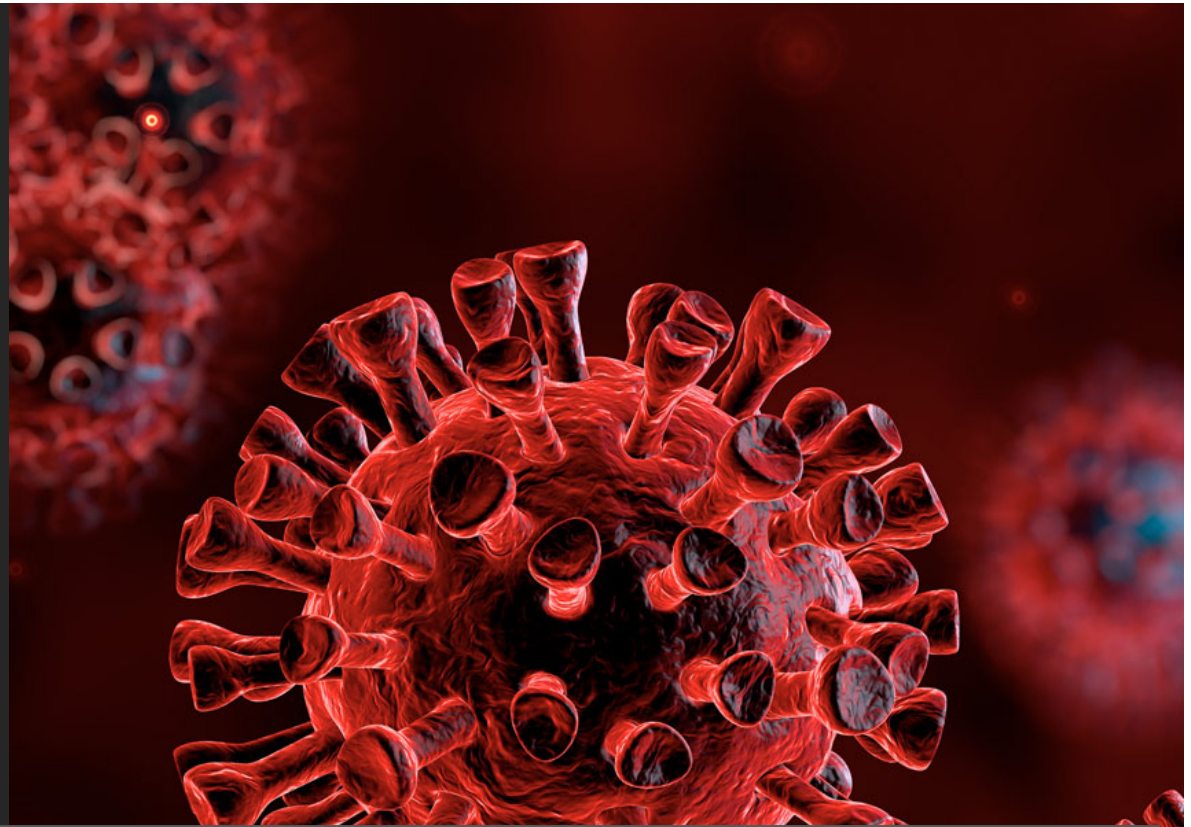



COVID-19 vaccination

Clinical Senate
19th March
2021



Chris Blyth
christopher.blyth@uwa.edu.au
 @ChrisBlyth74





Coronavirus
(COVID-19)

KEEP OUR MOB SAFE

HELP
STOP
THE
SPREAD
AND STAY HEALTHY

Summary:

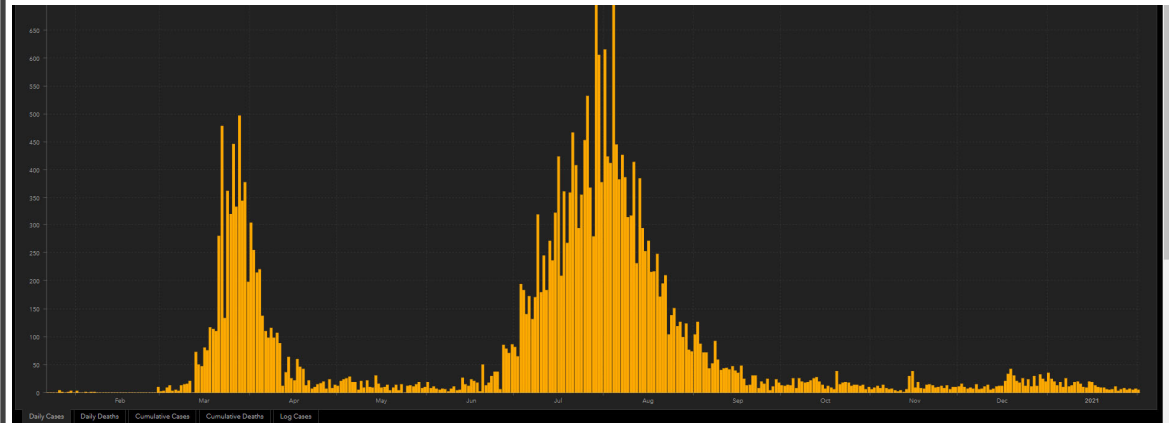
Why

What

Who

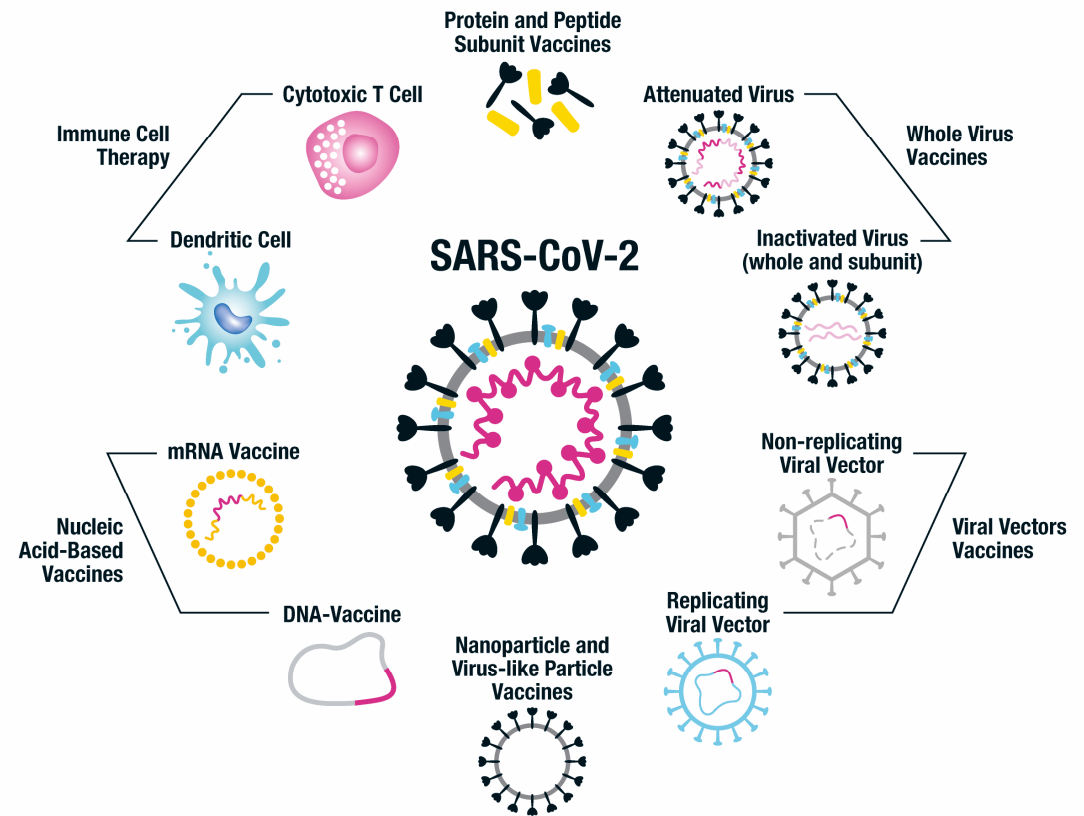
How

When



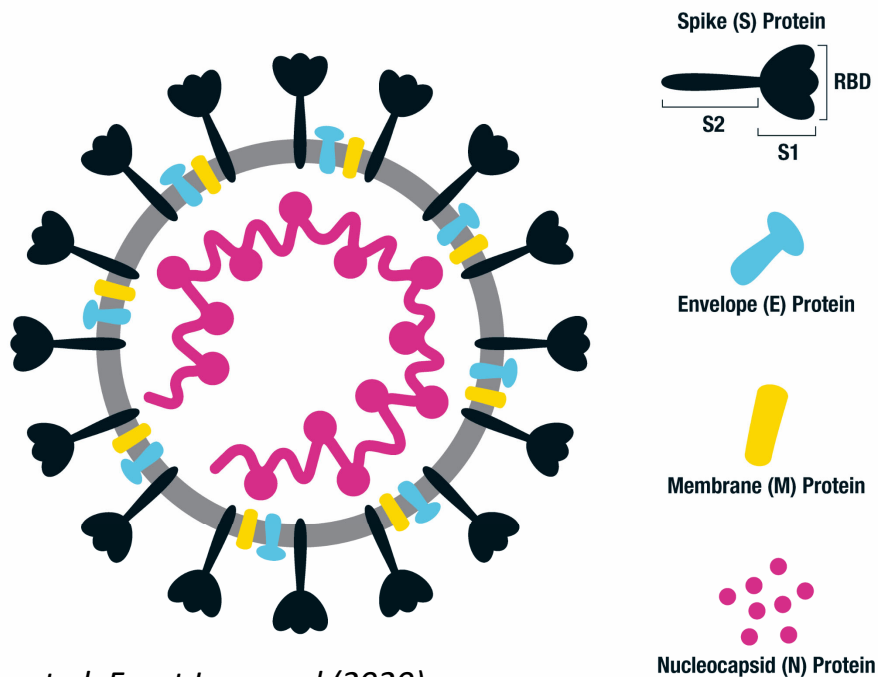
Summary:

Why
What
Who
How
When



Flanagan et al, *Front Immunol* (2020)

SARS-CoV-2 Structure and Key Vaccine Antigens



Flanagan et al, Front Immunol (2020)

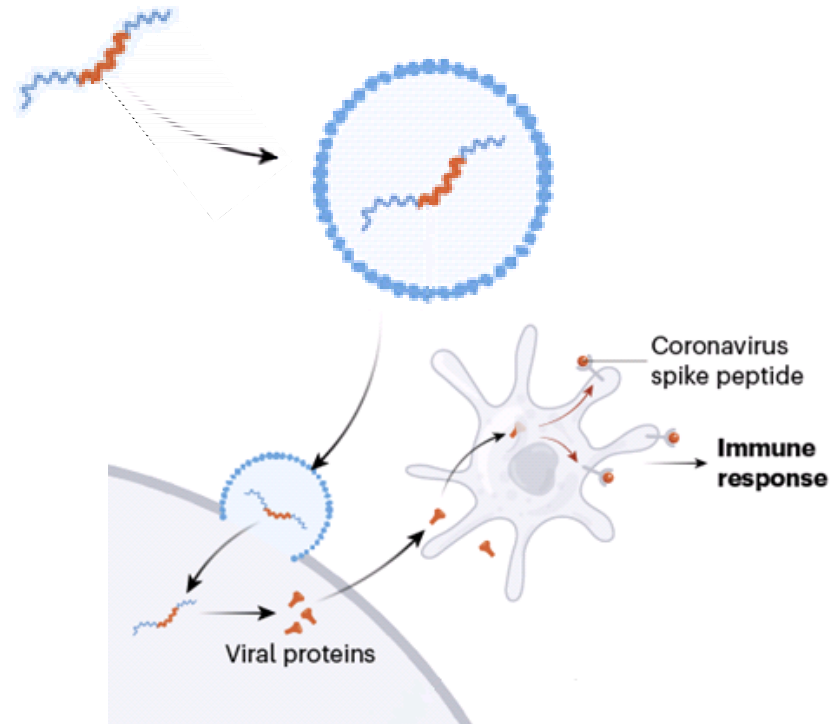
- Enveloped positive sense single stranded RNA virus: *Coronaviridae* family
- The genome of SARS-CoV-2 codes for the structural proteins spike (S), envelope (E), membrane (M) and nucleocapsid (N) and various accessory and non-structural proteins
- Most vaccines focused on eliciting neutralising antibodies to the Spike (S) Protein
 - Particularly the receptor binding domain (RBD region) which binds to the ACE2 receptor of host cells
- Some vaccines are targeting other antigens including E, M and N proteins

mRNA Vaccines

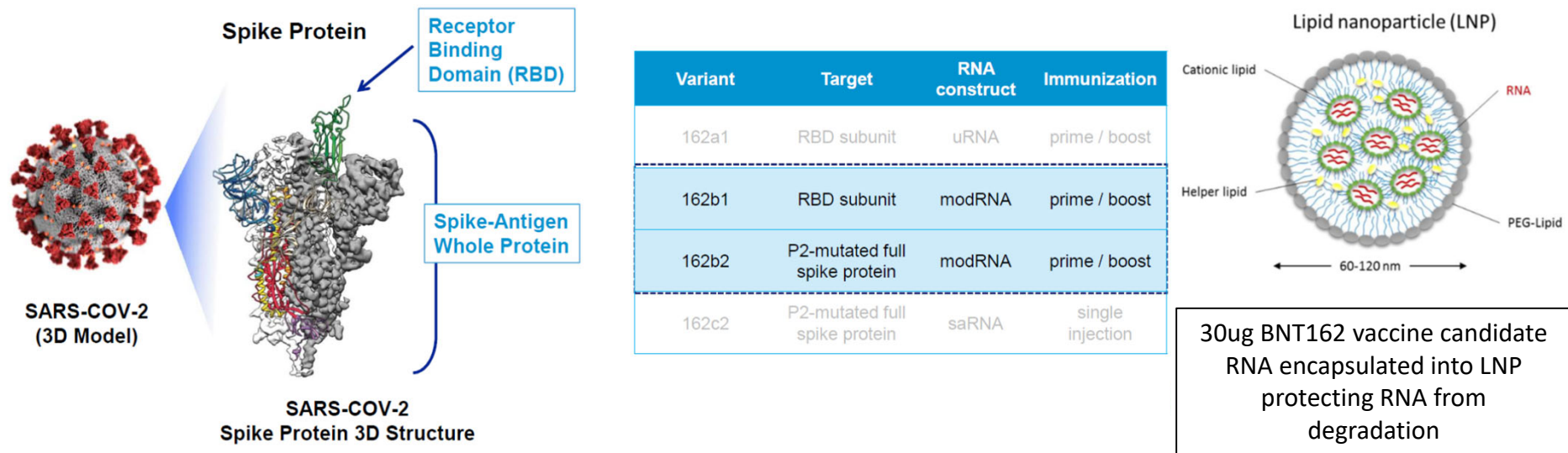
BioNTech-Pfizer

Moderna

CureVac

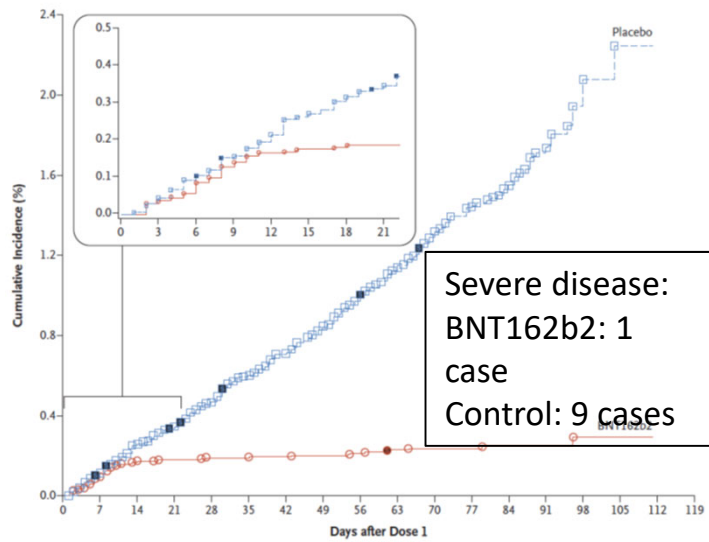


BNT162b2 (BioNTech-Pfizer)



Wrapp et al Science 2020

BNT162b2 (BioNTech-Pfizer)



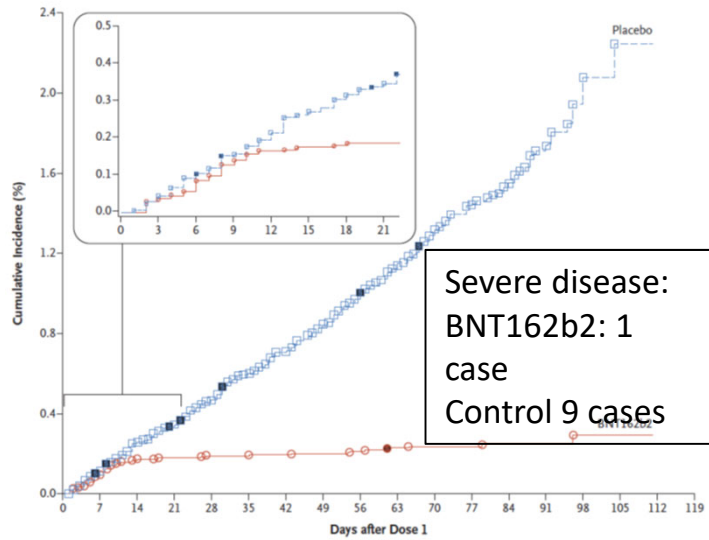
- Interim data from ongoing blinded RCTs
 - Enrolling adults ≥ 16y: US; Argentina/Brazil; South Africa; Germany
 - 1:1 randomization: BNT162b2 vs saline; 2 doses; 21d apart
 - 1^o endpoint: symptomatic COVID in SARS-CoV2 naïve individual with PCR positive swab more than 7d after 2nd dose
- 43548 participants; efficacy data reported on 36,523

	BNT162b2	Control	Vaccine efficacy
All recipients	8/18198	162/17511	95.0% (90.0;97.9)
16-55 years	5	114	95.6% (89.4;98.6)
56-64 years	3	48	93.7 (66.7; 99.9)

Efficacy End-Point Subgroup	BNT162b2, 30 µg (N=21,669)		Placebo (N=21,686)		VE (95% CI) percent
	No. of participants	Surveillance time person-yr (no. at risk)	No. of participants	Surveillance time person-yr (no. at risk)	
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

Polack FP et al NEJM 2020

BNT162b2 (BioNTech-Pfizer)



- Interim data from ongoing blinded RCTs
 - Enrolling adults ≥ 16 y: US; Argentina/Brazil; South Africa; Germany
 - 1:1 randomization: BNT162b2 vs saline; 2 doses; 21d apart
 - 1^o endpoint: symptomatic COVID in SARS-CoV2 naïve individual with PCR positive swab more than 7d after 2nd dose
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Efficacy End-Point Subgroup	BNT162b2, 30 μ g (N=21,669)		Placebo (N=21,686)		VE (95% CI) percent
	No. of participants	Surveillance time person-yr (no. at risk)	No. of participants	Surveillance time person-yr (no. at risk)	
Covid-19 occurrence					
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≥ 7 Days after dose 2	9		172		94.8 (89.8–97.6)

Polack FP et al NEJM 2020

COMIRNATY (BNT162n2)

Attachment 1: AusPAR - COMIRNATY (BNT162b2 mRNA) - Pfizer Australia Pty Ltd - PBL-2020-05461-1-2
FINAL, 25 January 2021. This is the Product Information that was approved with the submission described in
this AusPAR. It may have been superseded. For the most recent PI, please refer to the TGA website at
<https://www.tga.gov.au/product-information-pi>.

▼ This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PRODUCT INFORMATION – COMIRNATY™ (BNT162b2 [mRNA]) COVID-19 VACCINE

1. NAME OF THE MEDICINE

BNT162b2 [mRNA]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see Sections 4.2 and 6.6.

1 dose (0.3 mL) contains 30 micrograms of BNT162b2 [mRNA] (embedded in lipid nanoparticles).

The active ingredient is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

For the full list of excipients, see Section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Concentrated suspension for injection (sterile concentrate).

COMIRNATY is a white to off-white frozen suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine has **provisional approval** for the indication below:

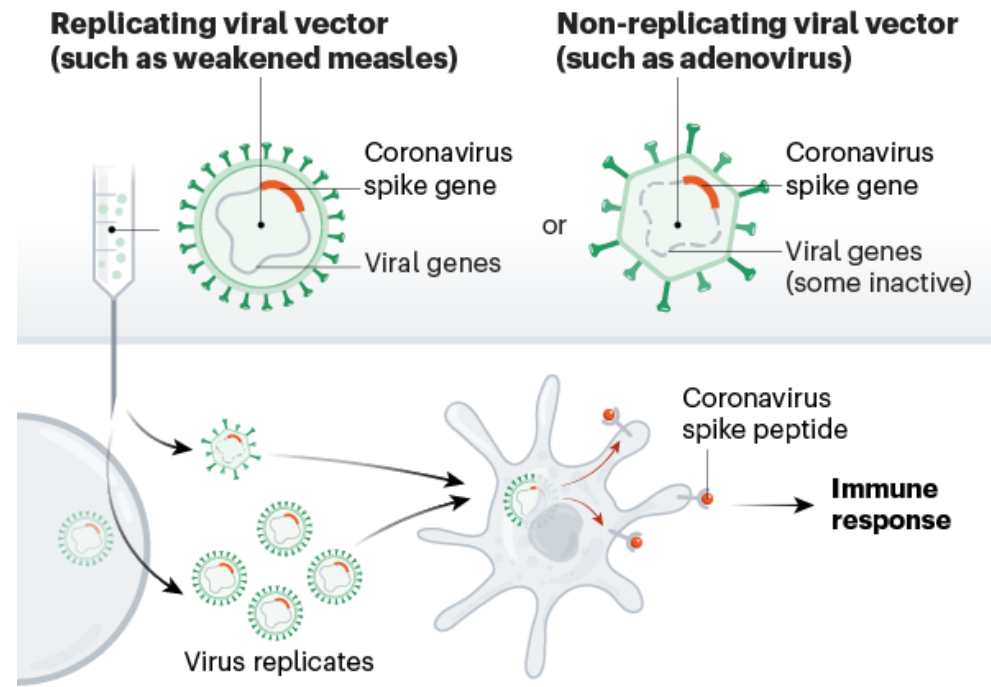
Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

- **Indication:** Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2 in individuals 16 years and older
- Two doses at least 21 days apart. Intramuscular injection
- Must be stored frozen
- Contraindications: hypersensitivity to the active substance of any excipients
- Given limited experience with use of COMIRNATY in pregnant women, administration in pregnancy should only be considered when the potential benefits outweigh any potential risks to mother and fetus

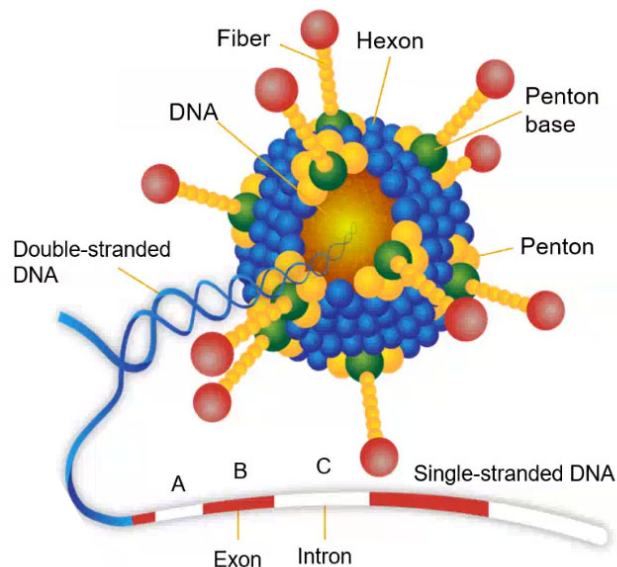
Viral-vector vaccines

Oxford-AZ
Gamaleya
CanSinoBIO
Johnson & Johnson



©nature

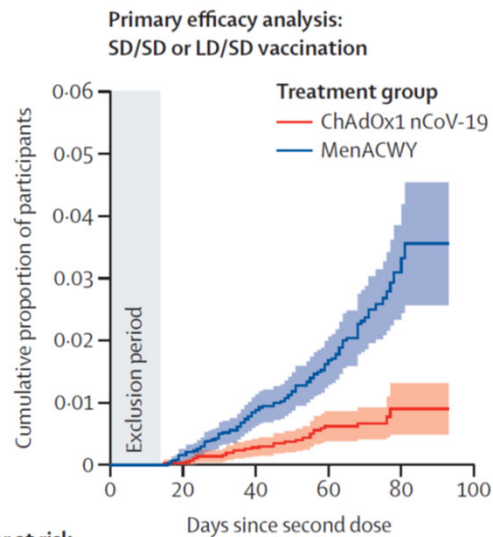
ChAdOx-1 nCoV-19 (now AZD1222 – Oxford/Astra Zeneca)



- ChAdOx-1 MERS showed encouraging early clinical safety
- Based on existing simian recombinant adenovirus vaccine vector
 - Non replicating
 - Simian adenovirus vector chosen to avoid preexisting immunity against human adenoviruses
 - Vector induced strong antibody and cellular responses against vaccine antigen
- Vector has been engineered to contains genetic material of the SARS CoV-2 spike protein

Van Doremalen N et al BioRxiv 2020; van Doremalen N et al Sci Adv 2020

ChAdOx-1 nCoV-19 / AZD1222



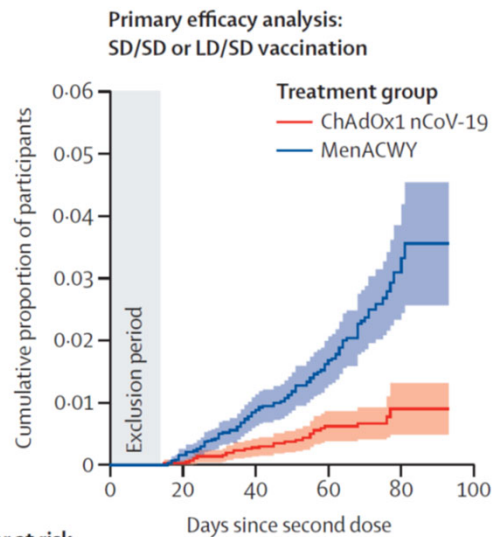
	0	20	40	60	80	100
Number at risk	5807	5639	4779	3181	499	0
(number censored)	(0)	(189)	(1162)	(2620)	(5300)	(5777)
ChAdOx1 nCoV-19	5829	5657	4765	3146	435	0
MenACWY	(0)	(182)	(1164)	(2636)	(5322)	(5728)

- Interim data from four ongoing blinded RCTs
 - Enrolling adults ≥ 18 y: UK; Brazil; South Africa
 - 1:1 randomization: ChAdOx1 vs MenACWY; 2 doses; minimum of 28d
 - Two dosing regimens: SD/SD and LD/SD
 - 1^o endpoint: PCR positive swab more than 14d after 2nd dose
- 23,848 participants; data reported on 11,636

	ChAdOx1	Control	Vaccine efficacy
All recipients	30/5807 (0.5%)	101/5829 (1.7%)	70.4% (54.8;80.6)
LD/SD recipients	3/1367 (0.2%)	30/1374 (2.2%)	90.0% (67.4;97.0)
SD/SD recipients	27/4440 (0.6%)	71/4455 (1.6%)	62.1% (41.0;75.7)
Any PCR +ve	68/5807 (1.2%)	153/5829 (2.6%)	55.7% (41.1;66.7)

Voysey M et al Lancet 2020

ChAdOx-1 nCoV-19 / AZD1222



Number at risk
(number censored)

	0	20	40	60	80	100
ChAdOx1 nCoV-19	5807 (0)	5639 (189)	4779 (1162)	3181 (2620)	499 (5300)	0 (5777)
MenACWY	5829 (0)	5657 (182)	4765 (1164)	3146 (2636)	435 (5322)	0 (5728)

- Interim data from four ongoing blinded RCTs
 - Enrolling adults ≥ 18 y: UK; Brazil; South Africa
 - 1:1 randomization: ChAdOx1 vs MenACWY; 2 doses; minimum of 28d
 - Two dosing regimens: SD/SD and LD/SD
 - 1^o endpoint: PCR positive swab more than 14d after 2nd dose
- 23,848 participants; data reported on 11,636

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Any PCR +ve	68/5807 (1.2%)	153/5829 (2.6%)	55.7% (41.1;66.7)

Voysey M et al Lancet 2020

COVID-19 Vaccine AZ (ChAdOx1-S)

Attachment 1: Product Information for AstraZeneca COVID-19 VACCINE AZTRAZENECA - ChAdOx1-S - AstraZeneca Pty Ltd - PM 2020 06118-1
2 FINAL 19 February 2021. This is the Product Information that was approved with the submission described in the AstraZeneca PM 2020 06118-1.
3 superseded. For the most recent PI, please refer to the TGA website at <https://www.tga.gov.au/products/indemeter/>.

▼ This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

AUSTRALIAN PRODUCT INFORMATION

COVID-19 Vaccine AstraZeneca (ChAdOx1-S) solution for injection

1 NAME OF THE MEDICINE

ChAdOx1-S (provisional ABN)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each multi-dose vial contains 5×10^{11} viral particles (vp) of (ChAdOx1-S^{a,b}) in 5 mL.

One dose (0.5 mL) contains 5×10^{10} vp of (ChAdOx1-S^{a,b}).

^a Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein (GP)

^b The vaccine is manufactured using material originally sourced from a human embryo (Human Embryonic Kidney cells - HEK293).

This product contains genetically modified organisms (GMOs).

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear to slightly opaque, colourless to slightly brown, particle free with a pH of 6.1 – 7.1.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

COVID-19 Vaccine AstraZeneca has **provisional approval** for the indication:

Active immunisation of individuals ≥ 18 years old for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

The use of this vaccine should be in accordance with official recommendations.

The decision has been made on the basis of short term efficacy and safety data. Continued approval is dependent upon the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment.

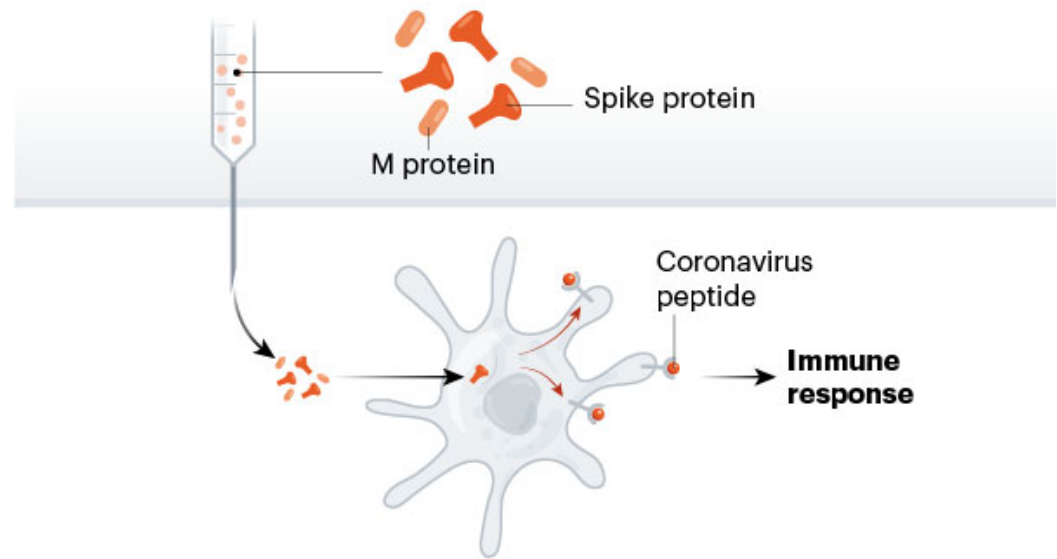
4.2 DOSE AND METHOD OF ADMINISTRATION

The COVID-19 Vaccine AstraZeneca vaccination course consists of two separate doses of 0.5 mL each. The second dose should be administered between 4 and 12 weeks after the first dose (see Section 5.1 Pharmacodynamic properties).

- **Indication:** Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2 in individuals 18 years and older
- Two doses 4-12 weeks apart. Intramuscular injection
- Must be stored at 2°C to 8°C
- Contraindications: hypersensitivity to the active substance of any excipients
- Given limited experience with use of ChAdOx1-S in pregnant women, administration in pregnancy should only be considered when the potential benefits outweigh any potential risks to mother and fetus

Protein Vaccines

(UQ-CSL)
Novavax
BekTop
Medicago
Clover-Dynavax
Others



NVX-CoV2373 (Novavax)

Antigen expressed in baculovirus-*S. frugiperda* system

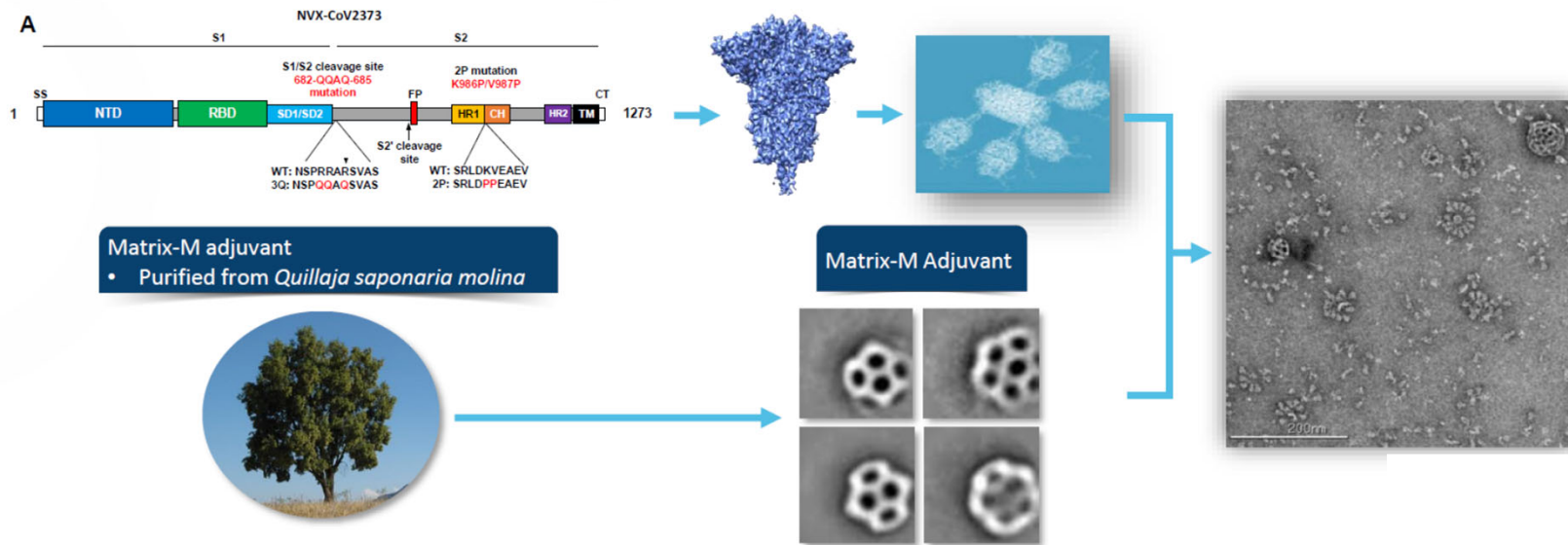
- Codon-optimized
- Full-length protein, including transmembrane domain

Drug Substance

- Native conformation trimers
- Stable PS80 nanoparticle

Drug Product

- Co-formulated with adjuvant
- Dispensed in vial
- Stored 2-8°C



NVX-CoV2373



Novavax Confirms High Levels of Efficacy Against Original and Variant COVID-19 Strains in United Kingdom and South Africa Trials

- 100% protection against severe disease
- Final analysis in U.K. trial confirms 96% efficacy against original strain of COVID-19
- Efficacy against variants confirmed in U.K. and South Africa

GAITHERSBURG, Md., March 11, 2021 – Novavax, Inc. (Nasdaq: NVAX), a biotechnology company developing next-generation vaccines for serious infectious diseases, today announced final efficacy of 96.4% against mild, moderate and severe disease caused by the original COVID-19 strain in a pivotal Phase 3 trial in the United Kingdom (U.K.) of NVX-CoV2373, the company's vaccine candidate. The company also announced the complete analysis of its Phase 2b trial taking place in South Africa, with efficacy of 55.4% among the HIV- negative trial participants in a region where the vast majority of strains are B.1.351 escape variants. Across both trials, NVX-CoV2373 demonstrated 100% protection against severe disease, including all hospitalization and death. Both studies achieved their statistical success criteria. Today's final analyses build on the successful interim results [announced](#) in January 2021, adding substantially more COVID-19 cases and statistical power.

"We are very encouraged by the data showing that NVX-CoV2373 not only provided complete protection against the most severe forms of disease, but also dramatically reduced mild and moderate disease across both trials. Importantly, both studies confirmed efficacy against the variant strains," said Stanley C. Erck, President and Chief Executive Officer, Novavax. "Today marks one year since the WHO officially declared the COVID-19 pandemic, and with this data in hand, we are even more motivated to advance our vaccine as a potential weapon in the fight to end the suffering caused by COVID-19."

United Kingdom Phase 3 Trial

The study enrolled more than 15,000 participants between 18-84 years of age, including 27% over the age of 65. The primary endpoint of the U.K. Phase 3 clinical trial is based on the first occurrence of PCR-confirmed symptomatic (mild, moderate or severe) COVID-19 with onset at least 7 days after the second study vaccination in serologically negative (to SARS-CoV-2) adult participants at baseline.

Efficacy was 96.4% (95% CI: 73.8, 99.5) against the original virus strain and 86.3% (95% CI: 71.3, 93.5) against the B.1.1.7/501Y.V1 variant circulating in the U.K. (post hoc). The primary efficacy endpoint demonstrated an overall vaccine efficacy of 89.7% (95% CI: 80.2, 94.6). 106 cases were observed, with 10 in the vaccine group and 96 in the placebo group. NVX-CoV2373 was effective against severe disease: five severe¹ cases were observed in the study, and all occurred in the placebo group. Four of the five severe cases were attributed to the B.1.1.7/501Y.V1 variant. Fourteen days after dose 1, vaccine efficacy was 83.4% (95% CI: 73.6, 89.5).

¹ Please see trial protocols for endpoint definitions of COVID-19 severity at <https://www.novavax.com/resources#protocols>

Results released by press release (28th Jan; 11th March)

Phase III results from the UK trial:

- >15,000 participants between 18-84 years of age, including 27% over the age of 65
- Primary endpoint: PCR-confirmed symptomatic COVID-19 with onset \geq 7 days after second dose
- 106 cases (10 in vaccine group; 96 in placebo; 5 severe cases)
- Vaccine efficacy: 89.7% (95%CI: 80.2; 94.6%)
original strain: 96.4% (95%CI: 73.8; 99.5%)
UK strain: 86.3% (95%CI: 71.3; 93.5%)

Phase IIb results from the South African trial:

- >2800 participants aged >18, including 240 HIV+ve adults
- Primary endpoint: PCR-confirmed symptomatic COVID-19
- 147 cases (51 in vaccine group; 96 in placebo; 5 severe cases)
- Vaccine efficacy: 48.6%% (95%CI: 28.4; 63.1%)
HIV negative: 55.4% (35.9; 68.9%)

<https://ir.novavax.com/node/15506/pdf>



Are some COVID vaccines
better than others?
Repaka RR et al, CID 2021

Numerous variables to consider when comparing

Study population:

Age and comorbidities

Race and social determinants of health

Baseline seropositivity

SARS-CoV-2 strains, prevalence and transmission:

Different circulating strains

Force of infection and non-pharmacological measures

Case ascertainment:

Definition of symptomatic infection / Severity of infection

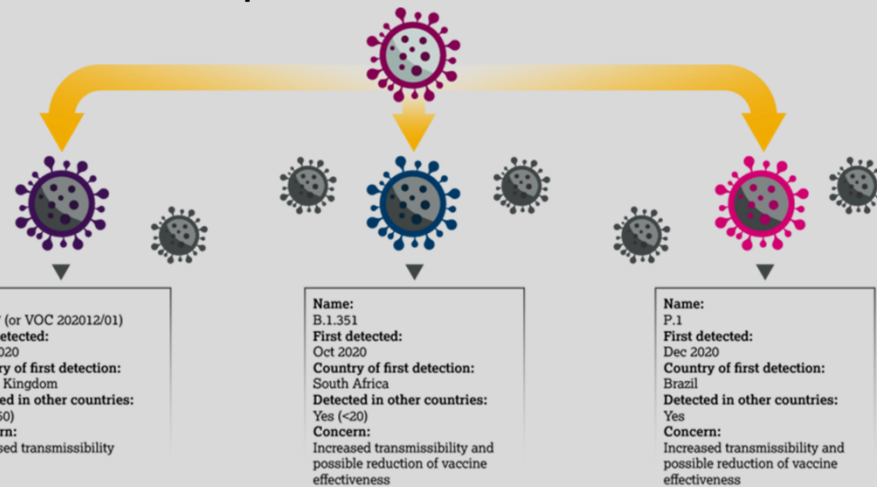
Time post vaccination to significant events

Use of therapeutics and supportive care

<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab213/6159795>

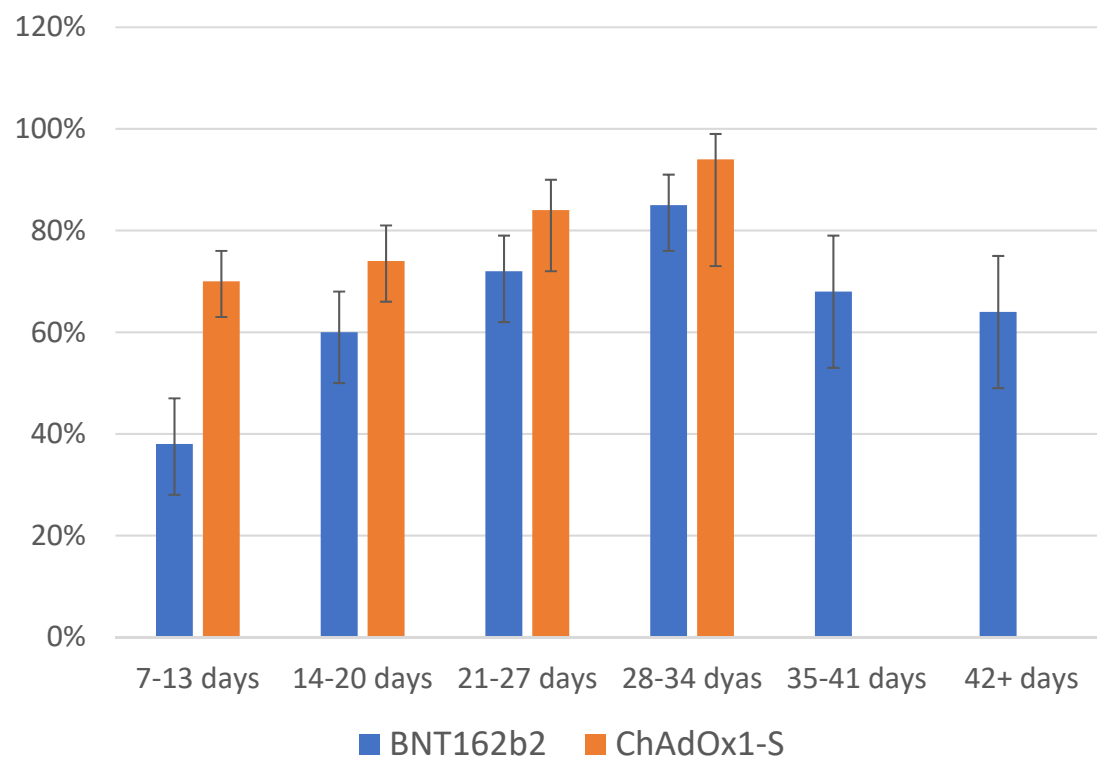
Uncertainties remain

- Comparative effectiveness data
- Impact on severe disease
- Impact of NP viral load and transmission
- Duration of efficacy and requirement for boosting
- Vaccine effectiveness in specific high risk groups
- Impact of escape mutants



Knowledge gaps are being rapidly closed

One dose effectiveness against COVID-19 related hospital admission: Scotland December 2020 to February 2021

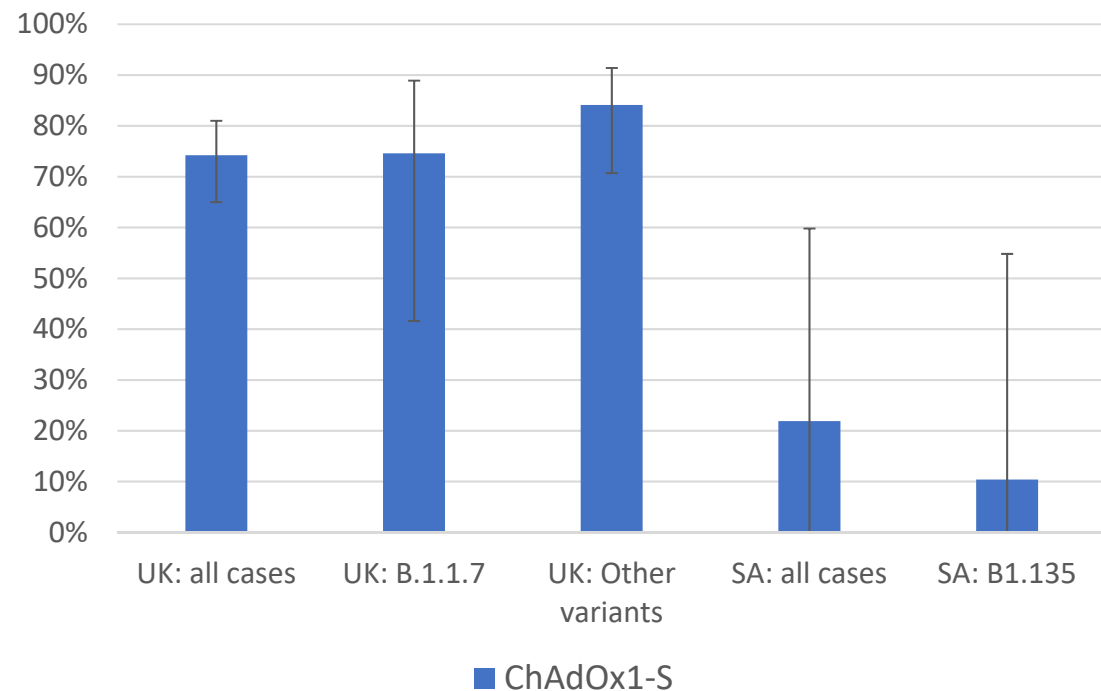


Vasileiou E et al, https://www.ed.ac.uk/files/atoms/files/scotland_firstvaccinedata_preprint.pdf

Knowledge gaps are being rapidly closed

AZ effectiveness against symptomatic COVID19: UK vs South

Africa



<https://www.medrxiv.org/content/10.1101/2021.02.10.21251247v1.full.pdf+html>;
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3779160

Summary:

Why
What
Who
How
When



A precious resource: programmatic goals and principles

Goal: To contribute significantly to the equitable protection and promotion of human well-being



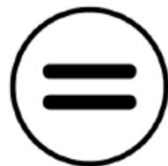
Human Well-Being



Global Equity



Reciprocity



Equal Respect



National Equity



Legitimacy

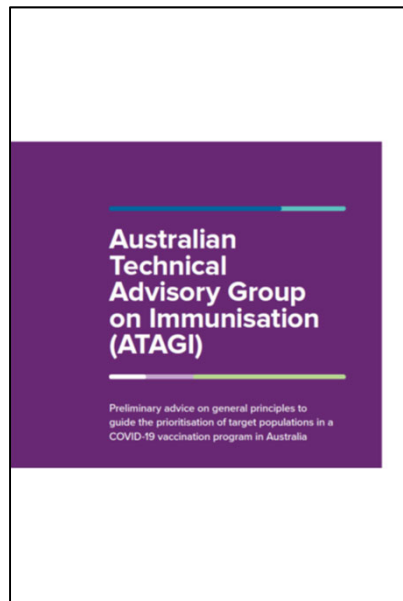
Strategic Advisory Group of Experts, WHO, 2020

Vaccine supply scenario	Community transmission	Sporadic cases or case clusters	No cases
Overall Aim	Initial focus should be on reducing morbidity and mortality, maintenance of critical services whilst considering reciprocity towards groups being placed at increased risk	Whilst aims are similar to community transmission, maximum benefits will be achieved if the focus on areas of greatest activity	Initial focus is on prevention of community transmission from importation of cases and reciprocity to critical workers, particularly frontline health staff
Stage 1 (1-10%)	HCW at high to very high risk of acquiring/transmitting COVID Older adults	HCW at high to very high risk of acquiring/transmitting COVID in areas with high transmission Older adults in areas with high transmission	HCW at high to very high risk of acquiring/transmitting COVID Essential travellers at risk of acquiring infection and reintroducing COVID Border protection staff Emergency reserve or focused outbreaks
Stage 2 (11-20%)	Older adults not covered in stage 1 Groups with comorbidities increasing risk of severe disease Sociodemographic groups at increased risk of severe disease HCW engaged with immunisation delivery Teachers and other essential workers	HCW at high to very high risk of acquiring/transmitting COVID in the rest of the country Older adults in the rest of the country Groups with comorbidities increasing risk of severe disease Sociodemographic groups at increased risk of severe disease	HCW at low to moderate risk of acquiring/transmitting COVID All travellers
Stage 3 (21-50%)	Remaining essential workers HCW at low to moderate risk of acquiring/transmitting COVID	HCW engaged with immunisation delivery Teachers and other essential workers Remaining essential workers HCW at low to moderate risk of acquiring/transmitting COVID	Older adults Age groups at high risk of transmitting infection

Vaccine supply scenario	Community transmission	No cases
Overall Aim	Initial focus should be on reducing morbidity and mortality, maintenance of critical services whilst considering reciprocity towards groups being placed at increased risk	Initial focus is on prevention of community transmission from importation of cases and reciprocity to critical workers, particularly frontline health staff
Stage 1 (1-10%)	HCW at high to very high risk of acquiring/transmitting COVID Older adults	HCW at high to very high risk of acquiring/transmitting COVID Essential travellers at risk of acquiring infection and reintroducing COVID Border protection staff Emergency reserve or focused outbreaks

WHO SAGE roadmap for prioritising uses of COVID-19 vaccines

What is the goal of the Australian Program?



Overarching goal of the COVID19 vaccination program in Australia

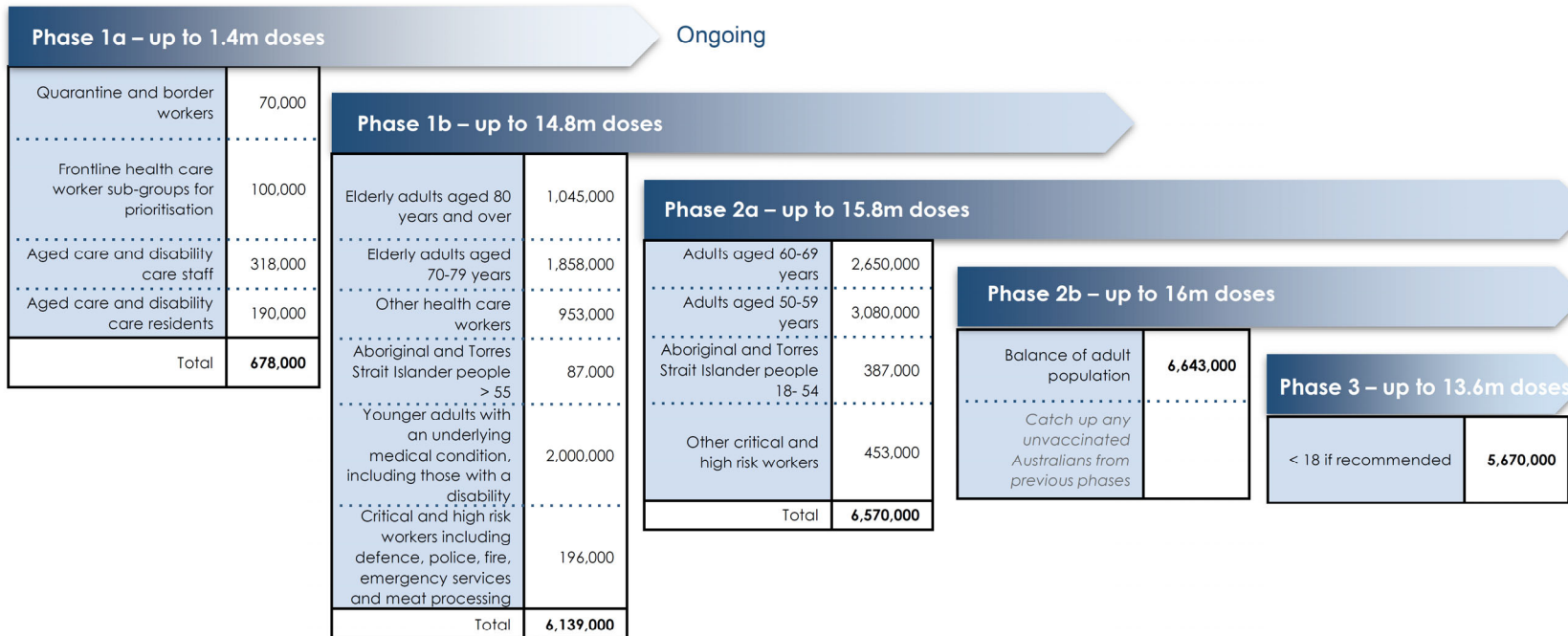
- The Australian COVID-19 vaccination program has the overarching goal of protecting all people in Australia from the harm caused by the novel coronavirus SARS-CoV-2.

Specific aims of the COVID-19 vaccination program

- Reduce COVID-19 related harm by preventing serious illness and death, and where possible, disease transmission
- Ensure equity of vaccine access and uptake, especially for groups likely to experience a disproportionate burden of disease
- Promote public and health professional trust in the utility of COVID-19 vaccines and their implementation to the Australian community
- Ensure COVID-19 Vaccines are listed within the national immunisation program
- Maintain functioning of health care and other essential services to preserve health, social and economic security

https://www.health.gov.au/sites/default/files/documents/2020/11/atagi-preliminary-advice-on-general-principles-to-guide-the-prioritisation-of-target-populations-in-a-covid-19-vaccination-program-in-australia_0.pdf

Priority populations



Population numbers are current estimates for each category.

How?

COVID-19 Vaccines and
Treatments for Australia –
Science and Industry Technical
Advisory Group

Therapeutics Goods
Administration

Australian Technical Advisory
Group on Immunisation

Jurisdictional Immunisation
Coordinators and Programs

Communicable Disease Network
of Australia

Australian government entered four separate agreements for the supply of COVID-19 vaccines, should they be proven safe and effective

- University of Oxford/AstraZeneca
 - Up to 53.8 million doses;
 - Initially made offshore
 - Capacity to make locally
- Pfizer/BioNTech
 - Up to 10 million doses
 - Entirely made offshore
- Novavax
 - Up to 51 million doses
 - Entirely made offshore
- ~~UQ/CSL~~
- COVAX Facility
 - 188 countries
 - Enable access of 9 vaccine candidates

How?

COVID-19 Vaccines and
Treatments for Australia –
Science and Industry Technical
Advisory Group

Therapeutics Goods
Administration

Australian Technical Advisory
Group on Immunisation

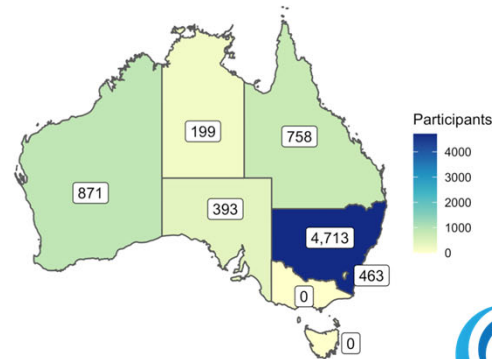
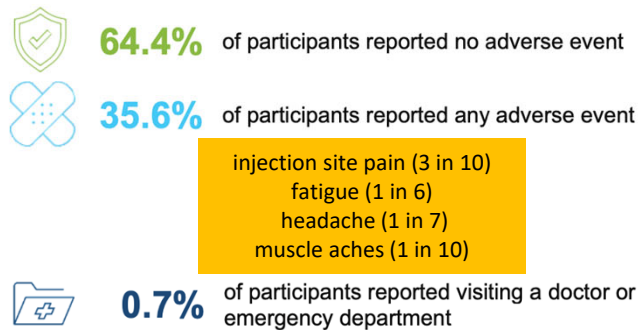
Jurisdictional Immunisation
Coordinators and Programs

Communicable Disease Network
of Australia



Real-time monitoring

11,079 surveys sent Australia wide
7,397 participants (66.8% response rate)



Australian Government
Department of Health
Therapeutic Goods Administration

AusVaxSafety
An NCIRS led collaboration



Enhancement of WA Vaccine Safety Surveillance
Weekly review of all reported adverse events
Additional clinics established to review those with or at risk of adverse events

How?

COVID-19 Vaccines and
Treatments for Australia –
Science and Industry Technical
Advisory Group

Therapeutics Goods
Administration

Australian Technical Advisory
Group on Immunisation

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ATAGI providing advice to the commonwealth through three streams of work:

- Vaccine utilization and prioritization
- Vaccine distribution and program implementation
- Vaccine safety, evaluation, monitoring and confidence

Bilateral discussion between Commonwealth and States and Territories have resulted in development of the COVID-19 vaccine program:

- Sites and staff
- Logistics
- Education and training
- Track and Trace
- Safety, monitoring and pharmacovigilance
- Communication and confidence

Using what works (and supplementing this where necessary)

Vaccine communication and confidence



Dominic Raab blasts Russia over fake news claims Oxford Covid vaccine could turn people into monkeys

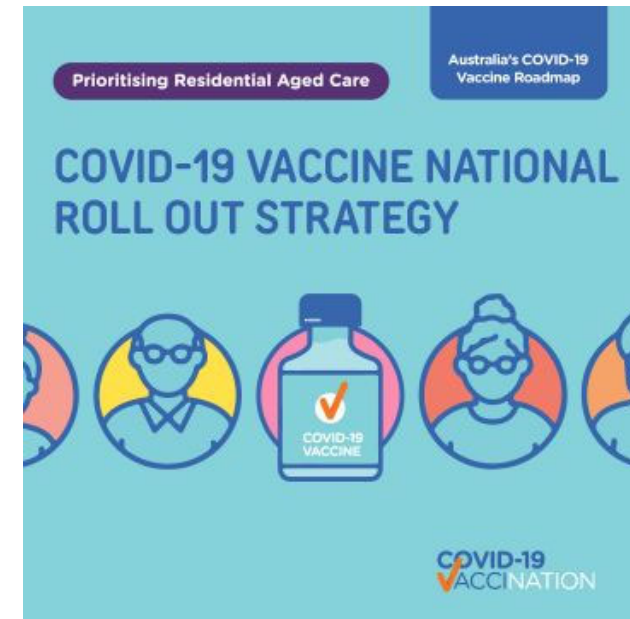


Dominic Raab blasts Russia over fake news claims Oxford Covid vaccine could...
DOMINIC Raab yesterday tore into Russia's campaign to discredit the Oxford coronavirus vaccine. Moscow is flooding social media with posts pretending th...
thesun.co.uk

Vaccine communication and confidence



Vaccine communication and confidence



Why, What, How, Who and When

Never before have we had both the pressing need and technology to develop a novel pandemic vaccine with a truly global distribution plan.

Hard decisions have been required. These decisions must be guided by clear aims, ethical principles and the evidence.

Clear communication and community engagement is critical to confidence and effective program roll-out.

We all have a critical role to play

Acknowledgements:
Slides from Katie Flanagan;
Margie Danchin; Claudio Rosa