months.

The below guidance is prepared to support completion of the Australian Immunisation Register immunisation medical exemption (IM011) form. Guidelines for immunisation medical exemption are available at: www.servicesaustralia.gov.au/im011.



Australian Government
Services Australia

medicare

Australian Immunisation Register immunisation medical exemption (IM011)

When to use this form

Use this form if you are a general practitioner, paediatrician, clinical immunologist, infectious disease physician or public health physician and would like to notify the Australian Immunisation Register (AIR) of an individual who has a vaccine exemption due to a medical contraindication or natural immunity.

You can record a vaccine exemption due to a medical contraindication or natural immunity online through the AIR site. Vaccine exemptions recorded on the AIR site are processed immediately.

This form will not be accepted if it has been altered in any way or is incomplete.

For more information

Go to **servicesaustralia.gov.au/hpair**

Filling in this form

You can fill and sign this form digitally in some browsers, or you can open it in Adobe Acrobat Reader. If you do not have Adobe Acrobat Reader, you can print this form and sign it.

If you have a printed form:

- Use black or blue pen.
- Print in BLOCK LETTERS.

Individual's details

1 Medicare card number

Ref no.

or

Individual Healthcare Identifier (if known)

8 0 0 3 6 0

2 Family name

First given name

Second given name

3 Postal address

Postcode

Vaccines exempt due to medical contraindication

The medical basis for vaccine exemption is to be based on guidance in *The Australian Immunisation Handbook*. Advice on what constitutes a valid medical exemption to vaccination is provided on page 3 of this form.

6 The individual identified on this form has a:

permanent vaccine exemption due to medical contraindication because of the following:

Tick one only

previous anaphylaxis (to vaccine/vaccine component) (DD MM YYYY)

significant immunocompromise (live attenuated vaccines only)

or

temporary vaccine exemption until (DD MM YYYY)

due to a non-permanent contraindication because of the following:

Tick one only

acute major medical illness

significant immunocompromise of short duration (live attenuated vaccines only)

the individual is pregnant (live attenuated vaccines only)

7 Select from the following vaccines:

Live	Tick all that apply		
	M-M-R II		ProQuad
	Priorix		Rotarix
	Priorix-Tetra		

Non-live	Tick all that apply		
	ActHIB		Hiberix
	AstraZeneca Vaxzevria		Infanrix
	Moderna Spikevax		Infanrix Hexa
	Novavax NUVAXOVID		Infanrix IPV
	Pfizer Comirnaty		Nimenrix
	Gardasil 9		Prevenar 13

Other Specify

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[ATAGI Expanded Guidance on temporary medical exemptions for COVID-19 vaccines (health.gov.au)]

[im011-2202en-f.pdf]

Temporary Medical Exemption

- For an mRNA COVID-19 vaccine, **inflammatory cardiac illness** within the past 3 months
- **Acute major medical condition** (e.g. undergoing major surgery or hospital admission for a serious illness).
- SARS-CoV-2 infection, vaccination can be temporarily deferred up until 4 months after the infection. Choose the category ‘acute major medical illness’ and that it is not for a duration longer than 4 months.
- Vaccination should be deferred for 90 days in people who have received anti-SARSCoV-2 monoclonal antibody or convalescent plasma therapy.

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Temporary Medical Exemption

- Any serious adverse event attributed to a previous dose of a COVID-19 vaccine, without another cause identified, and with no acceptable alternative vaccine available.
- If the vaccinee is a risk to themselves or others during the vaccination process they may warrant a temporary vaccine exemption. This may include a range of individuals with underlying developmental or mental health disorders.
- Long Covid or Pregnancy are not contraindications.

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‘Up-to-date' vaccination status, as defined by ATAGI

Table 1: COVID-19 vaccination schedules to be considered up-to-date

Age Group		Primary dose 1 and 2[1], second dose recommended interval is vaccine brand dependent	Primary dose 3[2], usually given from 2 months after second dose	Booster dose[3] recommended from 3 months after last primary dose
General Population	5–11 years	✓	not recommended	X
	12–15 years	✓		X
	16 years and over	✓		✓[4]
Severely Immuno-compromised	5–11 years	✓	✓	X
	12–15 years	✓	✓	X
	16 years and over	✓	✓[2]	✓[2][4]
People with evidence of previous SARS-CoV-2 infection[5]	5 years and over	Completion of vaccination according to above. The next dose can be deferred for up to 4 months from the date of diagnosis of the latest infection. For some people, prioritising vaccination sooner than 4 months after infection may be warranted.		

✓: required X: not required

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Kids welcome at Belmont Hub

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- Co-administration or near administration (e.g. within days) with another vaccine
- As a general rule, healthy individuals can receive inactivated vaccines at any time before or after, or at the same time as, all other vaccines registered in Australia. Please refer to disease-specific chapters for exceptions. People can receive multiple live parenteral vaccines either at the same time or at least 4 weeks apart.

Timing of administration of other vaccines

- COVID-19 vaccines can be co-administered (that is, given on the same day) with an influenza vaccine. Studies demonstrate the safety and immunogenicity of co-administration of COVID-19 and influenza vaccines.
- COVID-19 vaccines can also be co-administered with other vaccines if required.
- This includes routine childhood and adolescent vaccines.
- There is limited evidence on the safety and effectiveness of co-administering COVID-19 vaccines at the same time as other vaccines. Providers need to balance the opportunistic need for co-administration with the benefits of giving the vaccines on separate visits. There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g. within days) with another vaccine may also make it challenging to attribute potential adverse events.[14,15] Providers should ensure that parents/guardians of young children receiving COVID-19 vaccines are aware of the increased potential for local reaction

Clinical recommendations for COVID-19 vaccines | Australian Government Department of Health

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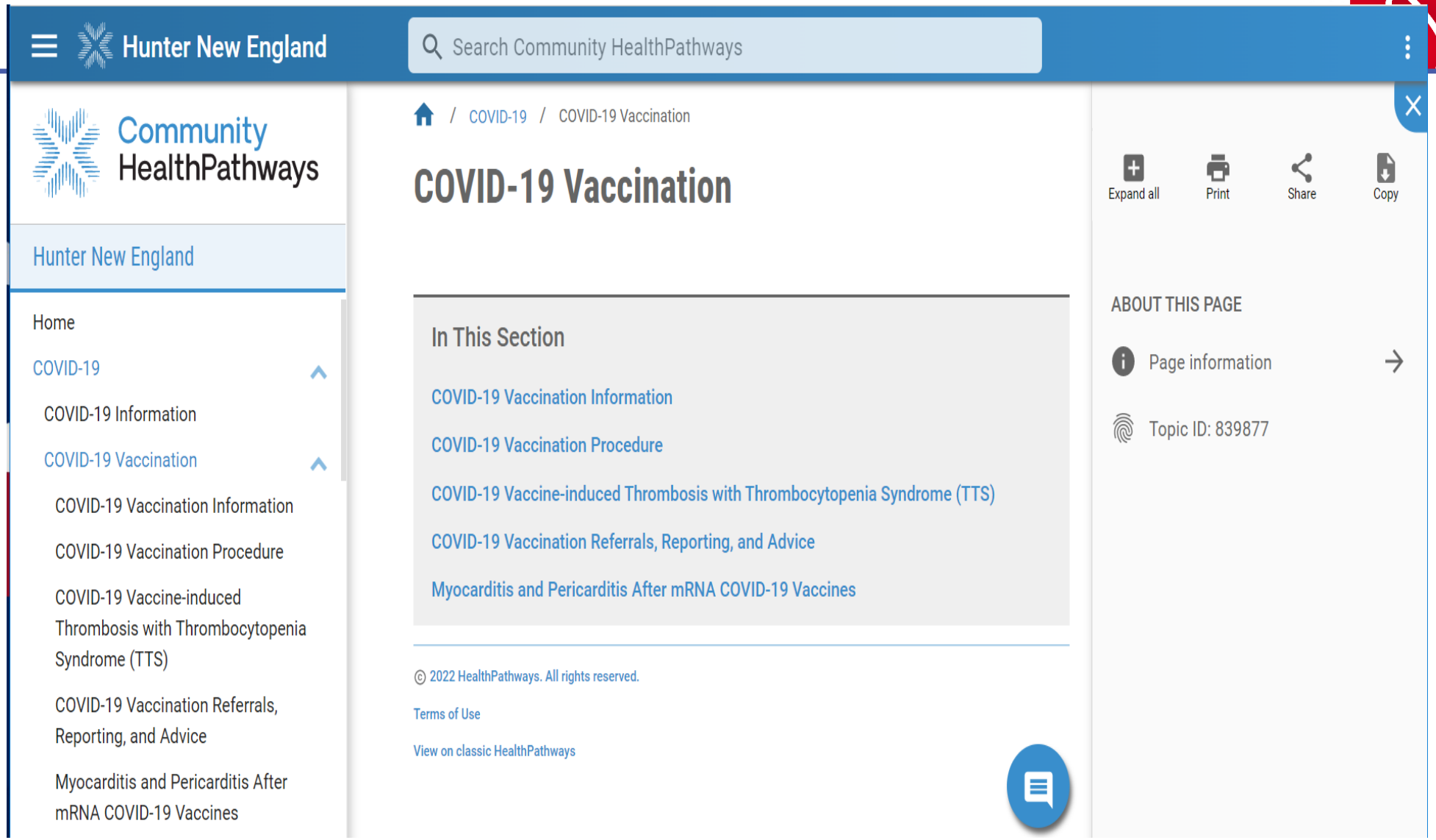

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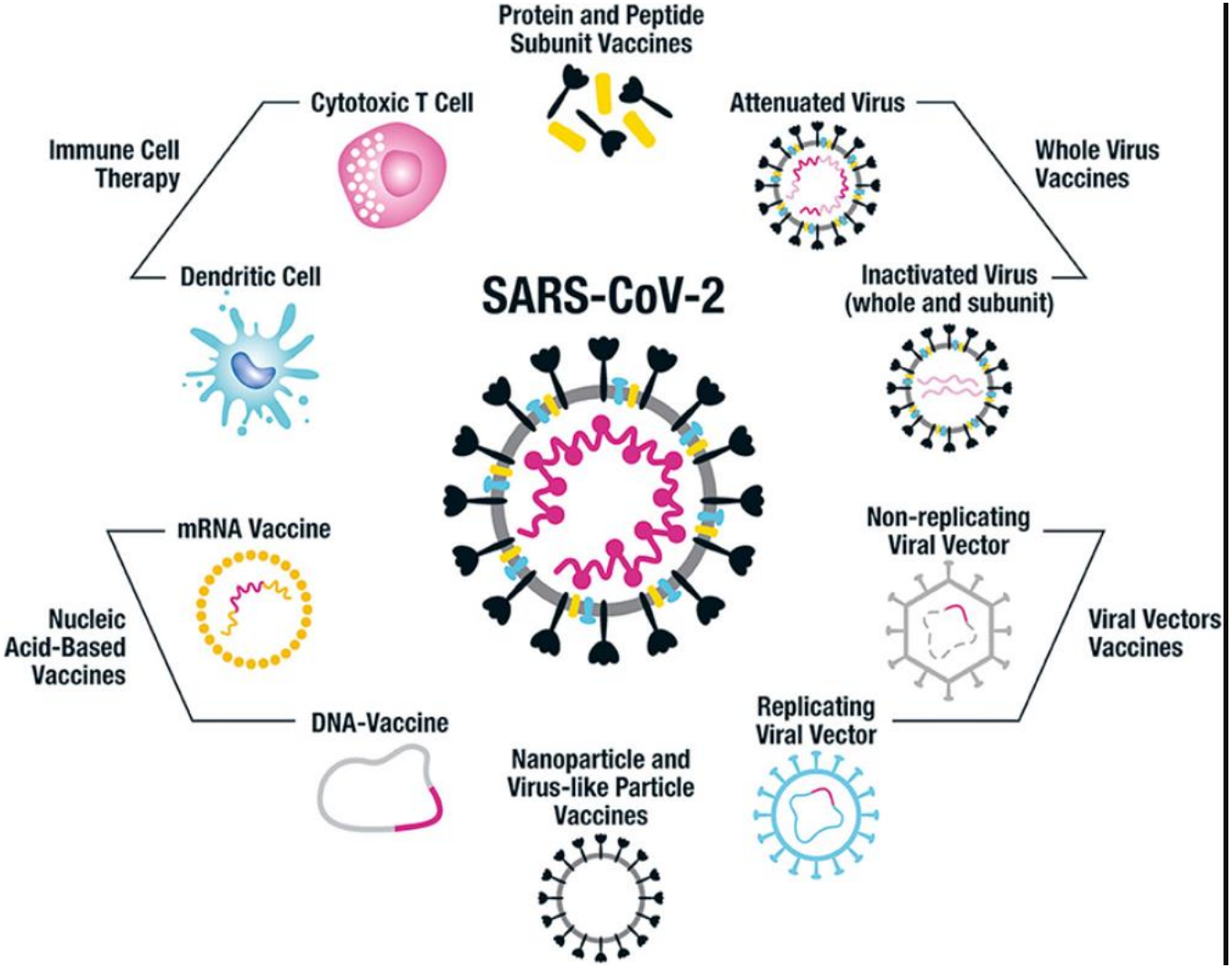
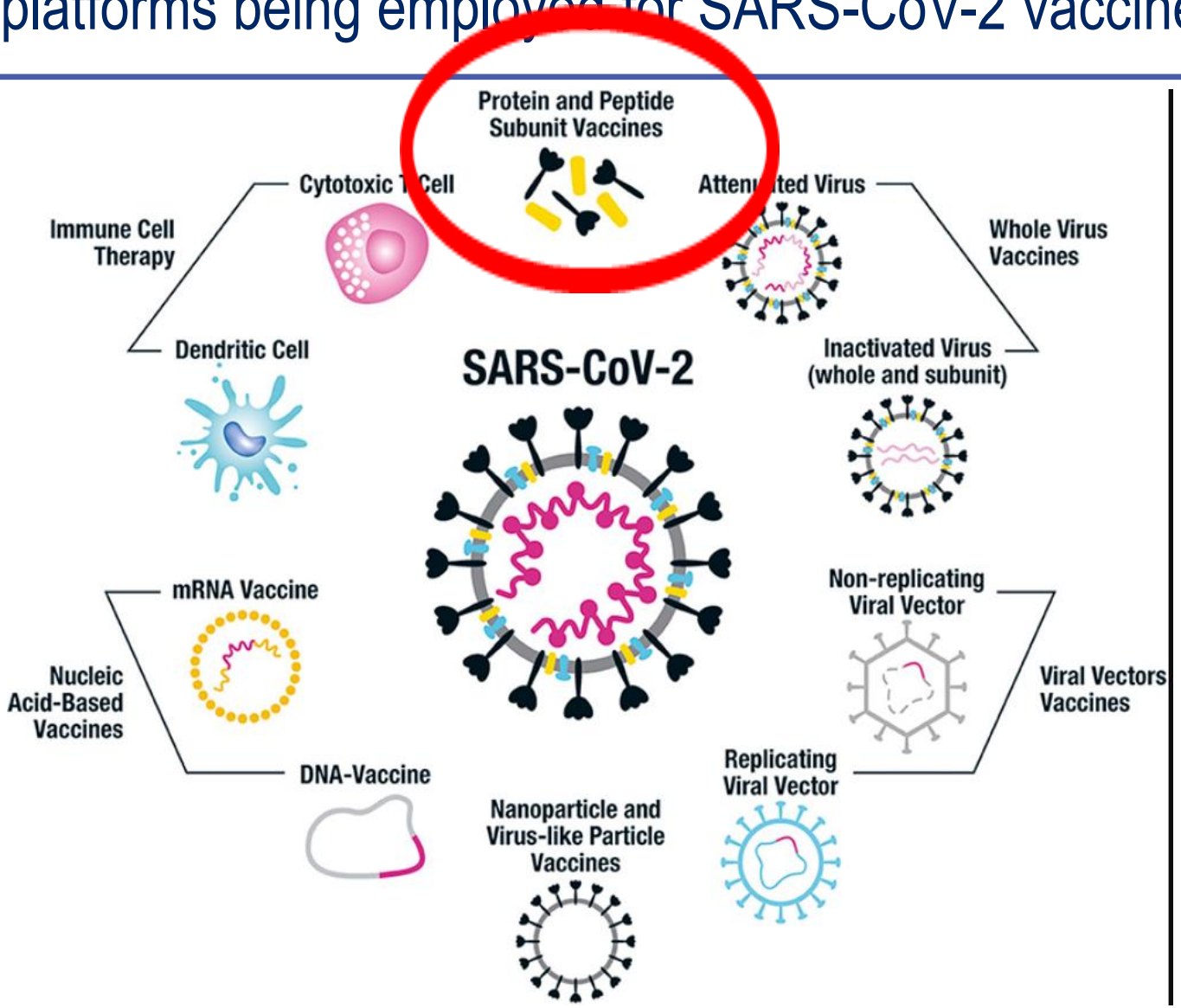
Vaccine platforms being employed for SARS-CoV-2 vaccine design



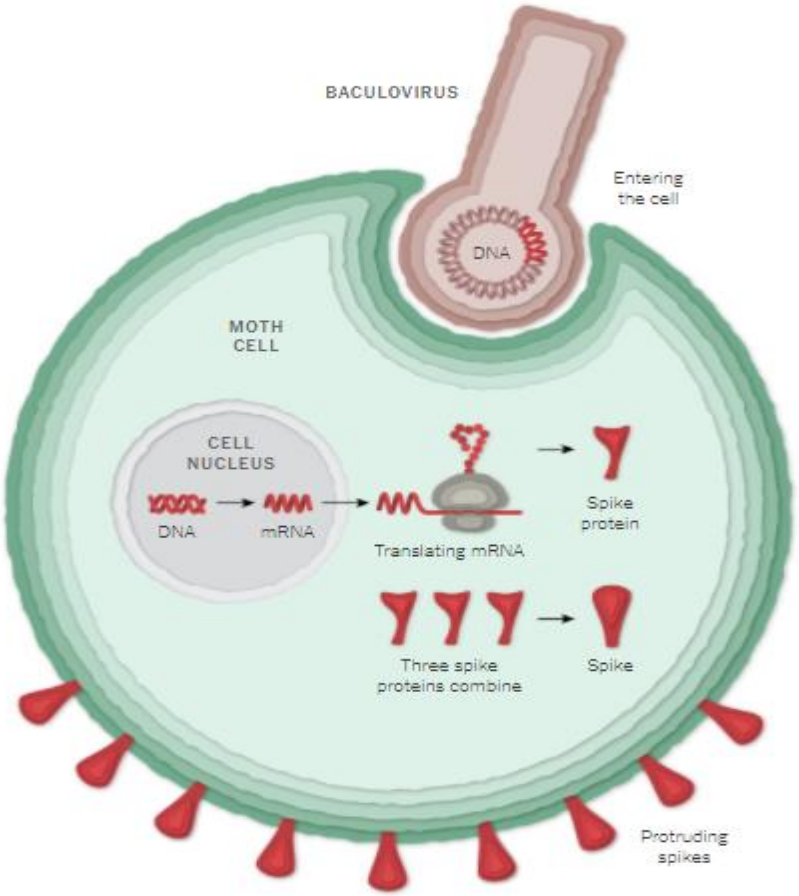
Flanagan KL, Best E, Crawford NW, Giles M, Koirala A, Macartney K, Russell F, Teh BW and Wen SCH (2020) Progress and Pitfalls in the Quest for Effective SARS-CoV-2 (COVID-19) Vaccines. Front. Immunol. 11:579250. doi: 10.3389/fimmu.2020.579250

Vaccine platforms being employed for SARS-CoV-2 vaccine design



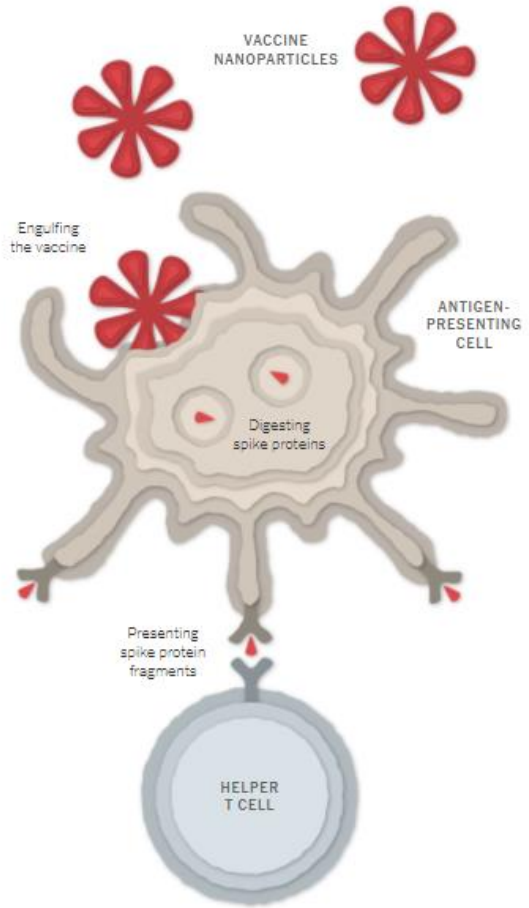
Novavax

Similar to HPV vaccine – harvesting viral proteins

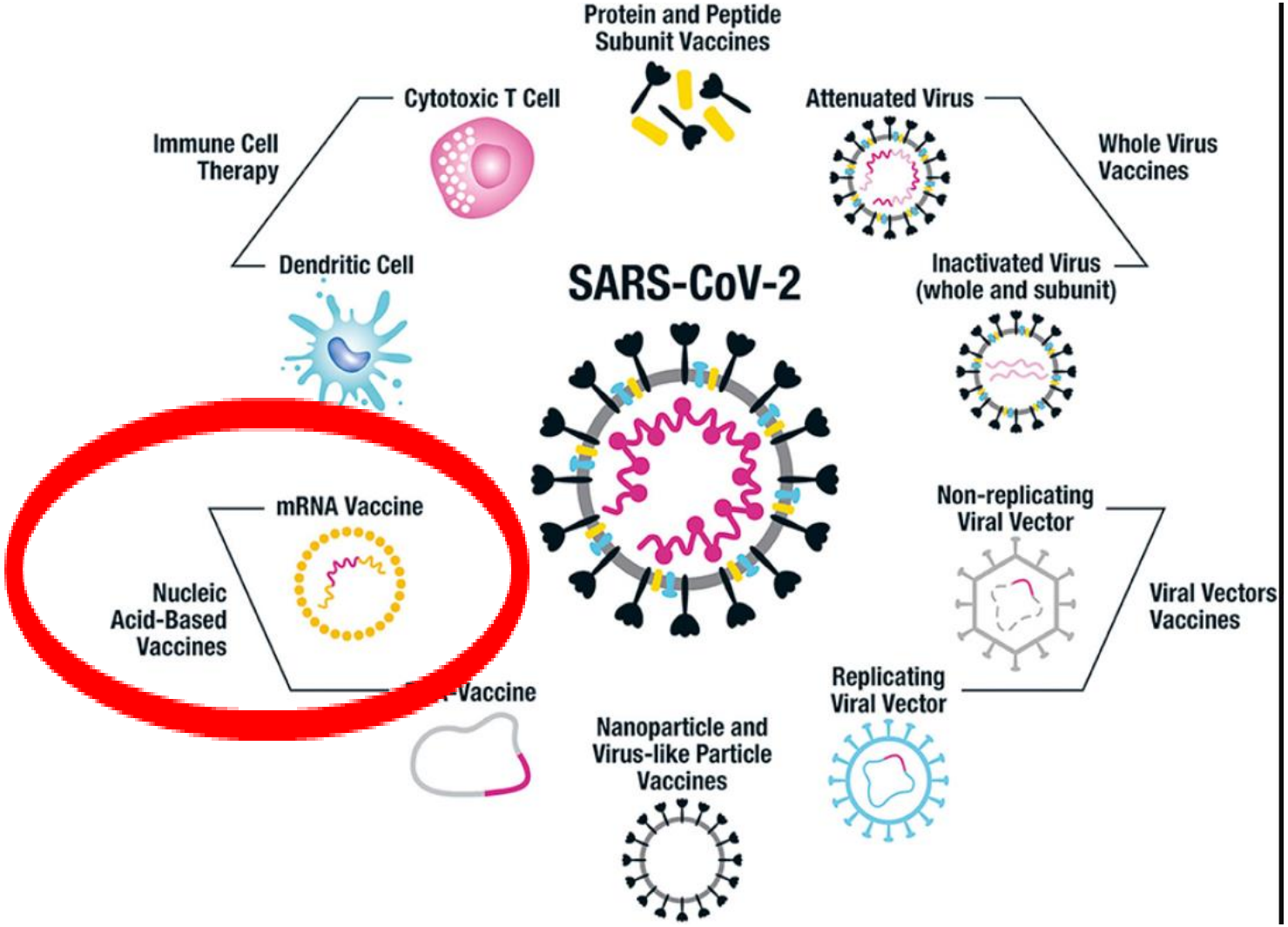


NSW GOVERNMENT

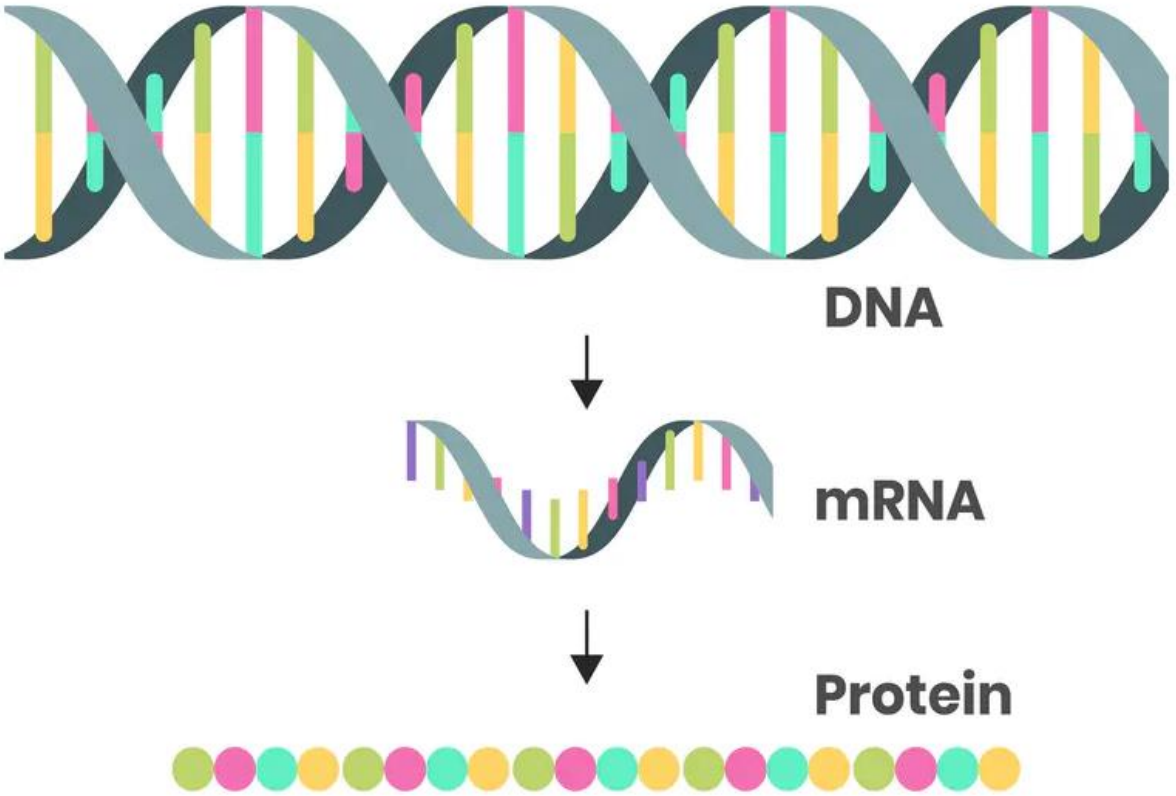
Novavax


VACCINE
NANOPARTICLES
Engulfing
the vaccine
ANTIGEN-
PRESENTING
CELL
Digesting
spike proteins
Presenting
spike protein
fragments
HELPER
T CELL

Vaccine platforms being employed for SARS-CoV-2 vaccine design



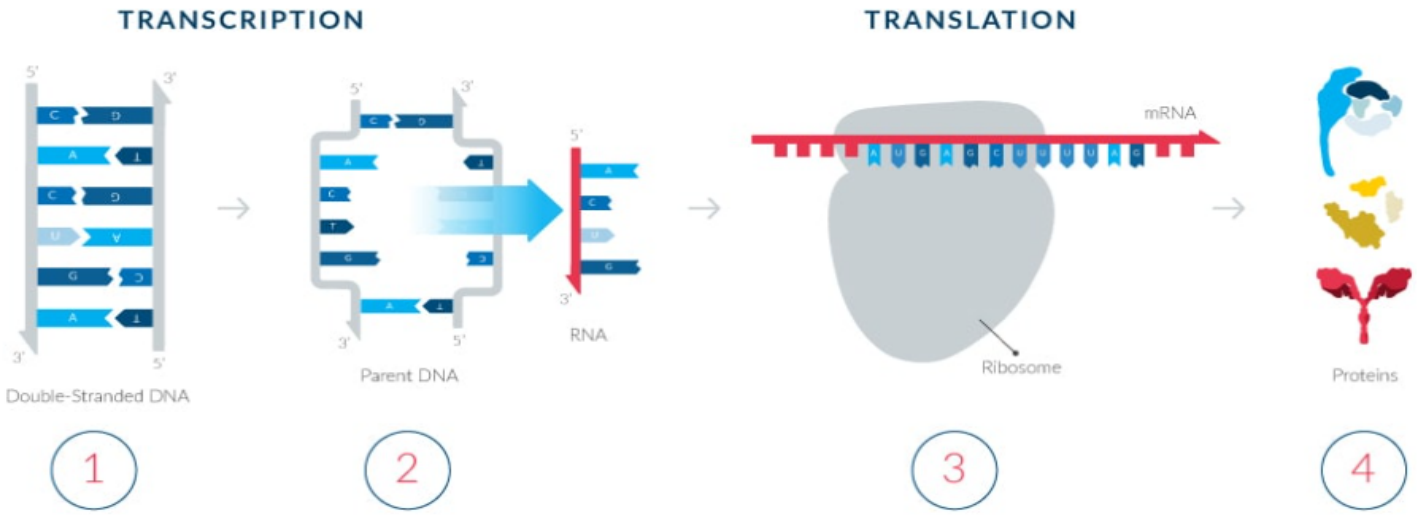
mRNA



The double-stranded DNA sequence is transcribed into an mRNA code so the instructions can be translated into proteins. AlkowiStock via Getty Images Plus

mRNA - Moderna

mRNA's role in protein synthesis



1 Through a process known as transcription, an RNA copy of a DNA sequence for creating a given protein is made.

2 This copy – mRNA – travels from the nucleus of the cell to the part of the cell known as the cytoplasm, which houses ribosomes. Ribosomes are complex machinery in the cells that are responsible for making proteins.

3 Then, through another process known as translation, ribosomes 'read' the mRNA, and follow the instructions, creating the protein step by step.

4 The cell then expresses the protein and it, in turn, carries out its designated function in the cell or the body.

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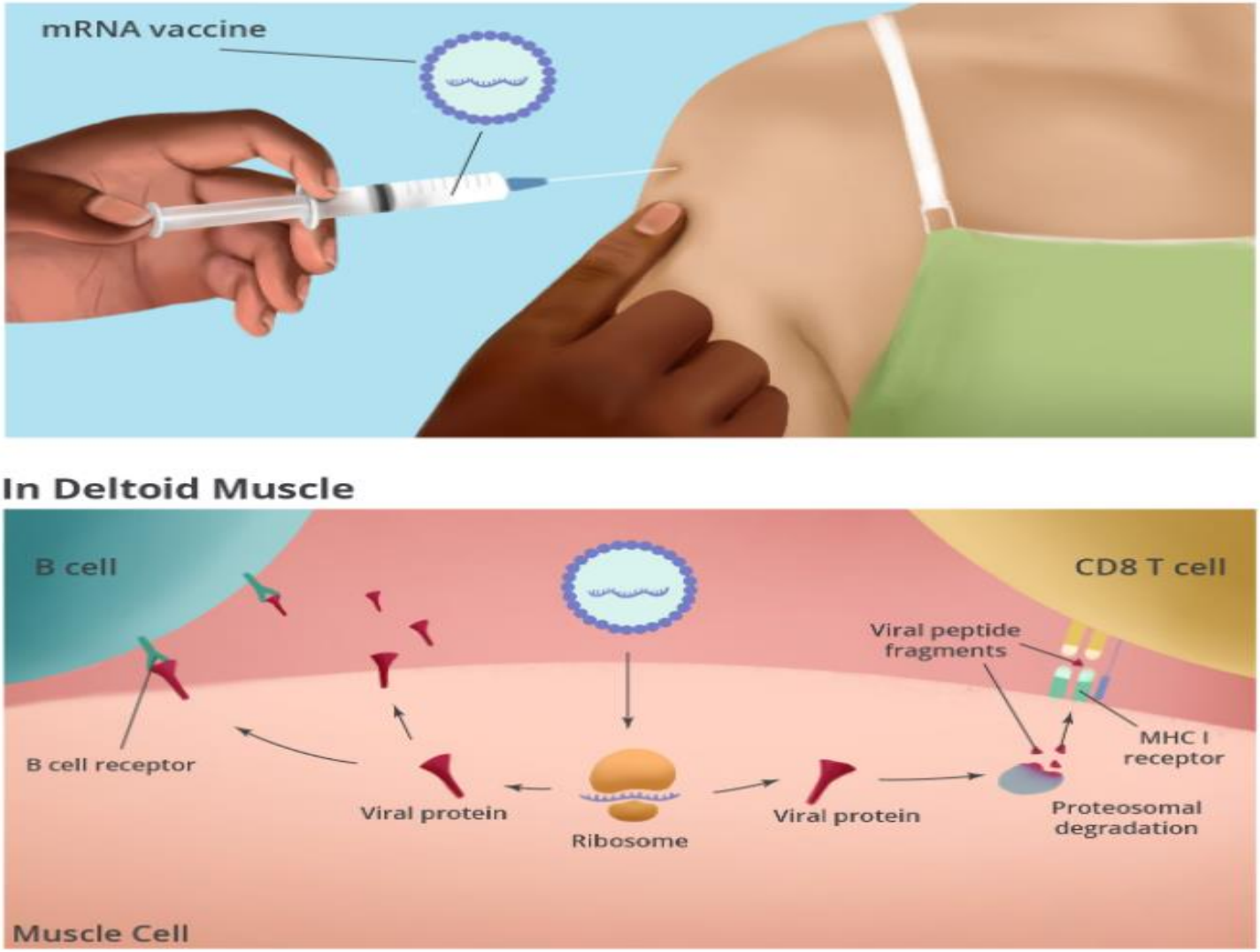
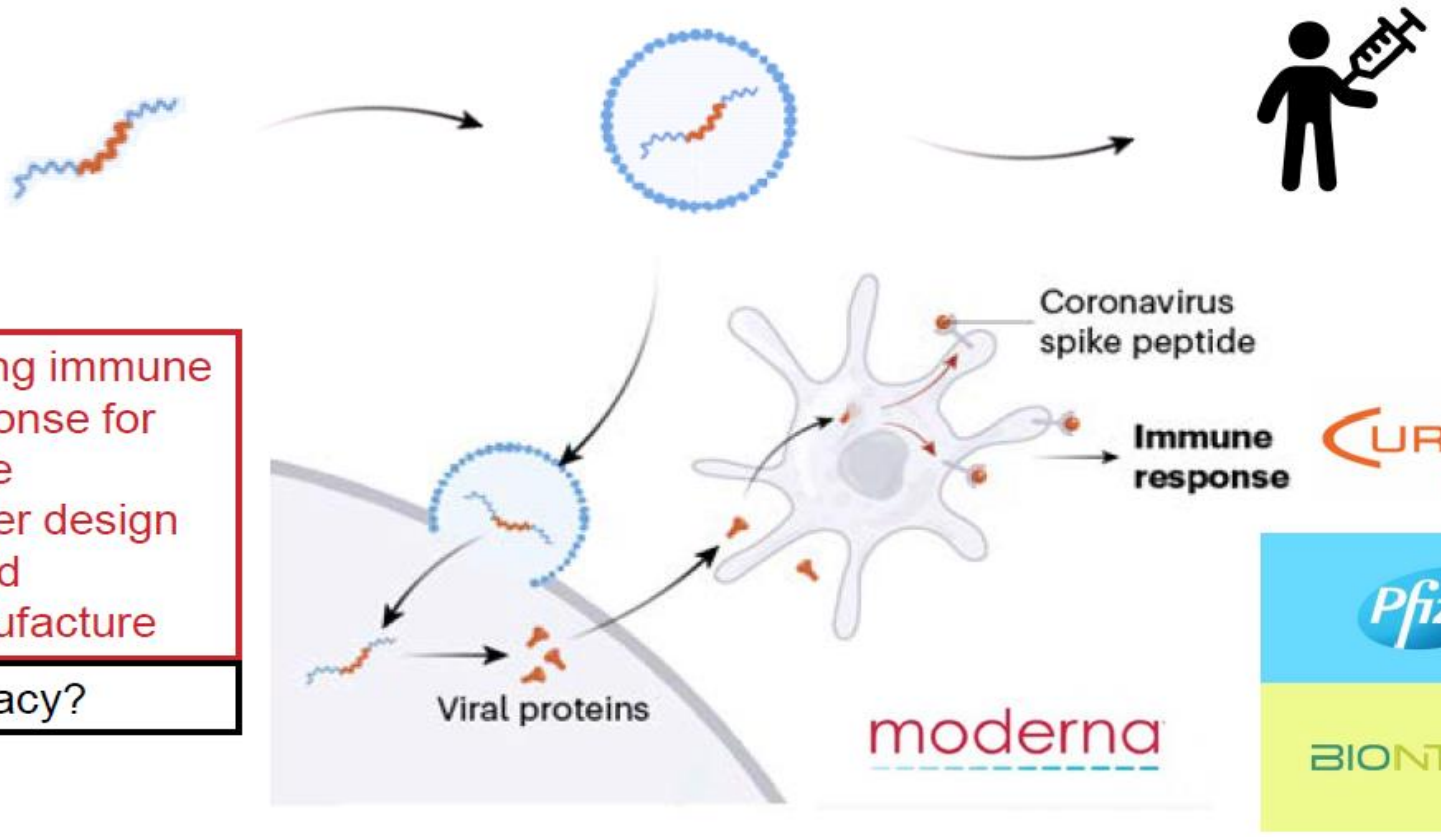
mRNA vaccine



[mRNA Vaccines for COVID-19 – How Do They Work? (ebsco.com)]

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

Ingredients mRNA vaccines

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

mRNA – Moderna's also uses mRNA technology to build antibodies against COVID-19.

Lipids

SM-102
1,2-dimyristoyl-rac-glycero3-methoxypolyethylene glycol-2000 [PEG2000-DMG]
cholesterol
1,2-distearoyl-snglycero-3-phosphocholine [DSPC]

Acids

Acetic acid

Acid Stabilizers

Tromethamine & Tromethamine hydrochloride

Salts

Sodium acetate

Sugar

Sucrose

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Molecular Therapy
Nucleic Acids
Original Article

Treatment of Hemophilia A Using Factor VIII Messenger RNA Lipid Nanoparticles

Chun-Yu Chen,[1] Dominic M. Tran,[1] Alex Cavedon,[2] Xiaohe Cai,[1] Raj Rajendran,[2] Meghan J. Lyle,[1] Paolo G.V. Martini,[2] and Carol H. Miao[1,3]

[1]Seattle Children's Research Institute, Seattle, WA, USA; [2]Moderna, Cambridge, MA, USA; [3]Department of Pediatrics, University of Washington, Seattle, WA, USA

Hemophilia A (HemA) patients are currently treated with costly and inconvenient replacement therapy of short-lived factor VIII (FVIII) protein. Development of lipid nanoparticle (LNP)-encapsulated mRNA encoding FVIII can change this paradigm. LNP technology constitutes a biocompatible and scalable system to efficiently package and deliver mRNA to the target site. Mice intravenously infused with the luciferase mRNA LNPs showed luminescence signals predominantly in the liver 4 h after injection. Repeated injections of LNPs did not induce elevation of liver transaminases. We next injected LNPs carrying mRNAs encoding different variants of human FVIII (F8 LNPs) into HemA mice. A single injection of B domain-deleted F8 LNPs using different dosing regimens achieved a wide range of therapeutic activities rapidly, which can be beneficial for various usages in hemophilia treatment. The expression slowly declined yet remained above therapeutic levels up to 5–7 days post-injection. Furthermore, routine repeated injections of F8 LNPs in immunodeficient mice produced consistent expression of FVIII over time. In conclusion, F8 LNP treatment produced rapid and prolonged duration of FVIII expression that could be applied to prophylactic treatment and potentially various other treatment options. Our study showed potential for a safe and effective platform of new mRNA therapies for HemA.

An alternative for protein replacement therapy is to utilize gene therapy to introduce a functional FVIII gene into patients for longer-term FVIII expression, thus reducing the treatment frequency while also reducing risk of spontaneous bleeding events. However, the method of delivery needs careful consideration. For example, using viruses carrying genetic material increases the risk of oncogenic mutagenesis due to viral integration.[4–6] In addition, FVIII transgene expression needs to be achieved and maintained at therapeutic levels, and sensitive genotoxicity detection assays remain yet to be developed for clinical gene therapy. Furthermore, immune responses to viral vectors and transgenes precluded its application to a significant portion of HemA patients. To avoid these problems encountered by DNA delivery using viral vectors, messenger RNA (mRNA)-based genetic materials can be used to rescue insufficient FVIII expression in HemA patients.

The advantages of mRNA therapy include no risk of oncogenic mutagenesis and rapid protein expression, as mRNAs do not translocate to the nucleus and are instead processed via translation in the cytoplasm. Recently, it was shown that functional protein was efficiently produced by using a 5-methoxy-U-modified codon-optimized mRNA successfully delivered into specific sites.[7] For example, intradermal injections of modified mRNA encoding vascular endothelial growth factor A (VEGF-A) led to local functional VEGF-A protein expression and transient skin blood flow enhancement in

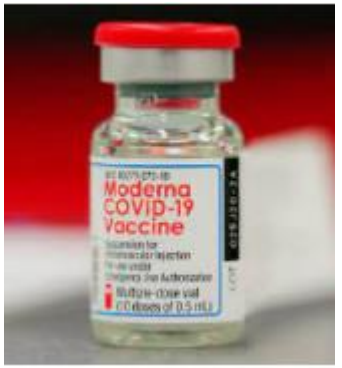
[Treatment of Hemophilia A Using Factor VIII Messenger RNA Lipid Nanoparticles (cell.com)]

Moderna's COVID-19 vaccine (SPIKEVAX) provisionally approved for use in individuals 6 years and older

2 doses at least 28 days apart

a lower dose of 0.25 mL (50 micrograms)

0.5 mL (100 microgram) dose used for those 12 years and older



Provisional approval of this vaccine for individuals 6 years and older is valid for two years. The approval is subject to certain strict conditions, such as the requirement for Moderna to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment.

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ATAGI recommendations on the use of the paediatric Pfizer COVID-19 vaccine in children aged 5 to 11 years in Australia

21 February 2022

- Third primary dose recommendations for children aged 5-11 years who are severely immunocompromised have been added

- COVID-19 vaccination can be deferred for 4 months (reduced from 6 months) following SARS-CoV-2 infection.

- The recommended schedule for vaccination in this age group is 2 doses, 8 weeks apart. Can shorten to 3 weeks.

- Two for use in adolescents (aged from 12 years) and in adults:
  - the purple top (PBS buffered formulation requiring diluent to be added; each dose 30ug in 0.3mL)
  - grey top: (Tris/sucrose buffered liquid formulation, not requiring dilution; each dose 30ug in 0.3mL)
  - One for children aged 5-11 years: (orange top: Tris/sucrose buffered requiring dilution; each dose 10ug in 0.2mL).

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Provisional registration of COVID-19 vaccine(s) in Australia

The Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA), is the body in Australia that reviews all the information required to license a vaccine in Australia. This includes a detailed dossier of all available trial information (preclinical and phases 1-3), as well as an extensive pharmacovigilance plan to be activated once the vaccine comes onto the market (phase 4 vaccine safety monitoring).

Provisional registration process

A number of sponsors of COVID-19 vaccines have applied to the TGA for registration using the so-called 'provisional approval pathway'.

The provisional pathway is only one of a number of pathways that a sponsor may use to apply for the approval of a vaccine. It allows for the temporary registration of promising medicines or vaccines based on early data, where the benefits of early access, outweigh any risks. It is very important to note that the TGA evaluation process under the 'provisional pathway' is still a full review of the vaccine and the TGA does not have a mechanism for emergency use authorisations (EUA).

Timeline: The provisional registration is for an initial period of 2-years, with the option to apply for up to two extensions, up to a maximum of 6-years. Sponsors may apply for 'full registration' when there is more clinical data to confirm the safety of the vaccine.

The TGA's provisional approval pathway consists of five steps:

1. provisional determination
2. pre-market registration
3. provisional registration period
4. extension of provisional registration (if required), and
5. transition to full registration.

[Provisional registration of COVID-19 vaccine(s) in Australia - The Melbourne Vaccine Education Centre (MVEC) (mcri.edu.au)]

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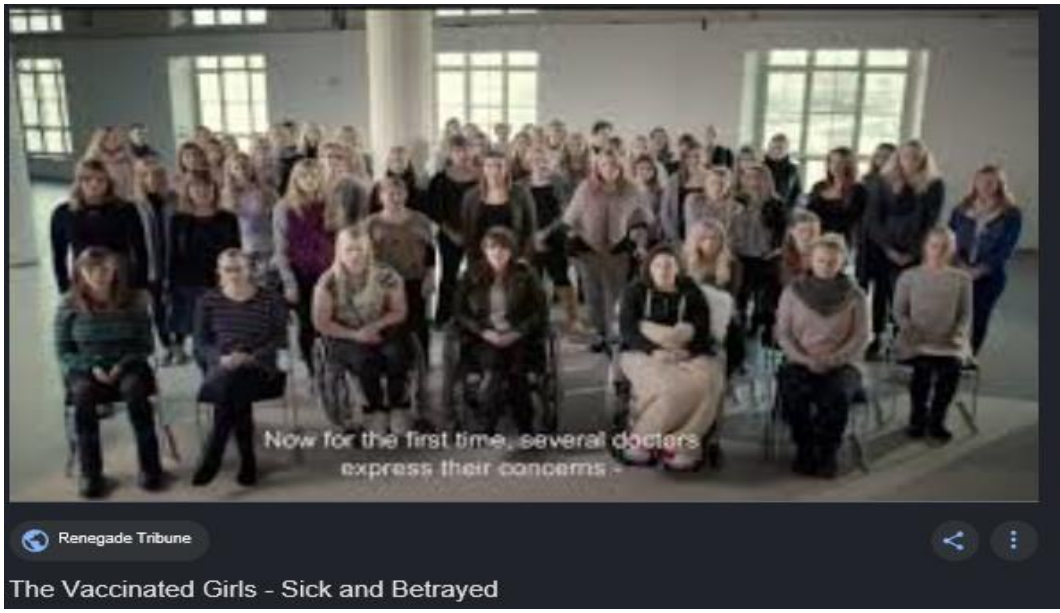
Please care for people with AEFI & notify

Canberra-based activist Michael Simms addresses a protest rally of anti-vaxxers SUPPLIED

Danish documentary



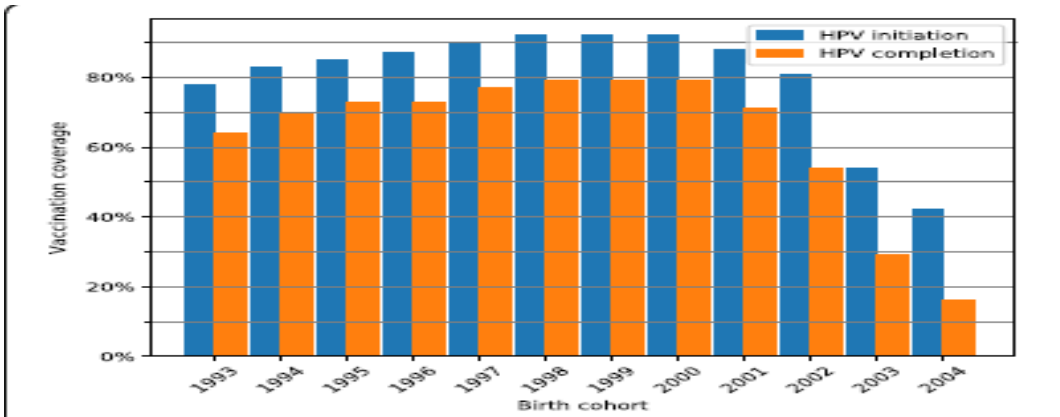
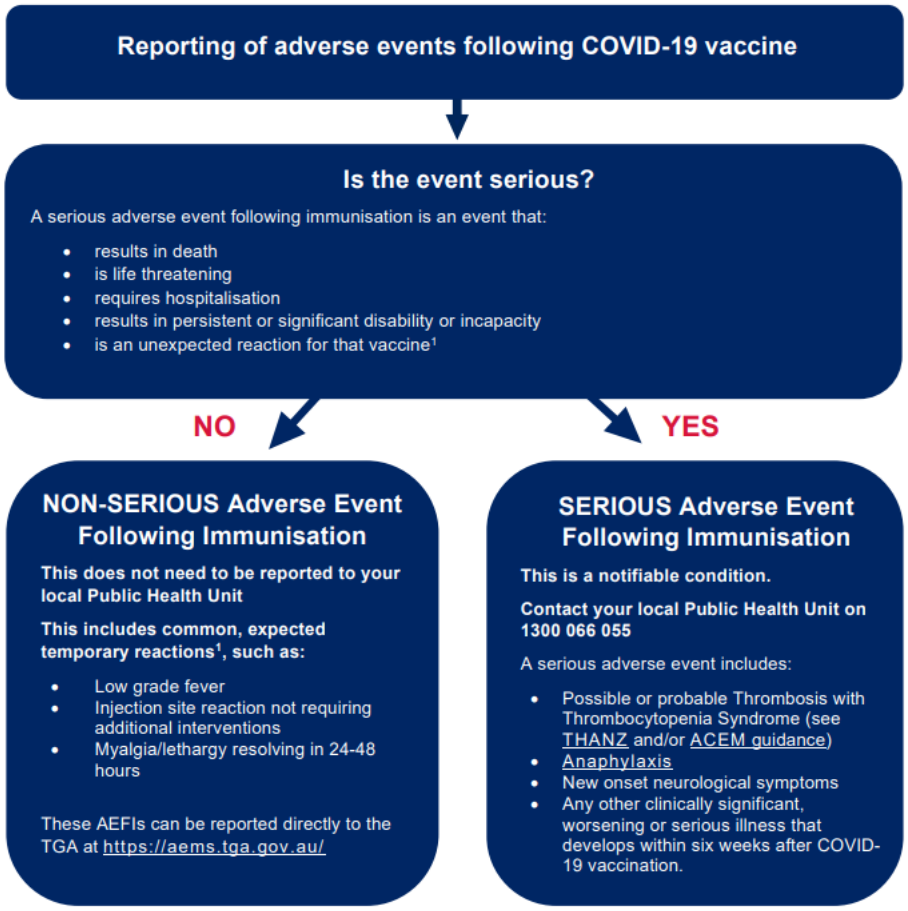


Fig. 1 HPV-vaccination in birth cohorts 1993–2003, Denmark. HPV-vaccination initiation and completion for girls in the childhood vaccination programme, Denmark birth cohorts 1993–2003. Three-dose vaccination schedule from 2009 until August 2014. Two-dose schedule from August 2014 until 14 October 2016. Data extracted June 2017

NSW GOVERNMENT

COVID-19 vaccine: Enhanced surveillance and adverse event reporting guidelines



Significant (rare) syndromes reported to date internationally include

- disorders of clotting and haemostasis
- anaphylaxis
- Bell's palsy
- Persistent lymphadenopathy
- Other new onset neurological disorders

[COVID-19 vaccine: Enhanced surveillance and adverse event reporting guidelines (nsw.gov.au)]

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Vaccine safety in children and adolescents

- To 20 February 2022, we have received about 3,600 reports from approximately 3.4 million doses of Comirnaty (Pfizer) and Spikevax (Moderna) in 12-17 year olds
- 5-11 year olds. To 20 February 2022, we have received 715 reports from approximately 1.1 million Comirnaty (Pfizer) doses administered in this age group.
- The most common reactions reported included chest pain, vomiting, fever, fainting and headache.
- 10 reports of suspected myocarditis and/or pericarditis in this age group. Following review of information in the reports, none were likely to represent myocarditis

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Australian Government
Department of Health

New item for cardiac magnetic resonance imaging (MRI) for myocarditis associated with mRNA COVID-19 vaccination - factsheet

Last updated: 16 December 2021

What are the changes?

From 1 January 2022, Medicare Benefits Schedule (MBS) item 63399 is being introduced for cardiac magnetic resonance imaging (MRI) to assist in diagnosing myocarditis that may occur after vaccination with the mRNA COVID-19 vaccines Comirnaty (Pfizer) and Spikevax (Moderna).

The item is for use in circumstances where myocarditis cannot be definitively diagnosed using conventional imaging and other diagnostic tests.

Factsheet-cardiac-MRI-myocarditis-COVID-19-vaccination.16.12.21.pdf (mbsonline.gov.au)

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Reports of death in people who have been vaccinated

- The TGA has identified 11 reports where the cause of death was linked to vaccination from 769 reports received and reviewed.
- The deaths linked to vaccination occurred after the first dose of Vaxzevria (AstraZeneca)
- 8 thrombosis with thrombocytopenia syndrome (TTS) cases,
- 2 were linked to Guillain-Barre syndrome (GBS)
- one was a ca se of immune thrombocytopenia (ITP).

COVID-19 vaccine weekly safety report - 24-02-2022 | Therapeutic Goods Administration (TGA)

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Pharmacovigilance

COVID-19 vaccine safety data - at a glance

As at 21 February 2022

6,032,282

safety surveys completed*

91,191

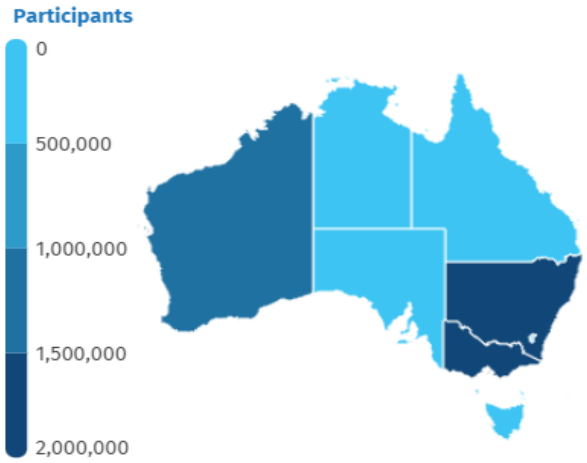
safety surveys completed by Aboriginal and Torres Strait Islander people*

44.8%

reported at least one adverse event

1.0%

reported visiting a GP or ED



* Surveys sent on Day 3 post vaccination. NOTE: Adverse events are self-reported, have not been clinically verified, and do not necessarily have a causal relationship with the vaccine.

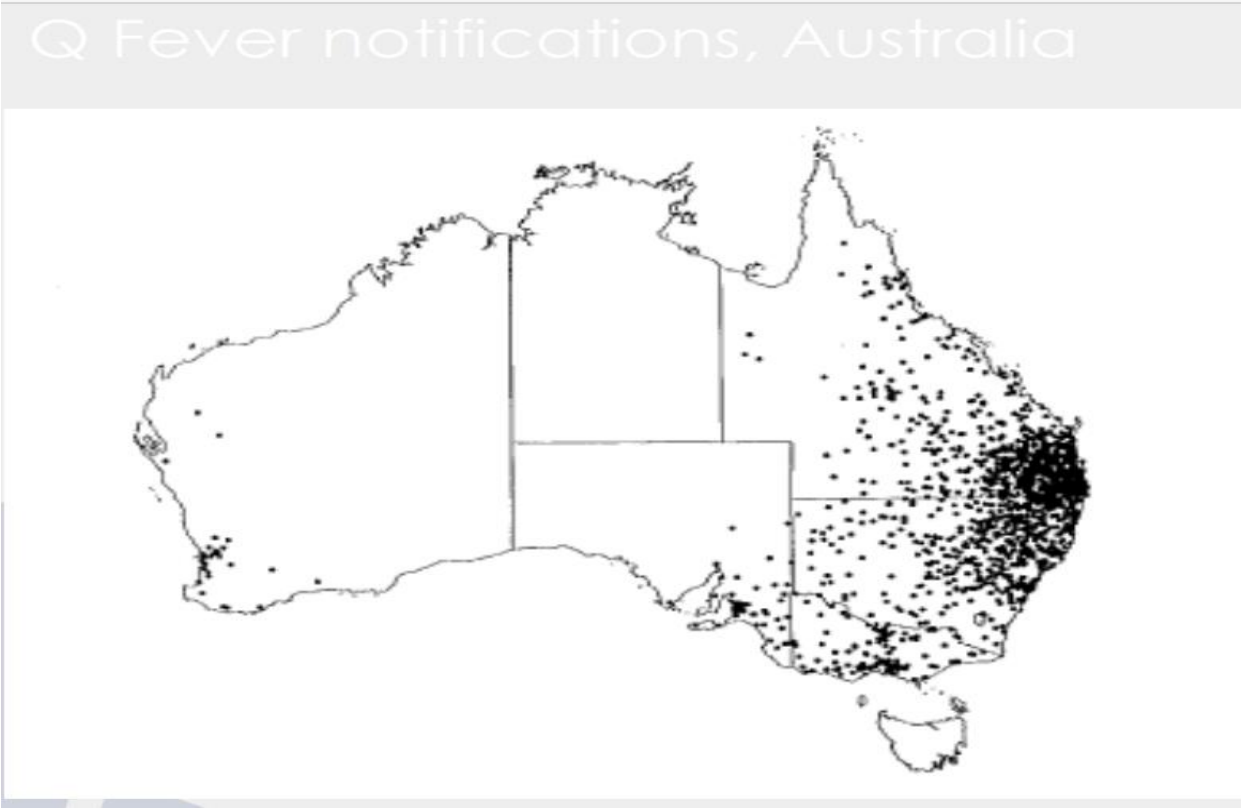
AusVaxSafety
An NCIRS led collaboration

Vaxtracker
Monitoring Vaccine Safety

AusVaxSafety
An NCIRS led collaboration

Q Fever http://www.qfeverfacts.com.au/

- Every year, more than 400 cases of Q-Fever are reported nationally.
- Each year over 200 people are hospitalised as a result of the disease, and there are at least three deaths.



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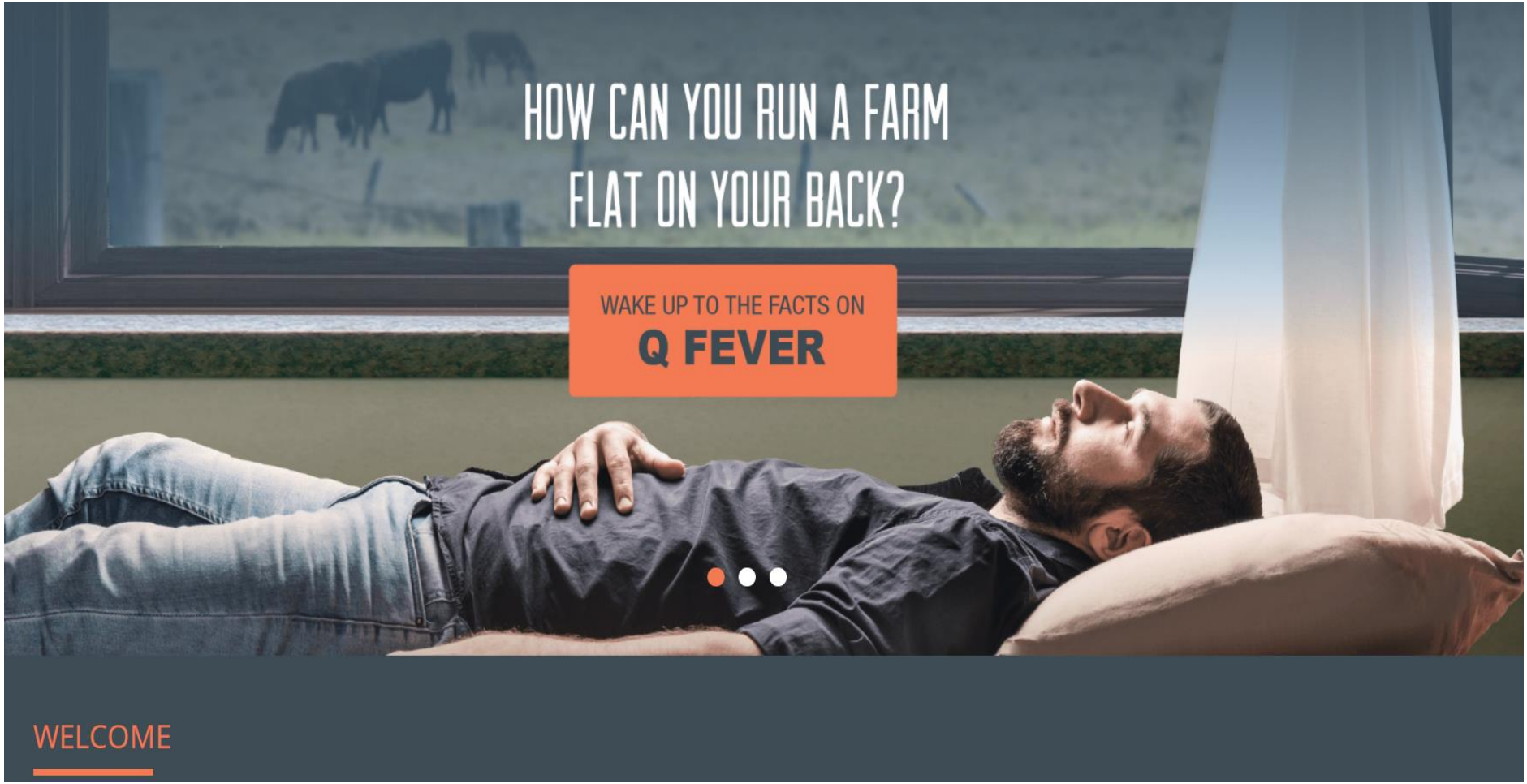
Q Fever



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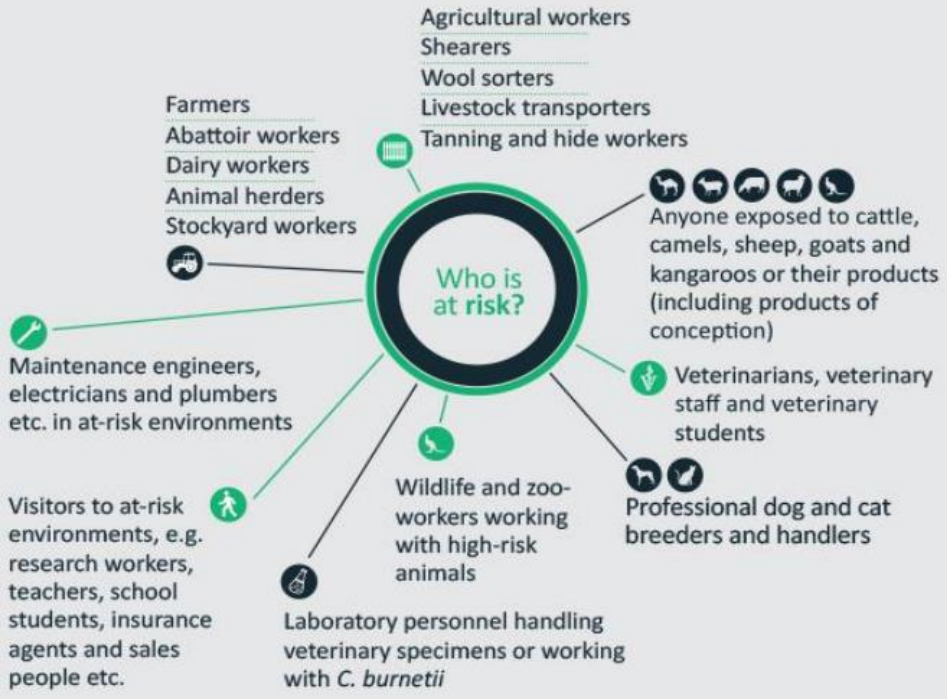
Q Fever

Who is at **risk?**

People at increased risk of Q fever infection include:



Other **considerations**

Even though Q fever is largely an occupation-associated disease, there have been many reports of exposure in the general population in proximity to infected animals in at-risk areas. Although exposure occurs mainly in men from rural areas, a recent study in Queensland, Australia found that there was a high rate of exposure among urban residents, including women and children.

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1. CHECK - if an Individual seeking vaccination has already been vaccinated.

- Ask the individual to logon to the Australian Q Fever Register (www.qfever.org) or call on 1300 733 837 (1300 QFEVER).

2. TEST - for previous exposure or vaccination.

- **Blood test** - CFT antibody test.
- **Skin test** - intradermal hypersensitivity test.

3. VACCINATE

Seven (7) days after initial tests, if both tests are negative and there are no other contraindications (e.g. allergy to eggs or the patient is a child), **vaccinate.**

Explain possible side effects of vaccination and inform patient that it takes at least two (2) weeks for the vaccine to be effective and the patient should not expose themselves to any risks until after this period.

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FluTracking
Tracking COVID-19

Weekly Interim Report: Australia
Week ending 20 February 2022
(Data received up to 09:00 AM, Thursday 24 February)

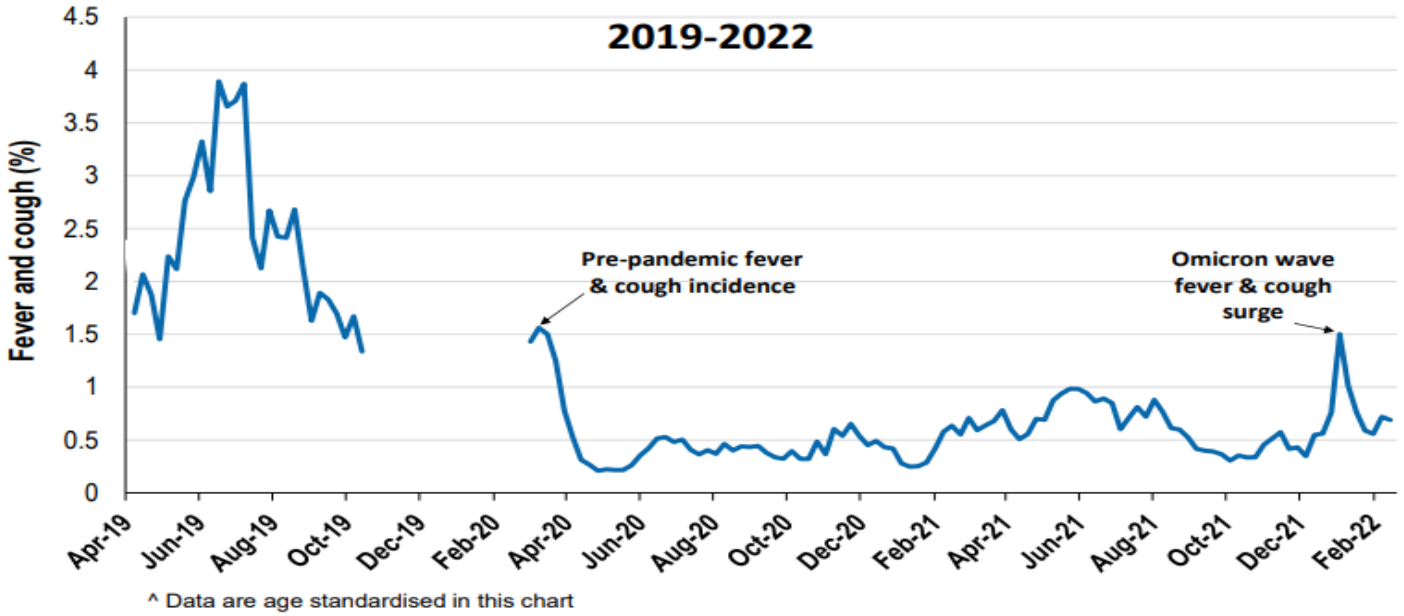
Respiratory illness levels are low, but increasing in school aged children (5-17 yrs)

58,568 participants this week

Respiratory illness activity*:

*Respiratory illness activity is defined as fever & cough for this report

0.7% this week: respiratory illness activity is low



^ Data are age standardised in this chart

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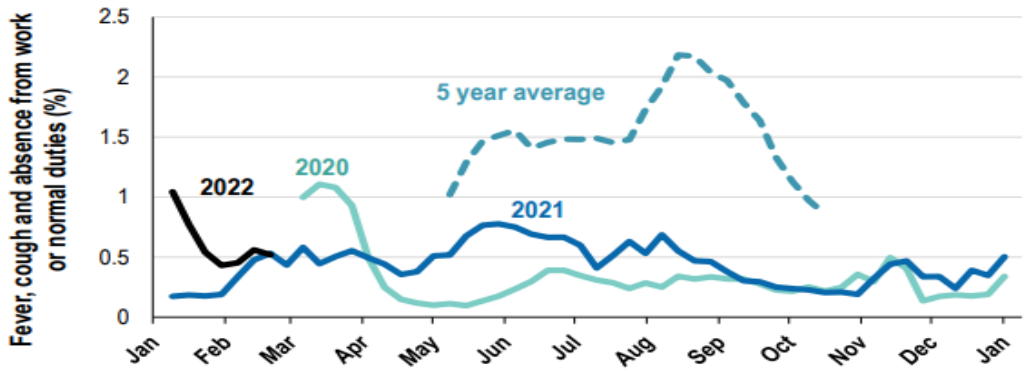
FluTracking
Tracking COVID-19

Weekly Interim Report: Australia
Week ending 20 February 2022
(Data received up to 09:00 AM, Thursday 24 February)

Fever, cough and absence from work or normal duties (Australia):

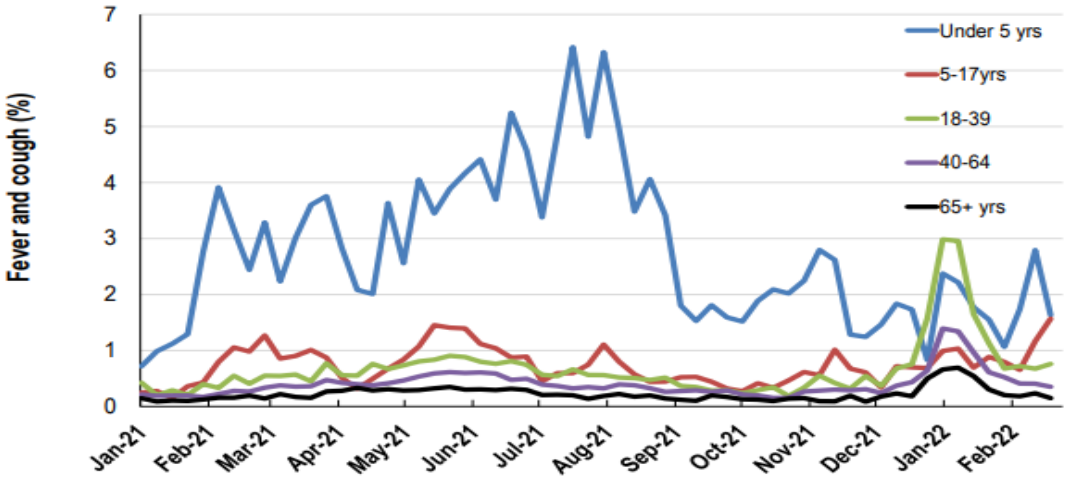


*5 year average is calculated using 2015, 2016, 2017 ,2018 and 2019 data

FluTracking
Tracking COVID-19

Weekly Interim Report: Australia
Week ending 20 February 2022
(Data received up to 09:00 AM, Thursday 24 February)

Respiratory illness activity by age group in 2021 and 2022 (Australia):



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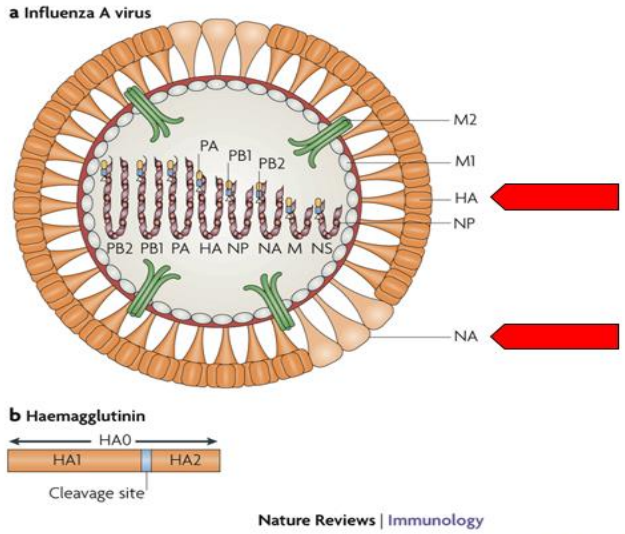
Influenza

On average, each year influenza causes

- 3,500 deaths
- 18,000 hospitalisations
- 300,000 GP consultations

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus
- an A/Darwin/9/2021 (H3N2)-like virus
- a B/Austria/1359417/2021-like (B/Victoria lineage) virus
- a B/Phuket/3073/2013-like (B/Yamagata lineage) virus



The haemagglutinin and neuraminidase are the main targets of the protective antibody response

nature REVIEWS IMMUNOLOGY

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2022 influenza vaccine presentation and free vaccine eligibility

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6 MONTHS TO LESS THAN 5 YEARS

Vaxigrip Tetra® and Fluarix® Tetra

Registered for use in people aged 6 months and over:

- All children 6 months to less than 5 years
- Give two doses one month apart for children aged 6 months to less than 5 years if first year of receiving flu vaccine
- Fluarix Tetra is available in 10 and single packs. Vaxigrip Tetra is only available in 10-dose packs.
- Children should receive a full dose (i.e. not a half dose)
- Do NOT contain latex

Ten pack dimensions:
9.7 cm (L) x 11.8 cm (H)
x 4.48 cm (W)

Ten pack dimensions:
17.8 cm (L) x 10.4 cm (W) x 4.2 cm (H)
Single pack dimensions:
13.3 cm (L) x 4.3 cm (W) x 2.4 cm (H)

5 YEARS TO 64 YEARS

Vaxigrip Tetra®, Fluarix® Tetra and Afluria® Quad

- People 5 years and over with medical risk factors predisposing to severe influenza
- All Aboriginal persons 5 years to 64 years of age
- Pregnant women
- Give two doses one month apart for children aged 5 years to less than 9 years if first year of receiving flu vaccine
- Fluarix Tetra is available in 10 and single packs. Vaxigrip Tetra and Afluria Quad are only available in a 10 pack.
- Children should receive a full dose (i.e. not a half dose)
- Do NOT contain latex
- Do not use Afluria Quad for children less than 5 years of age

Ten pack dimensions:
9.7 cm (L) x 11.8 cm (H)
x 4.48 cm (W)

Ten pack dimensions:
15.2cm (L) x 12.4cm (H)
x 4.1cm (W)

Ten pack dimensions:
17.8 cm (L) x 10.4 cm (W) x 4.2 cm (H)
Single pack dimensions:
13.3 cm (L) x 4.3 cm (W) x 2.4 cm (H)

65 YEARS AND OVER

Fluad® Quad

- Adjuvanted quadrivalent vaccine
- All persons aged 65 years and over
- Milky-white suspension
- Available in 10 packs
- Does NOT contain latex
- Do not use in pregnant women or children

Ten pack dimensions:
15.4 cm (L) x 13 cm (H)
x 2.3 cm (W)

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Ordering influenza vaccines

The timing of NIP influenza vaccine availability may be different to the availability of privately purchased influenza vaccines.

- The pre-allocation confirmation process will open on Monday 7th March. Providers who do not approve their pre-allocated order in time, can place an online order through the usual process, once online ordering opens. Only online orders are accepted. An influenza vaccination provider toolkit with information about the pre-allocation process will shortly be available.
- The first order may be delivered over a couple of deliveries. Each delivery received must be confirmed as received on the online vaccine ordering system. This includes pharmacies receiving NIP stock of influenza vaccine for people aged 65 years and over.
- Once a complete order of influenza vaccines has been received and the provider has confirmed receipt, a subsequent order can be placed (if required).
- Restrictions may be placed on the number of influenza vaccine doses that can be ordered and these may change over time based on vaccine supply and demand.
- Only order enough vaccines required for use in a maximum 4-week period. This helps to ensure that enough quantities of vaccine are available to all providers.
- **Vaccination clinics should only be scheduled once vaccines have been received.**
- Keep vaccines in their original cardboard packaging to protect them from light and temperature changes.
- **Please ensure that free influenza vaccines are only given to eligible people (see 'Eligibility for free influenza vaccine' below).**

Vaccine hesitancy

Also

Fragile and vulnerable settings

Weak primary health care

Which also contribute to under-vaccination

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Invisible Ink Could Reveal whether Kids Have Been Vaccinated

The technology embeds immunization records into a child's skin

By Karen Weintraub on December 18, 2019

M.I.T. engineers have developed a way to store medical information under the skin, using a quantum dot dye that is delivered, along with a vaccine, by a microneedle patch. The dye, which is invisible to the naked eye, can be read later using a specially adapted smartphone. Credit: Second Bay Studios

The Center for Countering Digital Hate is a not-for-profit NGO that seeks to disrupt the architecture of online hate and misinformation.

Analysis of a sample of anti-vaccine content that was shared or posted on Facebook and Twitter a total of 812,000 times between 1 February and 16 March 2021 shows that 65 percent of anti-vaccine content is attributable to the Disinformation Dozen.

Heuristics

- People use heuristics to process risk information.
- These are mental shortcuts that allow them to make rapid judgements when dealing with large volumes of information.
- Values they bring to weighing risks
- Give risks more weighting if highly publicised
- Some people anticipate negative emotions because of a decision and thus avoid taking that course (“anticipated regret”)
- People prefer to accept an outcome from doing nothing (not getting vaccinated) than an outcome from doing something (vaccinating) (“omission bias”),
- Avoid taking risks when the outcome is uncertain (“ambiguity aversion”).
- Determines how people think, feel and act on risk.

Communicating with patients and the public about COVID-19 vaccine safety: recommendations from the Collaboration on Social Science and Immunisation | The Medical Journal of Australia (mja.com.au)

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Potential social processes underpinning vaccine hesitancy

- Vaccine hesitancy for some people is mediated by their experiences of social exclusion.
- Mistrust of government, undermined social connectedness.
- These experiences led many marginalized people to distrust vaccination, to resist vaccination as a form of agency.

Full article: Vaccine hesitancy in the era of COVID-19: could lessons from the past help in divining the future? (tandfonline.com)

NSW GOVERNMENT

5 antivax radio hosts dead from Covid in US

Dangerous transmissions: anti-vax radio shows reach millions in US while stars die of Covid

Media watchdogs suggest that some basic level of responsibility to the public should be required to keep a broadcast license

▲ Phil Valentine died of Covid after mocking the vaccines. Photograph: Larry McCormack/AP

Phil Valentine, a prominent Tennessee rightwing talk radio host, had released a song called Vaxman, an anti-Covid vaccination ditty based on the Beatles track Taxman.

Marc Bernier, a host in Daytona Beach, Florida, had declared himself "Mr Anti-Vax". Dick Farrel, also from Florida, urged his listeners not to get vaccinated, and Jimmy DeYoung asked on air whether the vaccine could be a "form of government control of the people".

All four men died in August of coronavirus. A fifth conservative radio host, Bob Enyart, died on 13 September, weeks after he told his listeners to boycott vaccines that were "immorally developed".

[Dangerous transmissions: anti-vax radio shows reach millions in US while stars die of Covid | US news | The Guardian]

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Vaccinating Kids is BAU

Chris Staples

NSW GOVERNMENT