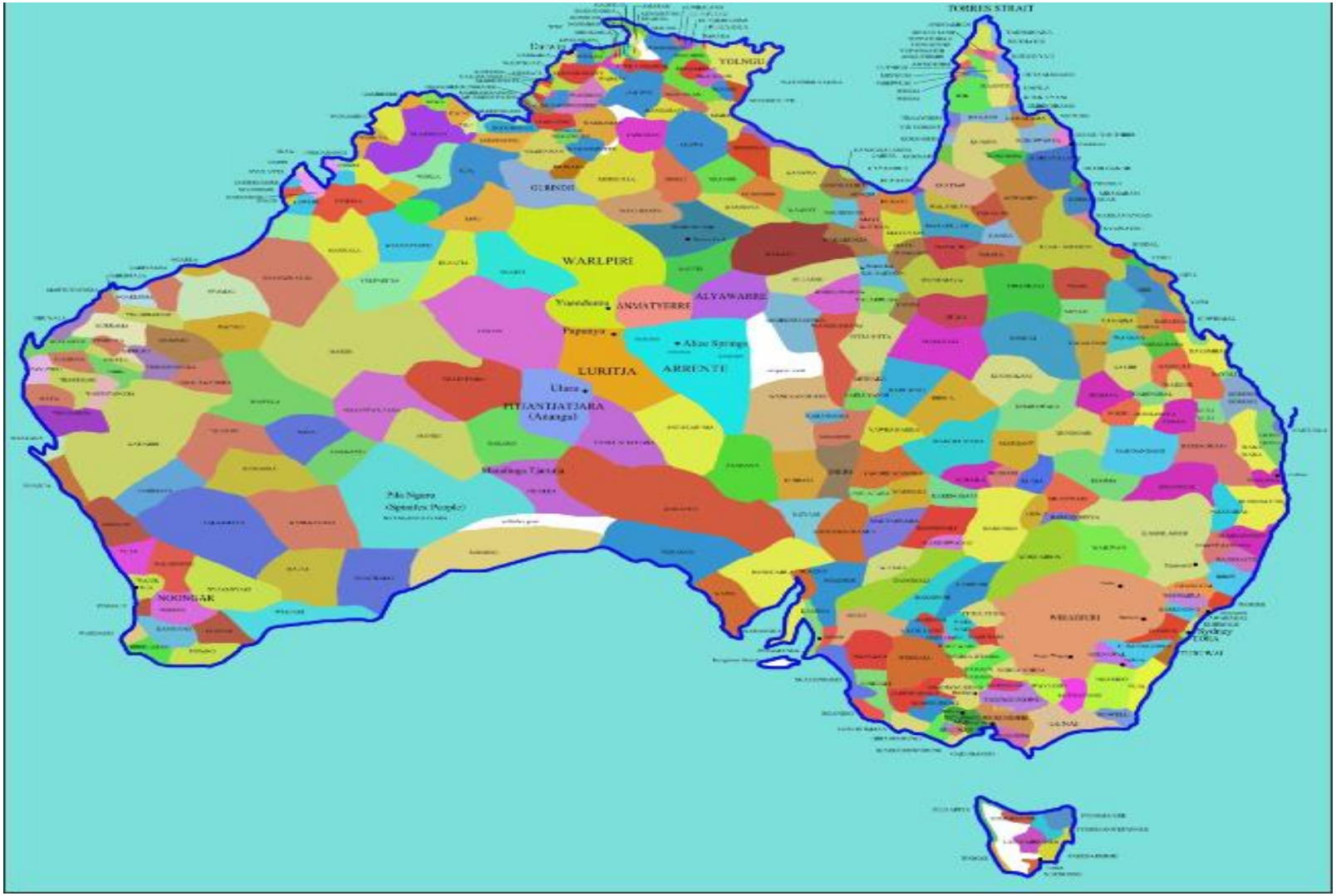
NSW GOVERNMENT Health
Hunter New England
Local Health District

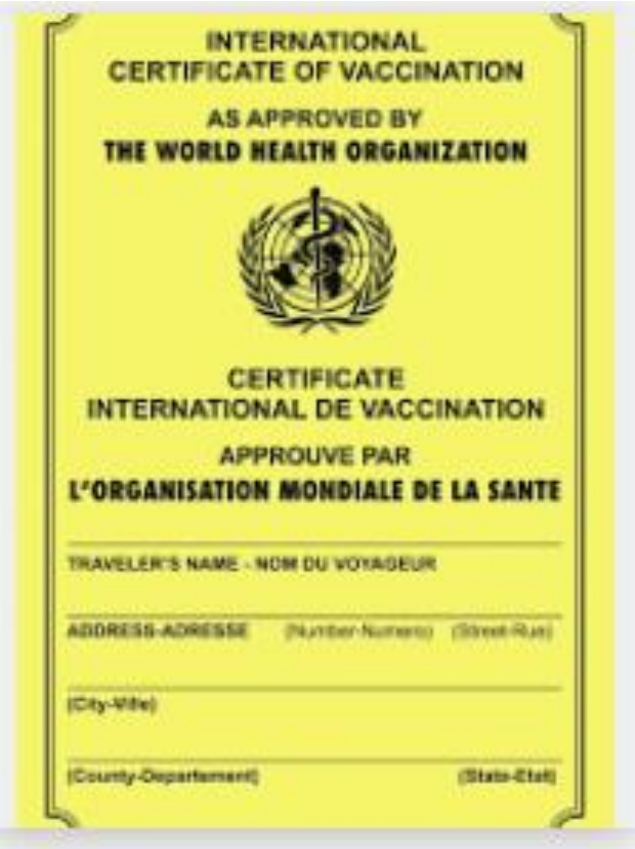
PHN Covid vaccine Sept 2021

patrick (paddy) cashman

Always Was, Always Will Be



Vaccination for travel


INTERNATIONAL
CERTIFICATE OF VACCINATION

AS APPROVED BY
THE WORLD HEALTH ORGANIZATION

CERTIFICATE
INTERNATIONAL DE VACCINATION

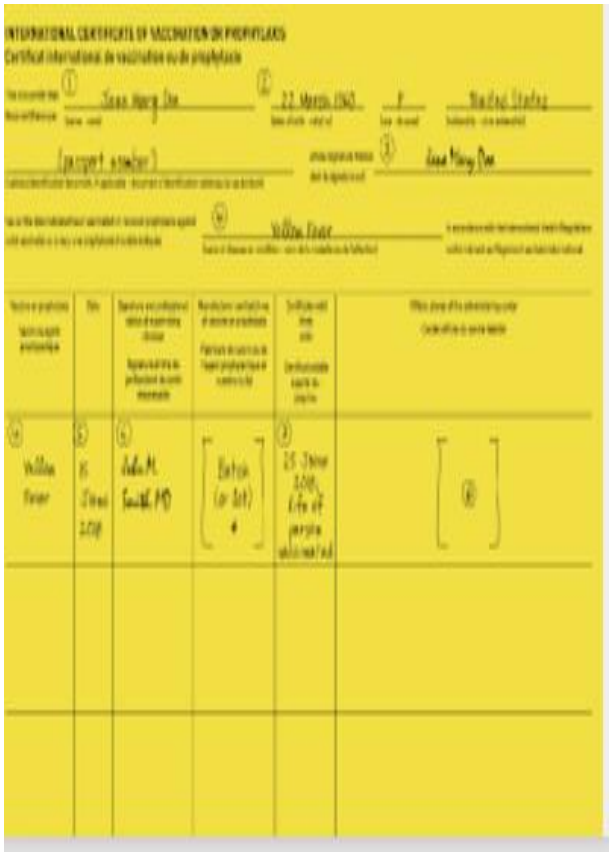
APPROUVE PAR
L'ORGANISATION MONDIALE DE LA SANTE

TRAVELER'S NAME - NOM DU VOYAGEUR

ADDRESS-ADRESSE (Number-Numero) (Street-Rue)

(City-Ville)

(County-Department) (State-Etat)



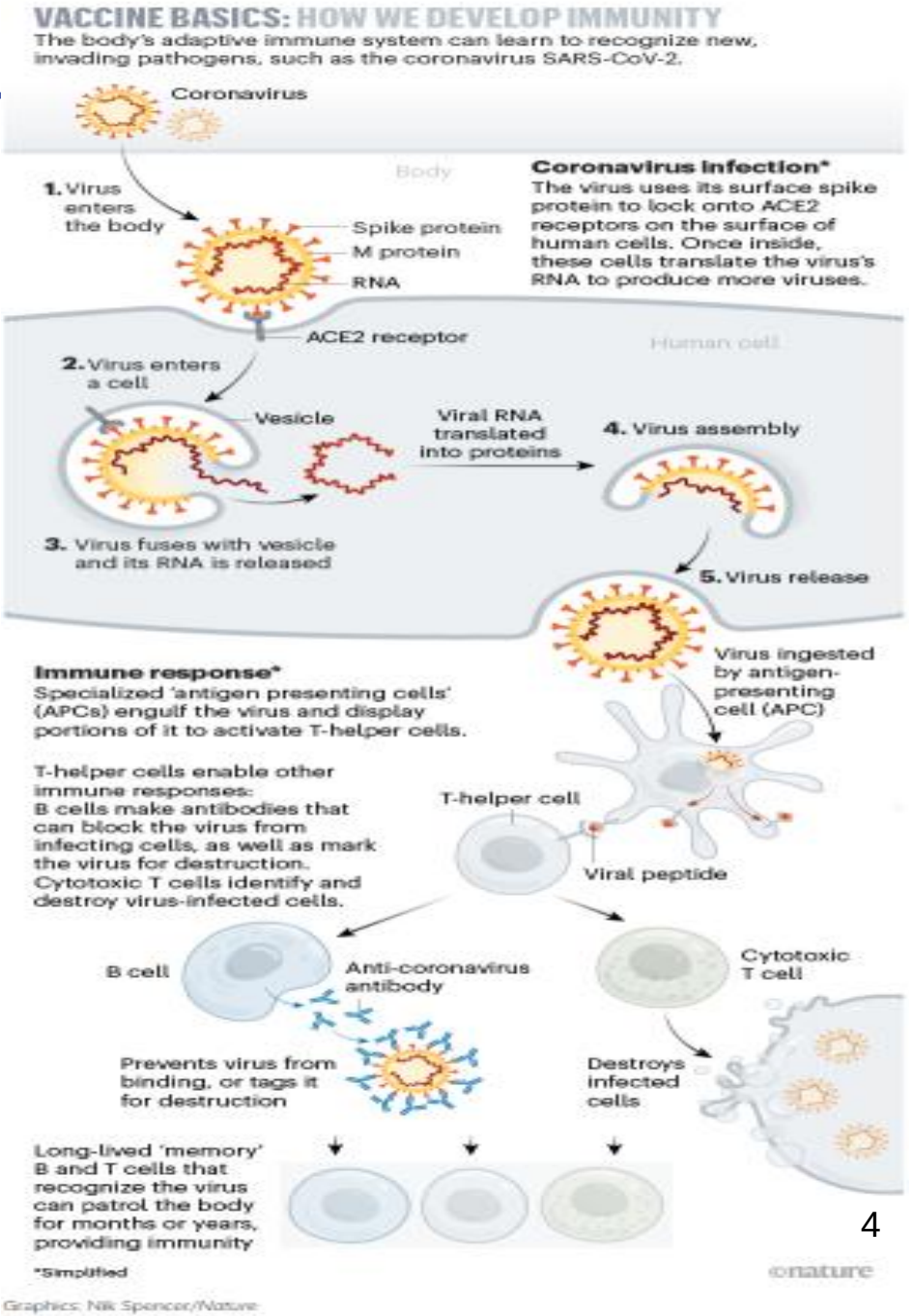
NEWS FEATURE · 28 APRIL 2020

The race for coronavirus vaccines: a graphical guide

Eight ways in which scientists hope to provide immunity to SARS-CoV-2 .

Ewen Callaway

https://www.nature.com/articles/d41586-020-01221-y



NSW GOVERNMENT Health
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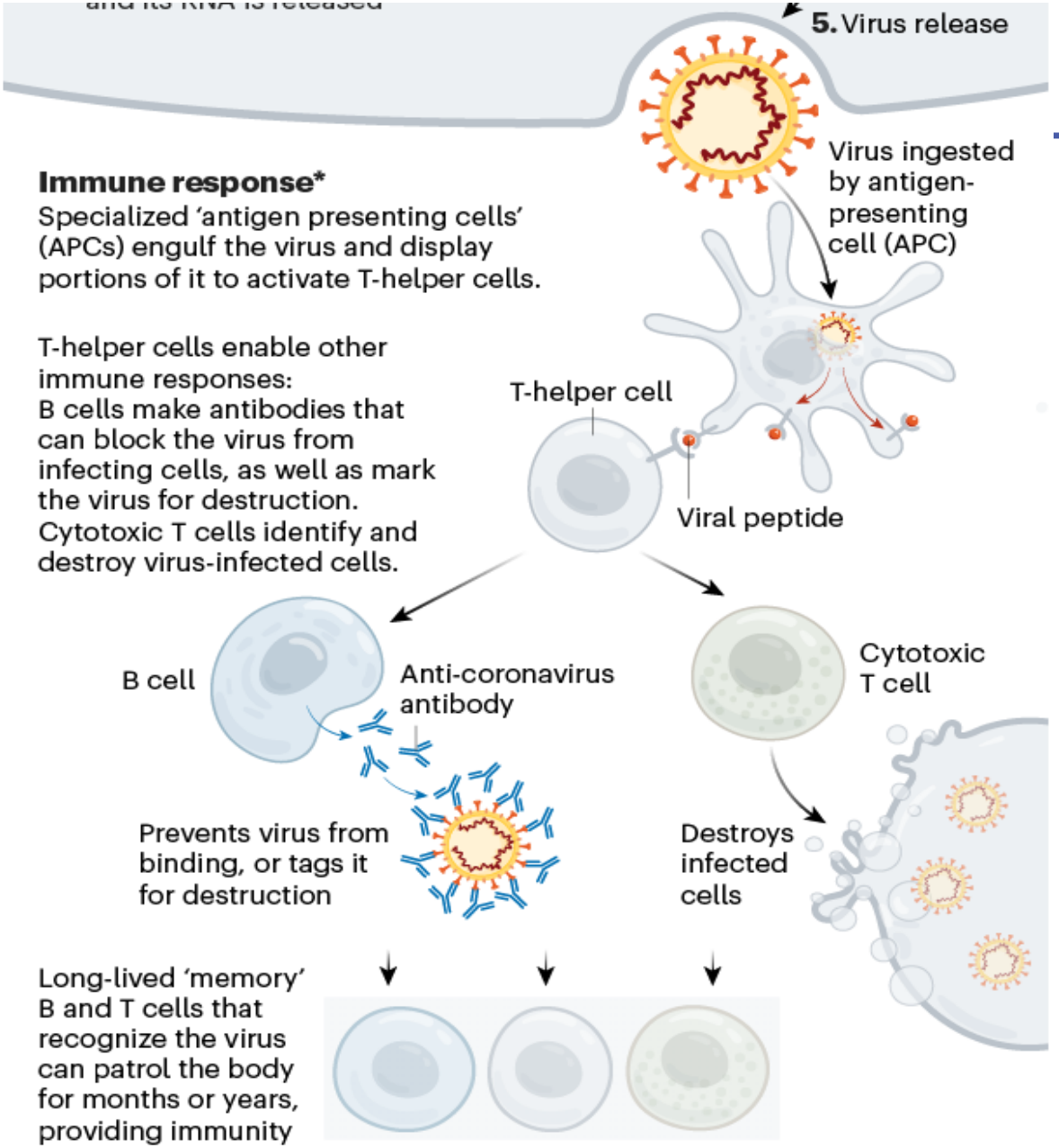
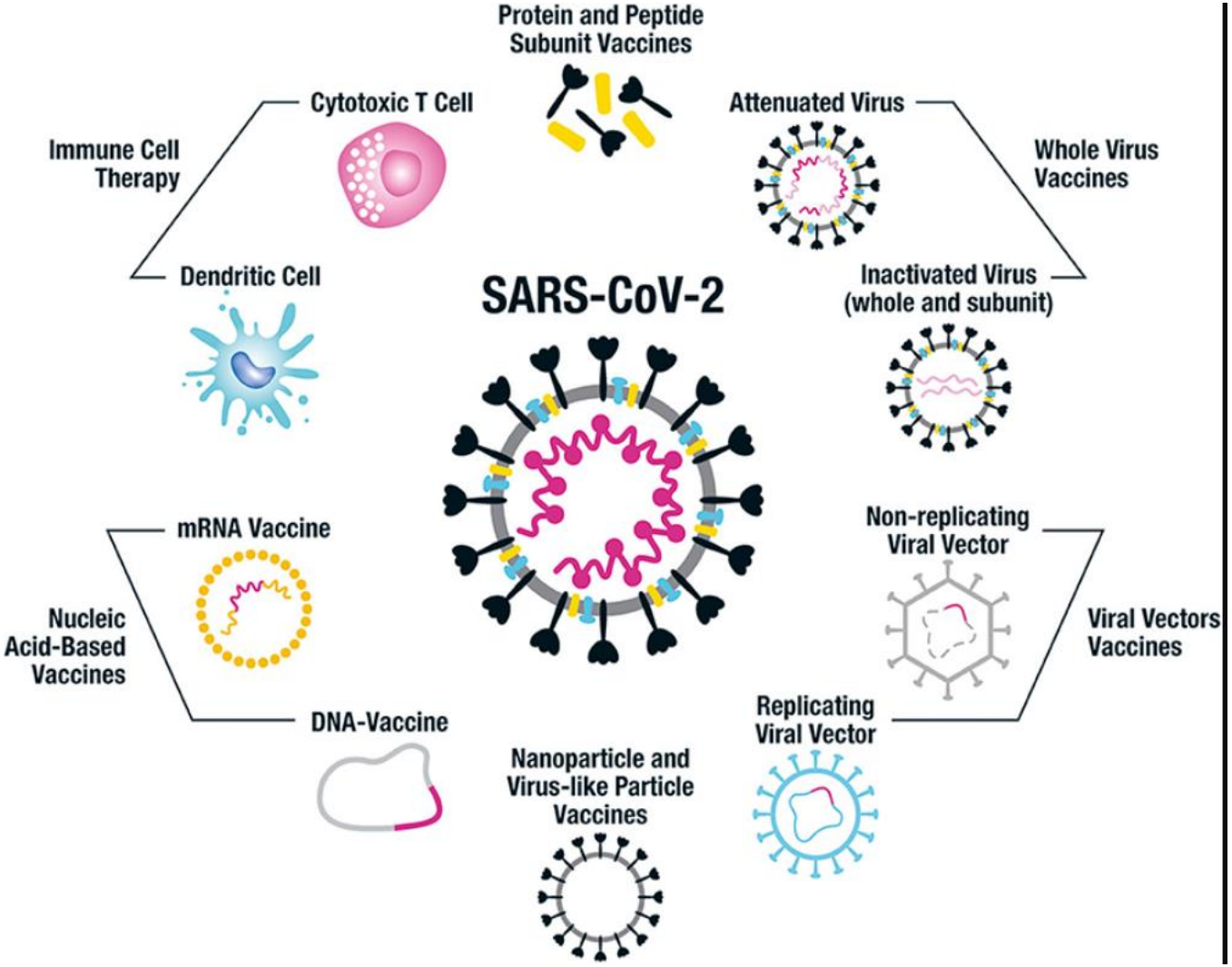


Graphics: Nik Spencer/*Nature*

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

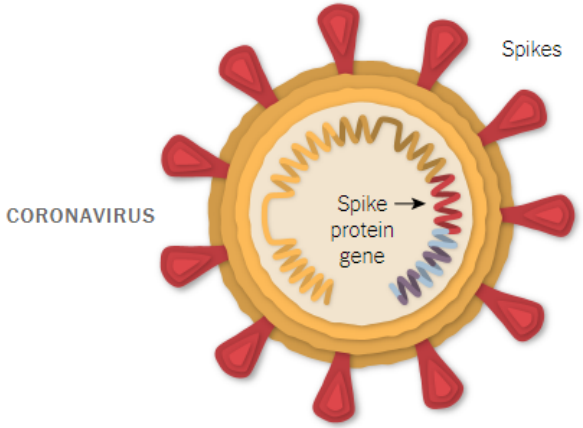


Flanagan KL, Best E, Crawford NW, Giles M, Koirala A, Macartney K, Russell F, Teh BW and Wen SCH (2020) Progress and Pitfalls in the Quest for Effective SARS-CoV-2 (COVID-19) Vaccines. Front. Immunol. 11:579250. doi: 10.3389/fimmu.2020.579250

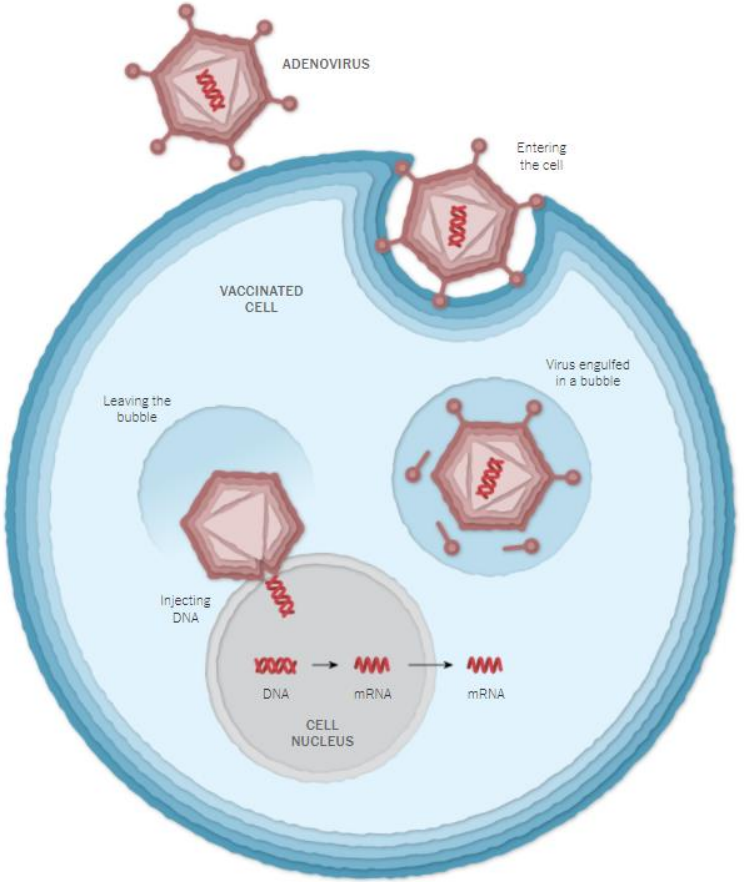
Astra Zeneca (ChAdOx1 nCoV-19)

A Piece of the Coronavirus

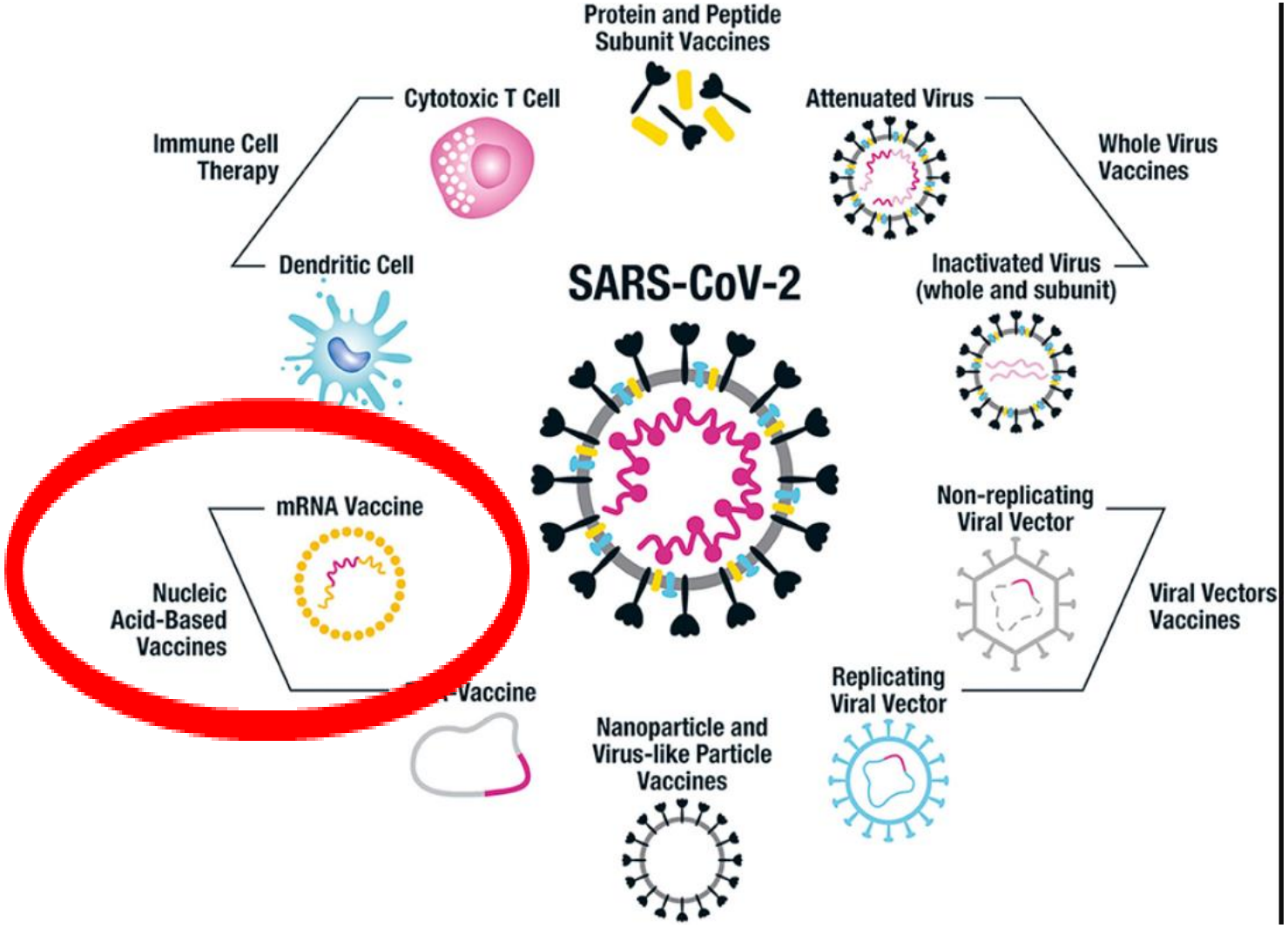
The SARS-CoV-2 virus is studded with proteins that it uses to enter human cells. These so-called spike proteins make a tempting target for potential vaccines and treatments.



The Oxford-AstraZeneca vaccine is based on the virus's genetic instructions for building the spike protein. But unlike the Pfizer-BioNTech and Moderna vaccines, which store the instructions in single-stranded RNA, the Oxford vaccine uses double-stranded DNA.

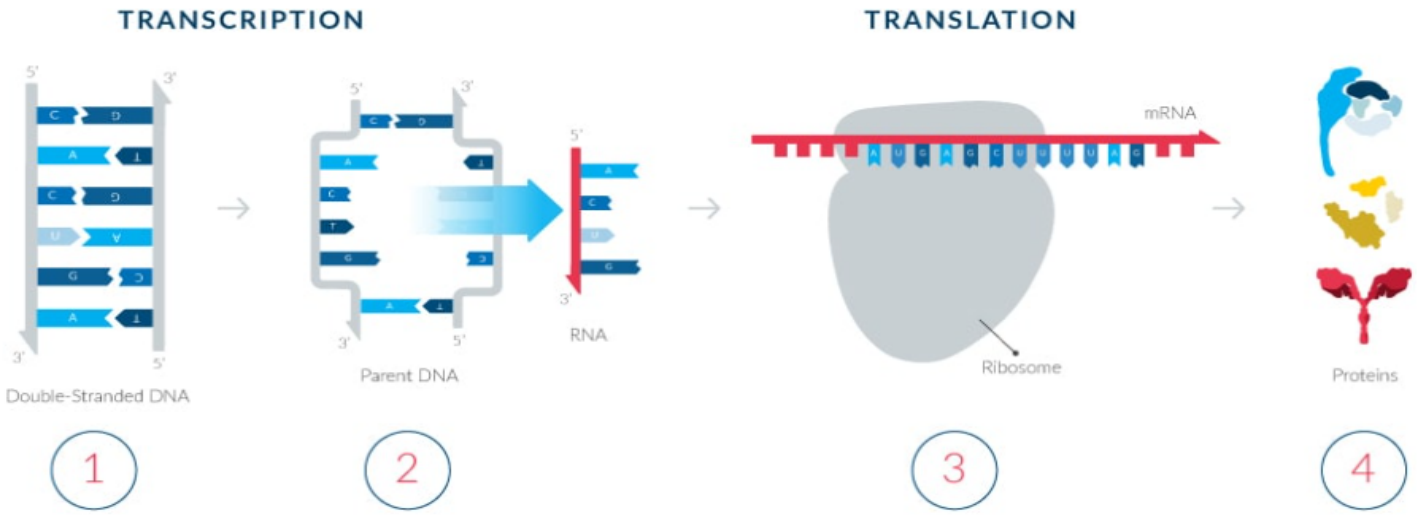


Vaccine platforms being employed for SARS-CoV-2 vaccine design



mRNA - Moderna

mRNA's role in protein synthesis



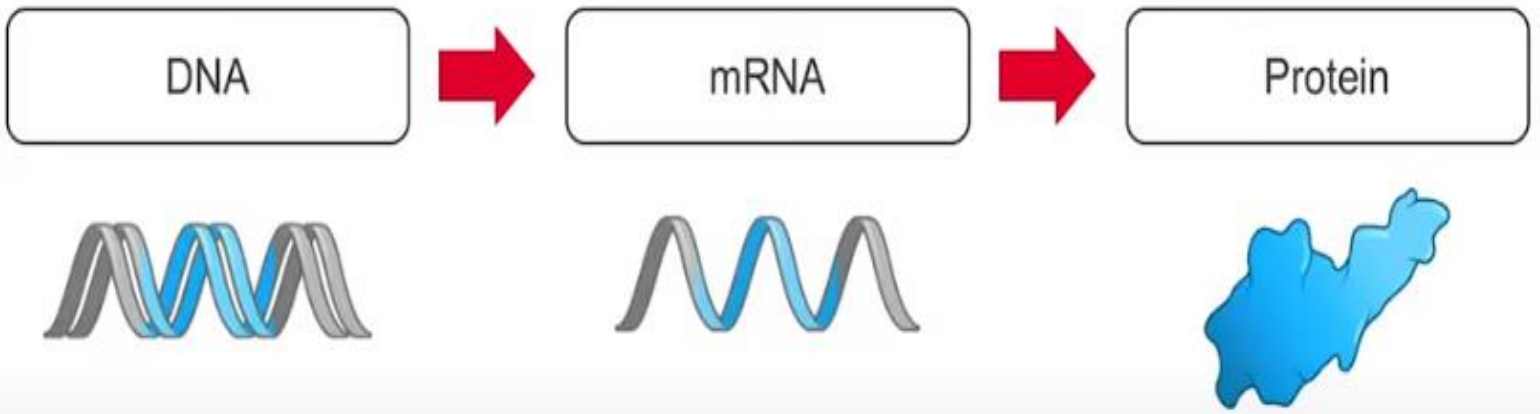
1 Through a process known as transcription, an RNA copy of a DNA sequence for creating a given protein is made.

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.

mRNA is universally utilized for protein production



Storage

DNA stores instructions for proteins in the nucleus

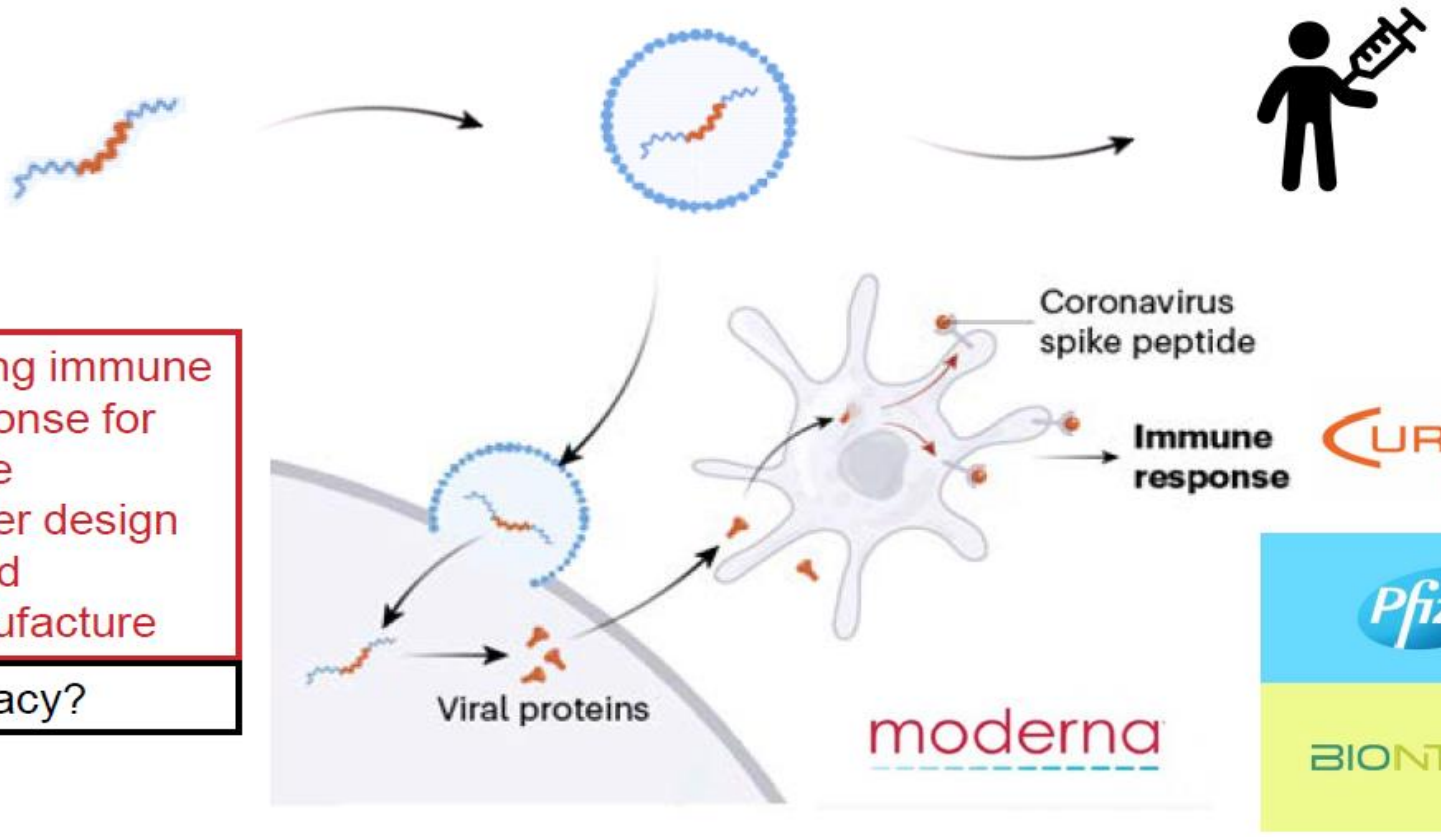
Software

mRNA is a temporary set of instructions for cells to make a protein; mRNA is made using DNA

Applications

Proteins form the basis of life by performing the functions required by every cell; proteins are made using mRNA

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

The Moderna COVID-19 Vaccine ingredients:

- **mRNA –** Moderna's also uses mRNA technology to build antibodies against COVID-19.
- **Lipids** – The Moderna vaccine also requires lipids to help deliver the mRNA to the cells.
  - SM-102
  - 1,2-dimyristoyl-rac-glycero3-methoxypolyethylene glycol-2000 [PEG2000-DMG]
  - cholesterol
  - 1,2-distearoyl-snglycero-3-phosphocholine [DSPC]
- The remaining ingredients (below), including acids, acid stabilizers, salt and sugar all work together to maintain the stability of the vaccine after it's produced.
- **Acids**
  - Acetic acid
- **Acid Stabilizers**
  - Tromethamine & Tromethamine hydrochloride
- **Salts**
  - Sodium acetate
- **Sugar**
  - Sucrose

A Simple Breakdown of the Ingredients in the COVID Vaccines - COVID-19, Health Topics - Hackensack Meridian Health

Deep freezers

A worker passes a line of freezers holding coronavirus disease (COVID-19) vaccine candidate BNT162b2 at a Pfizer facility in Puurs, Belgium in an undated photograph. Pfizer/Handout via REUTERS

https://www.reuters.com/article/us-health-coronavirus-freezers/u-s-states-race-to-buy-ultra-cold-vaccine-freezers-fueling-supply-worries-idINKBN27T2S6

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

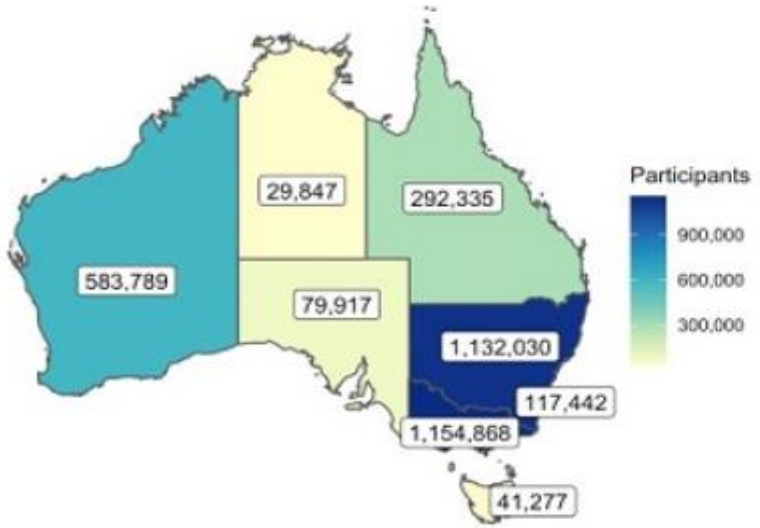
Treatment of Hemophilia A Using Factor VIII Messenger RNA Lipid Nanoparticles (cell.com)

Pharmacovigilance

As at 12 September 2021

All people

6,215,995 surveys sent Australia wide*
3,431,505 participants (55.2% response rate)



Aboriginal and Torres Strait Islander people

69,203 surveys sent Australia wide*
44,509 participants (64.3% response rate)

55.8% of participants reported no adverse event

44.2% of participants reported any adverse event

0.8% of participants reported visiting a doctor or emergency department

Vaxtracker
Monitoring Vaccine Safety

AusVaxSafety
An NCIRS led collaboration

AusVaxSafety - Pfizer

Comirnaty vaccine Dose 1 - All participants

Current as at 16 August 2021

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

62.8%
reported **no** adverse event

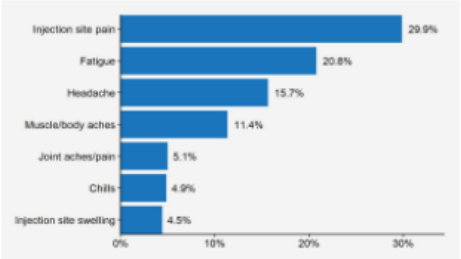
37.2%
reported any adverse event

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

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

374,832 people reported one or more adverse events.

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



These symptoms are known to occur after vaccination. They are generally mild and short-lived. As with any adverse event reports, not all symptoms reported may be caused by the vaccine; **they may be coincidental and due to other causes.** Refer to Comirnaty Product Information on the TGA website for further details.

Comirnaty vaccine Dose 2 - All participants

Current as at 16 August 2021

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

43.6%
reported **no** adverse event

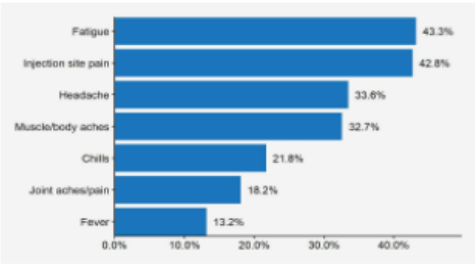
56.4%
reported any adverse event

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

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

434,988 people reported one or more adverse events.

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



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NSW GOVERNMENT Health
Hunter New England
Local Health District

AusVaxSafety – Astra Zeneca

COVID-19 Vaccine AstraZeneca Dose 1 - All participants

Current as at 16 August 2021

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

44.4%
reported **no** adverse event

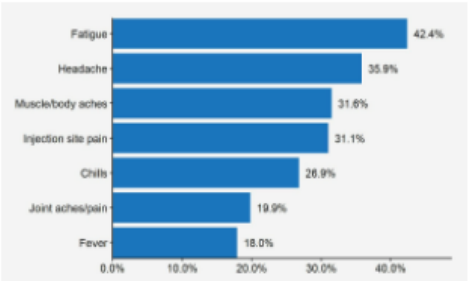
55.6%
reported any adverse event

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

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

238,715 people reported one or more adverse events.

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



These symptoms are known to occur after vaccination. They are generally mild and short-lived. As with any adverse event reports, not all symptoms reported may be caused by the vaccine; **they may be coincidental and due to other causes.** Refer to COVID-19 Vaccine AstraZeneca Product Information on the TGA website for further details.

COVID-19 Vaccine AstraZeneca Dose 2 - All participants

Current as at 16 August 2021

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

73.6%
reported **no** adverse event

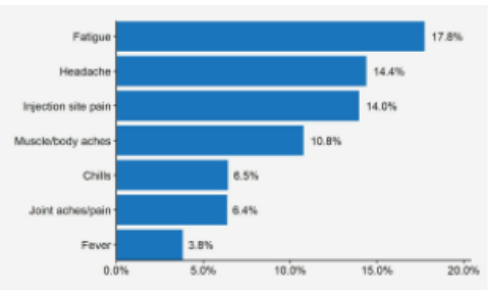
26.4%
reported any adverse event

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

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

52,489 people reported one or more adverse events.

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



These symptoms are known to occur after vaccination. They are generally mild and short-lived. As with any adverse event reports, not all symptoms reported may be caused by the vaccine; **they may be coincidental and due to other causes.** Refer to COVID-19 Vaccine AstraZeneca Product Information on the TGA website for further details.

NSW GOVERNMENT Health
Hunter New England
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TGA

Total adverse event reports to 22 August 2021

3.1	52,849	17,150,654
Reporting rate per 1000 doses	Total AEFI reports received	Total doses administered
32,818	19,706	338
Total reports for Vaxzevria	Total reports for Comirnaty	Total reports for brand not specified

To date, 6 deaths have been assessed as related to TTS – 5 of the 6 deaths occurred in women aged 34, 48 (2 cases), 52 and 72-years-old. The other death was in a 44-year-old man.

Table 2: Total confirmed and probable TTS cases to date by age and CDC classification

Age	Total cases	Reports per 100,000 doses‡	CDC classification†		
			Tier 1	Tier 2	Not classified
<30 years	4	2.5 (<50 years)	1	1	2
30-39	3		3	-	-
40-49	6		6	-	-
50-59	26	2.7	13	8	4
60-69	28	1.6	10	8	10
70-79	33	2.1	9	10	14
80+	16	1.6	4	6	6
All ages	**116 (50 men, 66 women)**	**2.0**	**46**	**34**	**36**

‡ Rates of TTS are calculated based on first doses of the Vaxzevria (AstraZeneca) vaccine as of 12 August to account for the time to onset of TTS. These rates are estimates of risk based on small numbers of cases so far.

† The US CDC classification is defined as:

- Tier 1 = clots in an unusual location (such as the brain or abdomen) **and** a low platelet count with or without antibodies that activate platelets (anti-PF4 antibodies)
- Tier 2 = clots found in common locations (such as the leg or lungs) **and** a low platelet count **and** anti-PF4 antibodies

NSW Health Factsheet Template Plain

Reporting of adverse events following COVID-19 vaccine

Is the event serious?

A serious adverse event following immunisation is an event that:

- results in death
- is life threatening
- requires hospitalisation
- results in persistent or significant disability or incapacity
- is an unexpected reaction for that vaccine

No

Non-serious adverse event following immunisation

This does not need to be reported to your local Public Health Unit This includes common, expected temporary reactions [1], such as:

- low grade fever
- injection site reaction not requiring additional interventions
- myalgia/lethargy resolving in 24-48 hours.

These AEFIs can be reported directly to the TGA .

Yes

Serious adverse event following immunisation

This is a notifiable condition.

Contact your local Public Health Unit on 1300 066 055.

A serious adverse event includes:

- possible or probable Thrombosis with Thrombocytopenia Syndrome (see THANZ and/or ACEM guidance)
- anaphylaxis
- new onset neurological symptoms
- any other clinically significant, worsening or serious illness that develops within six weeks after COVID19 vaccination.

Specialist immunisation advice

If specialist advice is needed, for example in relation to management of the second dose, contact the National Centre for Immunisation Research and Surveillance (NCIRS) NSW Immunisation Specialist Service (NSWISS).

Phone: 1800 679 477 (Monday-Friday 9am-5pm) or email: SCHN-NSWISS@health.nsw.gov.au.

For urgent after-hours clinical support, contact NSWISS via The Children's Hospital at Westmead switchboard on 02 9845 0000 (ask for Immunisation Specialist Service).

NSW GOVERNMENT

health.nsw.gov.au

COVID-19 vaccine:

NSW Health adverse event following immunisation case notification form

Instructions

- This form has been designed to collect initial clinical information regarding an Adverse Event Following Immunisation (AEFI) related to COVID-19 vaccination.
- The information provided will be used to investigate the reported adverse event following immunisation and will be reported to the Therapeutics Goods Administration to support vaccine safety surveillance.
- The form should be completed by a health professional and submitted by email on MOH-covidaefi@health.nsw.gov.au. Alternatively, cases can be notified by phone to the local Public Health Unit on **1300 066 055**.
- The Public Health Unit may contact you during business hours for further information regarding this case notification.

Vaccinated person's details		
Surname		
First name		
Date of birth		
Age		
Gender	Male	☐
	Female	☐
	Other	☐
Street address		
Postcode		
Suburb		
State		
Phone number		
Aboriginal status: Is the person of Aboriginal or Torres Strait Islander origin?	☐ No ☐ Yes, Aboriginal ☐ Yes, Torres Strait Islander ☐ Yes, both Aboriginal and Torres Strait Islander	

Reporter details	
Surname	
First name	

Anaphylaxis

Action of adrenaline in anaphylaxis

Rapid systemic release of large quantities of histamine

Causing angio-oedema and capillary leakage

Mucosal oedema, Bronchospasm,asyphyxia

Shock, BP drops, reduced cardiac output

Suppresses release of inflammatory mediators decreasing angio-oedema

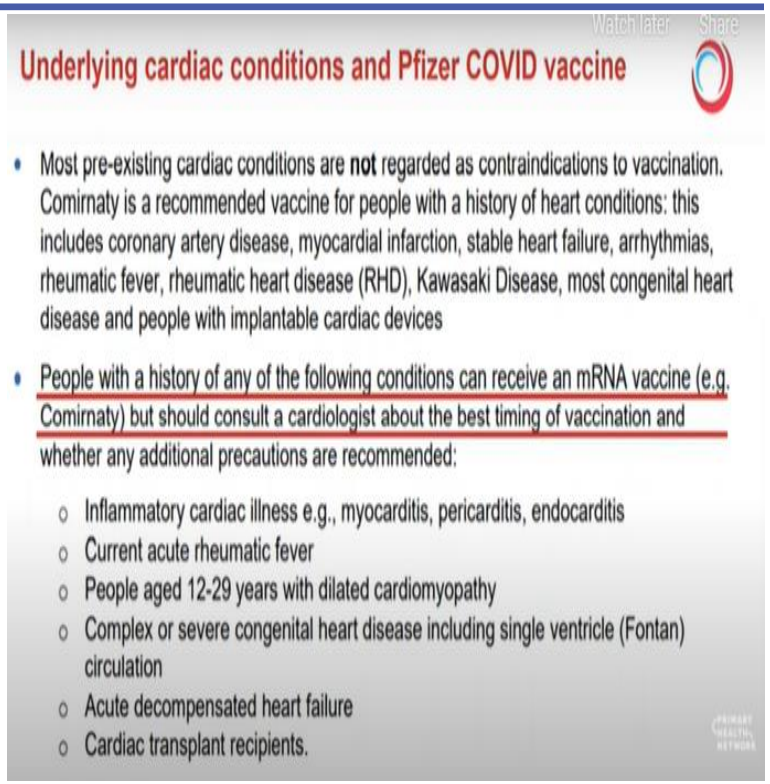
Reverses peripheral vasodilation

Causes bronchodilation, improving respiration

Increases cardiac contraction, improving BP and cardiac perfusion

Adrenaline

Myocarditis and Pericarditis



What to look out for after vaccination

During the consent process, all people who receive Comirnaty should be advised of the very rare risk of myocarditis and/or pericarditis after vaccination, and should be advised of possible symptoms, which include:

- chest pain, pressure or discomfort
- palpitations (irregular heartbeat, skipped beats or 'fluttering').
- syncope (fainting)
- shortness of breath
- pain with breathing.

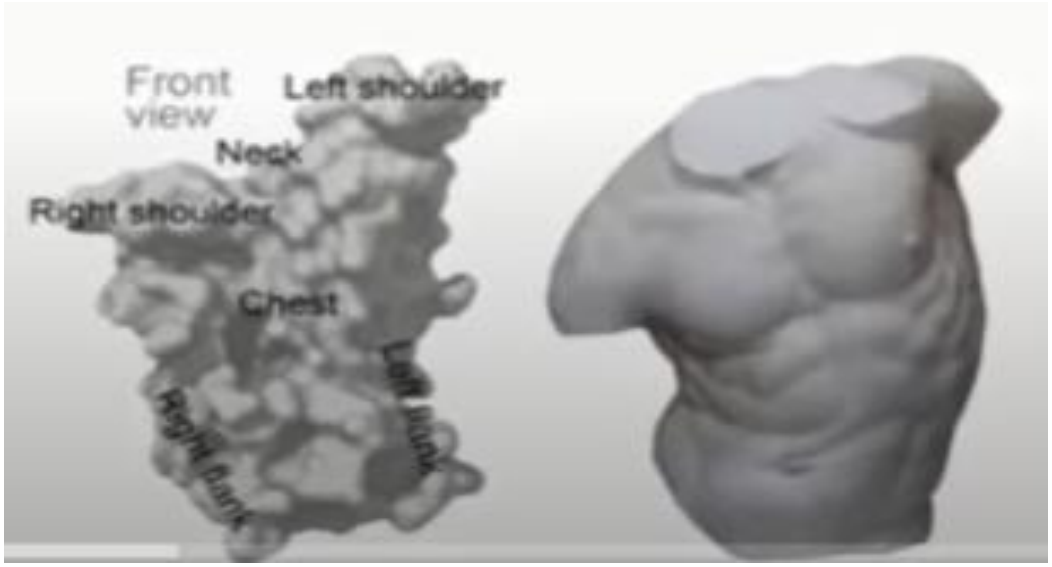
Assessment of suspected myocarditis or pericarditis

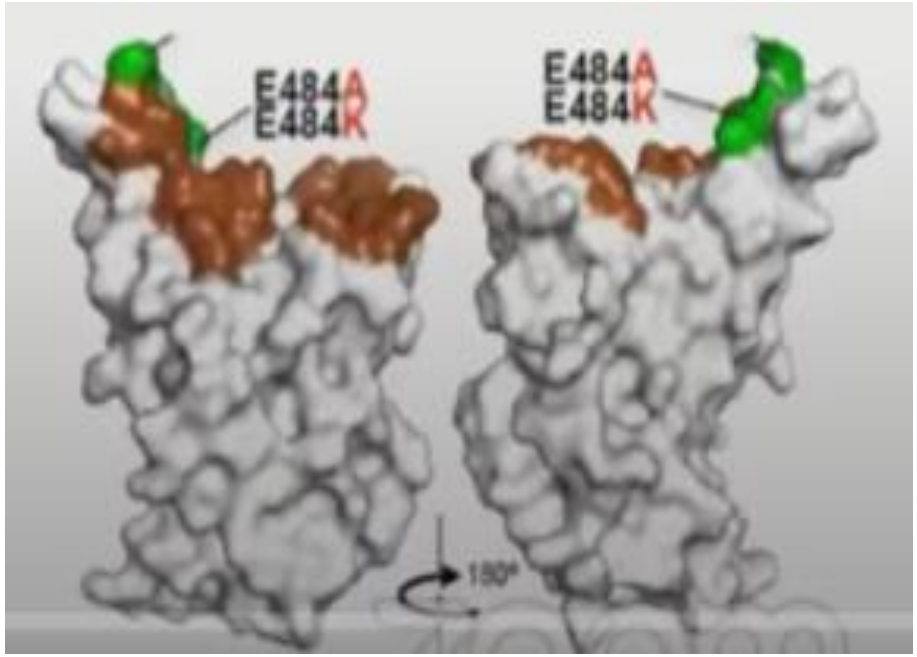
People presenting with any of the above symptoms within the first 2 weeks of receiving Comirnaty should be assessed by a healthcare professional, and those who appear unwell should be referred immediately to an emergency department. Initial investigations should include:

- a 12-lead ECG
- troponin
- chest X-ray
- other tests for other differential diagnoses as clinically indicated.

Immune responses target 2 main areas of the spike protein:

- **Receptor-binding domain (RBD)**
- **N-terminal domain**





[Prof Salim Abdool Karim
Scientific panel discussion on the new variant, 501Y.V2. - YouTube]

UK Variant

TGA approves Moderna vaccine for 12 to 17-year-olds

Australia's medicines regulator, the Therapeutic Goods Administration, has provisionally approved the use of the Moderna (Spikevax) COVID-19 vaccine for adolescents aged 12 to 17 years.

The Hon Greg Hunt MP
Minister for Health and Aged Care

Listen Print Share

Media event date: 4 September 2021

Date published: 5 September 2021

Media type: Media release

Audience: General public

The Australian Government has welcomed today's decision by Australia's medicines regulator, the Therapeutic Goods Administration (TGA), to provisionally approve the use of the Moderna (Spikevax) COVID-19 vaccine for adolescents aged 12 to 17 years.

The approval by the TGA to allow the 12 to 17-year-old age group to be vaccinated with the Moderna COVID-19 vaccine follows the approval last month of its use in adults aged 18 years