COVID-19 vaccination: efficacy, effectiveness and priority populations

Gold Coast PHN 23rd March 2021



Chris Blyth <u>christopher.blyth@uwa.edu.au</u> @ChrisBlyth74



WESFARMERS CENTRE OF VACCINES & INFECTIOUS DISEASES



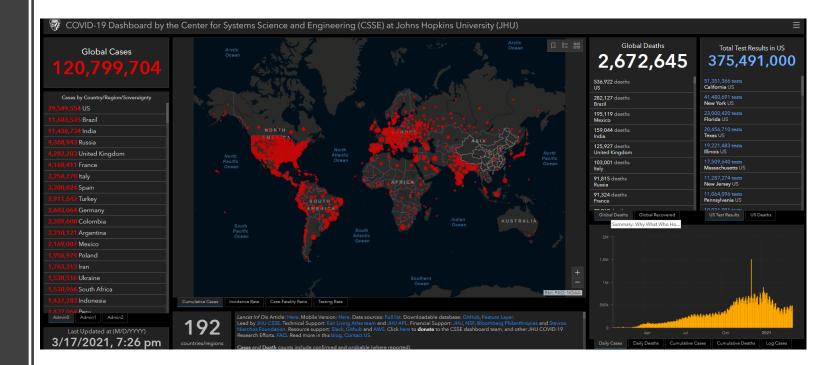




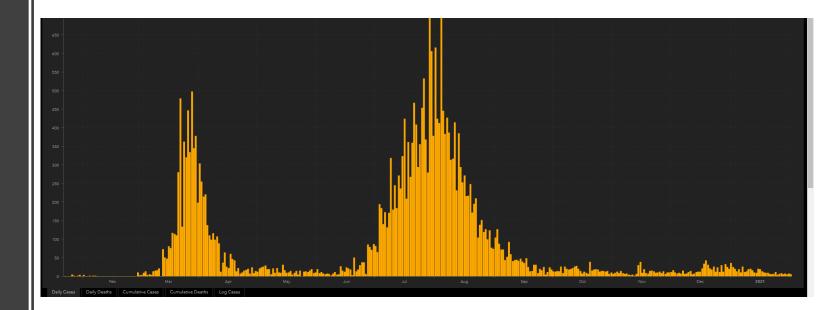
PathWest



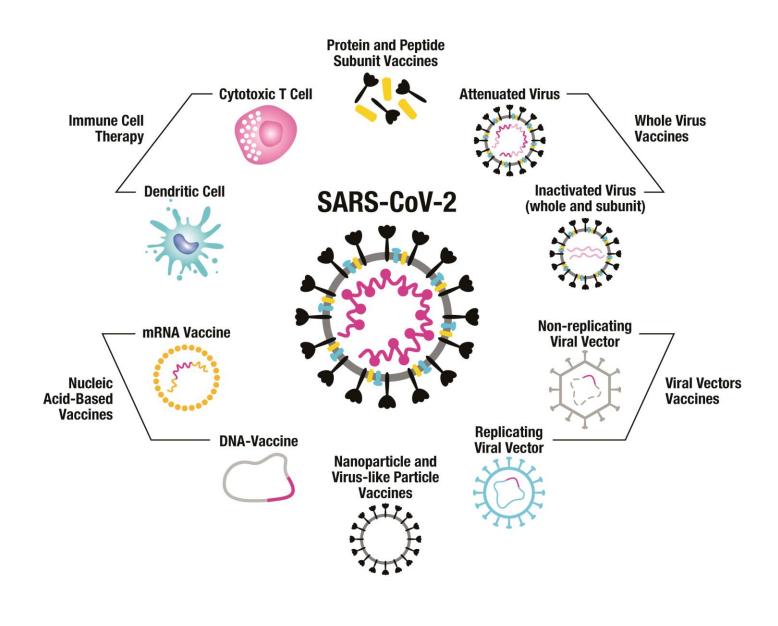
Summary: Why What Who How When



https://coronavirus.jhu.edu/map.html (17th March 2021) Summary: Why What Who How When

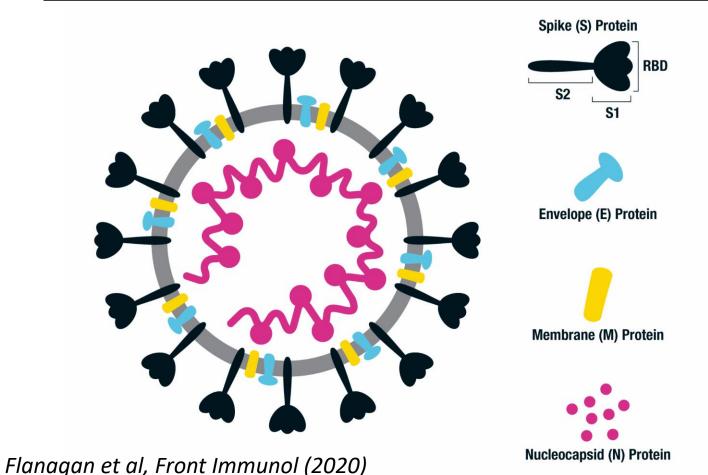


Summary: What Who How When



Flanagan et al, Front Immunol (2020)

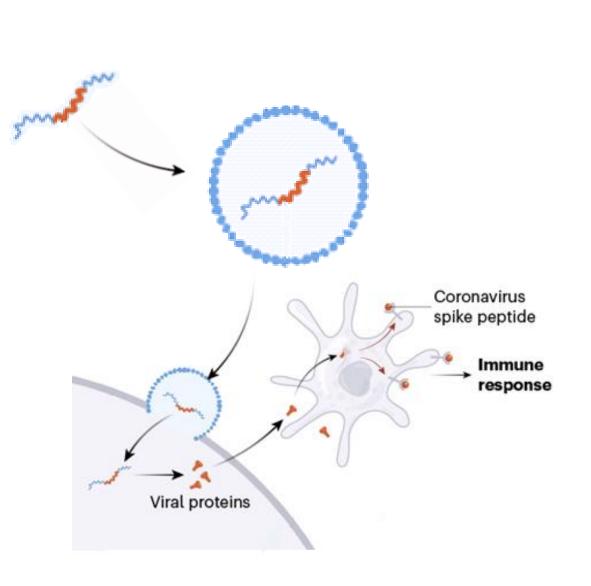
SARS-CoV-2 Structure and Key Vaccine Antigens



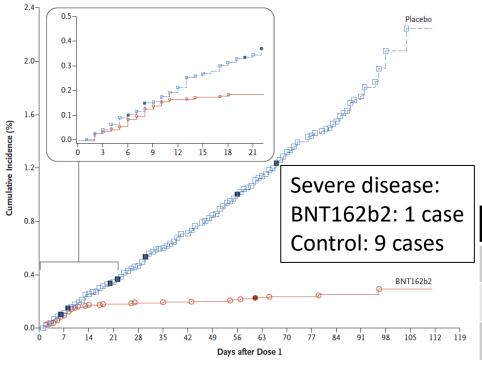
- Enveloped positive sense single stranded RNA virus: *Coronaviridae* family
- The genome of SARS-CoV-2 codes for the structural proteins spike (S), envelope (E), membrane (M) and nucleocapsid (N) and various accessory and non-structural proteins
- Most vaccines focused on eliciting neutralising antibodies 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)



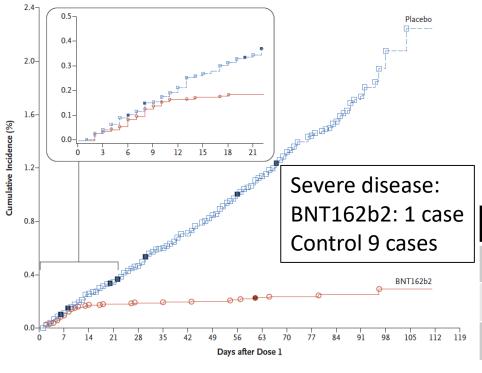


- Interim data from ongoing blinded RCTs
 - Enrolling adults ≥ 16y: US; Argentina/Brazil; South Africa; Germany
 - 1:1 randomization: BNT162b2 vs saline; 2 doses; 21d apart
 - 1^o endpoint: symptomatic COVID in SARS-CoV2 naïve individual with PCR positive swab more than 7d after 2nd dose
- 43548 participants;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

Polack FP et al NEJM 2020

BNT162b2 (BioNTech-Pfizer)





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Polack FP et al NEJM 2020

COMIRNATY (BNT162n2)

Attachment 1: AusPAR - COMIENATY - INST1622 (InRNA) - Pfizer Australia Pri Lud - PM-320-0564-1-5 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 PL, please refer to the TGA website at < dttps://www.seg.or.au/product-information.pl>

▼ 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 <u>www.tga.gov.au/reporting-problems</u>.

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.

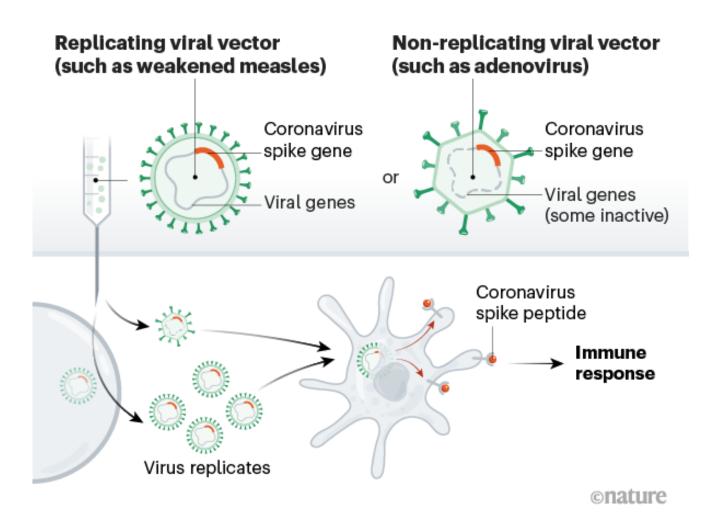
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Supersedes: N/A Page 1 of 15

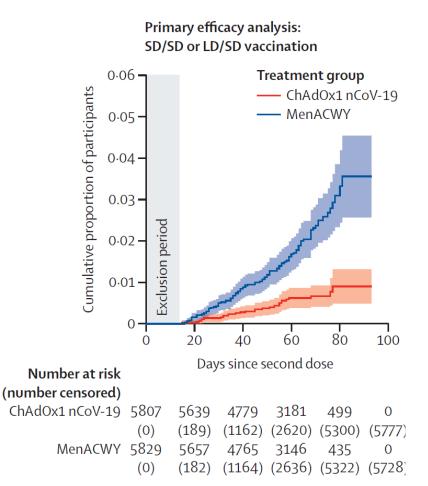
- Indication: Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2 in individuals 16 years and older
- Two doses at least 21 days apart. Intramuscular injection
- Must be stored frozen
- Contraindications: hypersensitivity to the active substance of any excipients
- 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



ChAdOx-1 nCoV-19 / AZD1222

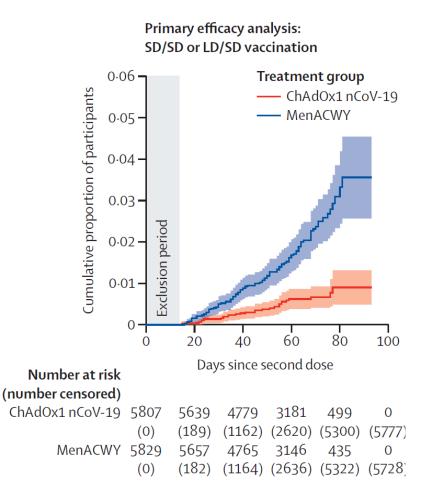


- Interim data from four ongoing blinded RCTs
 - Enrolling adults ≥ 18y: UK; Brazil; South Africa
 - 1:1 randomization: ChAdOx1 vs MenACWY; 2 doses; minimum of 28d
 - Two dosing regimens: SD/SD and LD/SD
 - 1^o endpoint: PCR positive swab more than 14d after 2nd dose
- 23,848 participants; data reported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



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 - Enrolling adults ≥ 18y: UK; Brazil; South Africa
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Voysey M et al Lancet 2020

COVID-19 Vaccine AZ (ChAdOx1-S)

Attachment 1: Product information for AusPAR-COVID-19 VACCINE ASTRAZENECA - ChAdOALS - AstraZeneea Pty Ltd - PM-2020.06115-1 2 FFNAL15 February 2021. This is the Product Information that was approved with the submission described in this AusPAR. It may have been superseded. For the most revent PL phases refers to the Tox Avelation at "Signation work tagge are appeader-advantametry-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

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 5x1011 viral particles (vp) of (ChAdOx1-S a, b) in 5 mL

One dose (0.5 mL) contains 5x1010 vp of (ChAdOx1-S a, b).

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

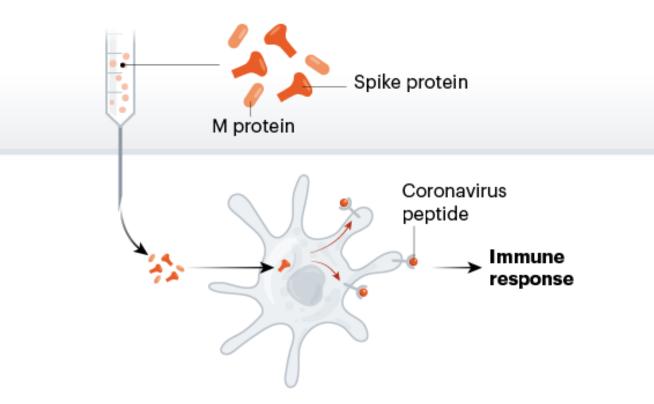
The COVID-19 Vaccine AstraZeneca vaccination course consists of two separate doses of 0.5 mL each. The second dose should be administered between 4 and 12 weeks after the first dose (see Section 5.1 Pharmacodynamic properties).

1 of 12

- 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 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 B1.351 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 <u>announced</u> 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 ≥ 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

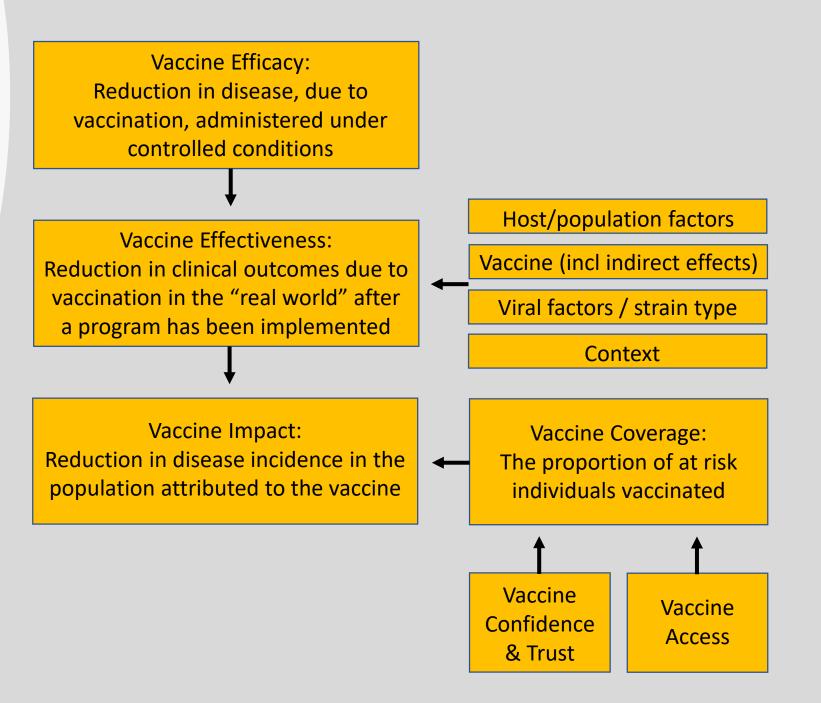
Force of infection and non-pharmacological measures

Case ascertainment:

Definition of symptomatic infection / Severity of infection Time post vaccination to significant events Use of therapeutics and supportive care

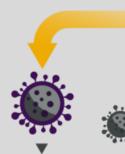
https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab213/6159795

Efficacy vs Effectiveness vs Impact



Uncertainties remain

- Comparative effectiveness data
- Impact on severe vs mild 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



Name:

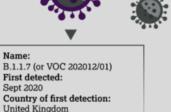
Sept 2020

Yes (>50)

Concern:

Detected in other countries:

Increased transmissibility





Detected in other countries:

Increased transmissibility and

possible reduction of vaccine

Name:

B.1.351

Oct 2020

Yes (<20)

Concern:

effectiveness

First detected:

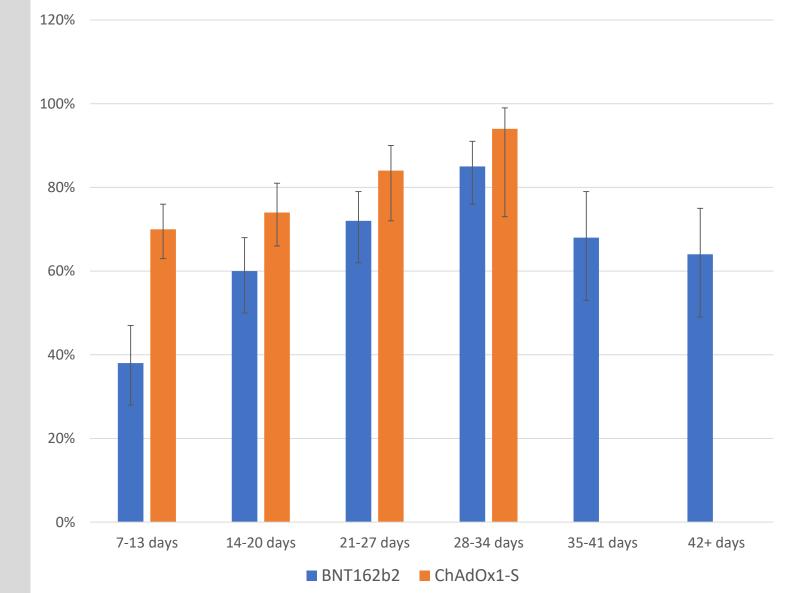
South Africa



Name: First detected: Dec 2020 Country of first detection: Brazil Detected in other countries: Yes Concern: Increased transmissibility and possible reduction of vaccine effectiveness

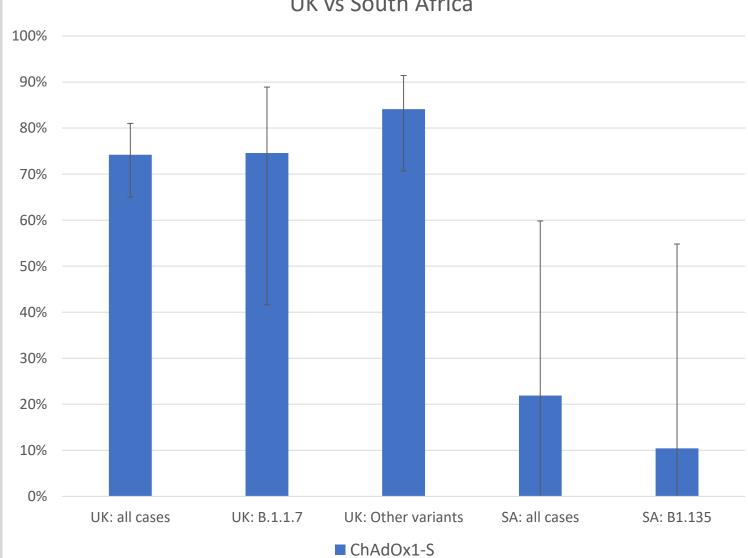
Knowledge gaps are being rapidly closed

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



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

AZ effectiveness against symptomatic COVID19: UK vs South Africa

AZD1222

AZD1222 US Phase III trial met primary efficacy endpoint in preventing COVID-19 at interim analysis

22 March 2021 07:00 GMT

79% vaccine efficacy at preventing symptomatic COVID-19

100% efficacy against severe or critical disease and hospitalisation

Comparable efficacy result across ethnicity and age, with 80% efficacy in participants aged 65 years and over

Favourable reactogenicity and overall safety profile

The AstraZeneca US Phase III trial of AZD1222 demonstrated statistically significant vaccine efficacy of 79% at preventing symptomatic COVID-19 and 100% efficacy at preventing severe disease and hospitalisation.

This interim safety and efficacy analysis was based on 32,449 participants accruing 141 symptomatic cases of COVID-19. The trial had a 2:1 randomisation of vaccine to placebo.

Vaccine efficacy was consistent across ethnicity and age. Notably, in participants aged 65 years and over, vaccine efficacy was 80%. Knowledge gaps are being rapi...

The vaccine was well tolerated, and the independent data safety monitoring board (DSMB) identified no safety concerns related to the vaccine. The DSMB conducted a specific review of thrombotic events, as well as cerebral venous sinus thrombosis (CVST) with the assistance of an independent neurologist. The DSMB found no increased risk of thrombosis or events characterised by thrombosis among the 21,583 participants receiving at least one dose of the vaccine. The specific search for CVST found no events in this trial.

Ann Falsey, Professor of Medicine, University of Rochester School of Medicine, US, and co-lead Principal Investigator for the trial, said: "These findings reconfirm previous results observed in AZD1222 trials across all adult populations but it's exciting to see similar efficacy results in people over 65 for the first time. This analysis validates the AstraZeneca COVID-19 vaccine as a much-needed additional vaccination option, offering confidence that adults of all ages can benefit from protection against the virus."

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "These results add to the growing body of evidence that shows this vaccine is well tolerated and highly effective against all severities of COVID-19 and across all age groups. We are confident this vaccine can play an important role in protecting millions of people worldwide against this lethal virus. We are preparing to submit these findings to the US Food and Drug Administration and for the rollout of millions of doses across America should the vaccine be granted US Emergency Use Authorization."

AstraZeneca will continue to analyse the data and prepare for the primary analysis to be submitted to the US Food and Drug Administration for Emergency Use Authorization in the coming weeks. In parallel, the primary analysis will be submitted for publication in a peer-reviewed journal.

Amongst participants in the interim analysis, approximately 79% were white/Caucasian, 8% black/African American, 4% native American and 4% Asian, and 22% of participants were Hispanic.

Approximately 20% of participants were 65 years and over, and approximately 60% had co-morbidities associated with an increased risk for progression of severe COVID-19, such as diabetes, severe obesity or cardiac disease.

This AstraZeneca-led US Phase III trial included two doses administered at a four week interval. Previous trials have shown that an extended interval of up to 12 weeks demonstrated greater efficacy, which was also supported by immunogenicity data. This evidence suggests administration of the second dose with an interval longer than four weeks could further increase efficacy and accelerates the number of people who can receive their first dose.

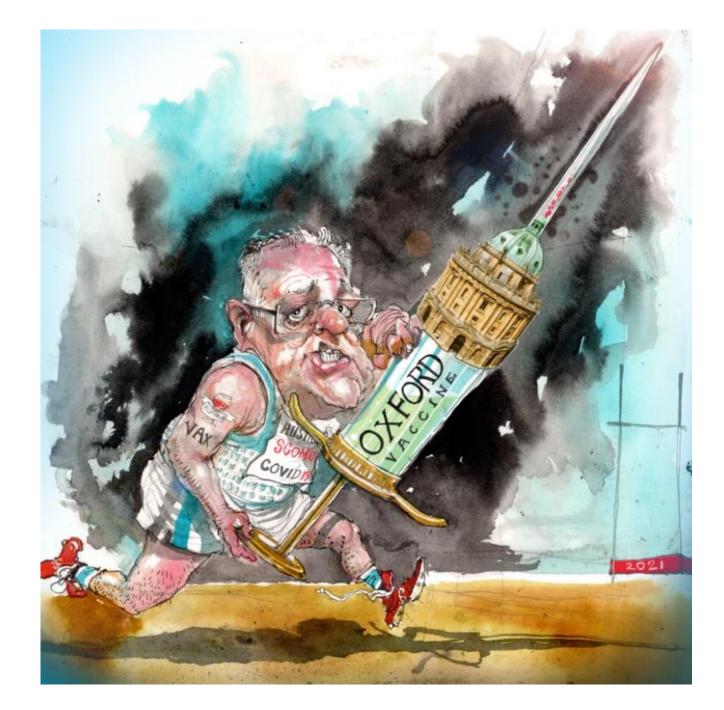
Results released by press release (22nd March 2021)

Phase III results from the American trial (US; Chile; Peru):

- >32,000 participants from 18 years of age, including 20% over the age of 65 and 60% with comorbidities
- Randomised 2:1 to AZD1222 and placebo (4 week interval)
- Primary endpoint: PCR-confirmed symptomatic COVID-19 with onset ≥ 15 days after second dose
- 141 symptomatic cases
- Overall vaccine efficacy: 79%
- Vaccine efficacy against severe disease: 100%
- No safety concerns identified (including cases of cerebral venous sinus thrombosis)

https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2021/astrazeneca-us-vaccine-trial-met-primary-endpoint.html#!

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



Strategic Advisory Group of Experts, WHO, 2020

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?

Australian Technical Advisory Group on Immunisation (ATAGI)

reliminary advice on general principles to uide the prioritisation of target populations in a OVID-19 vaccination program in Australia

Overarching goal of the COVID19 vaccination program in Australia

• The Australian COVID-19 vaccination program has the overarching goal of <u>protecting all people in</u> <u>Australia</u> 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-ina-covid-19-vaccination-program-in-australia_0.pdf

Priority populations

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Quarantine and border workers	70,000	Phase 1b – up to 14.8m doses							
Frontline health care worker sub-groups for prioritisation	100,000	Elderly adults aged 80 years and over	1,045,000	Phase 2a – up to	15.8m dose	es			
Aged care and disability care staff	318,000	Elderly adults aged 70-79 years	1,858,000	Adults aged 60-69 years	2,650,000		11 1		
Aged care and disability care residents	190,000	Other health care workers	953,000	Adults aged 50-59 years	3,080,000	Phase 2b – up to 16m doses			
Total	678,000	Aboriginal and Torres Strait Islander people > 55	87,000	Aboriginal and Torres Strait Islander people 18- 54	387,000	Balance of adult population	6,643,000	Phase 3 – up to 13.6	m dos
		Younger adults with an underlying medical condition, including those with a	2,000,000	Other critical and high risk workers	453,000	Catch up any unvaccinated Australians from previous phases		< 18 if recommended	5,670,00
		disability Critical and high risk	•••••	Total	6,570,000				
		workers including defence, police, fire,	196,000						
		emergency services and meat processing							

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 20 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



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 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



The Cow Pock _ or _ the Wonderful Effects of the New Inoculation !_ vine the Publication of y data Macine Society.



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

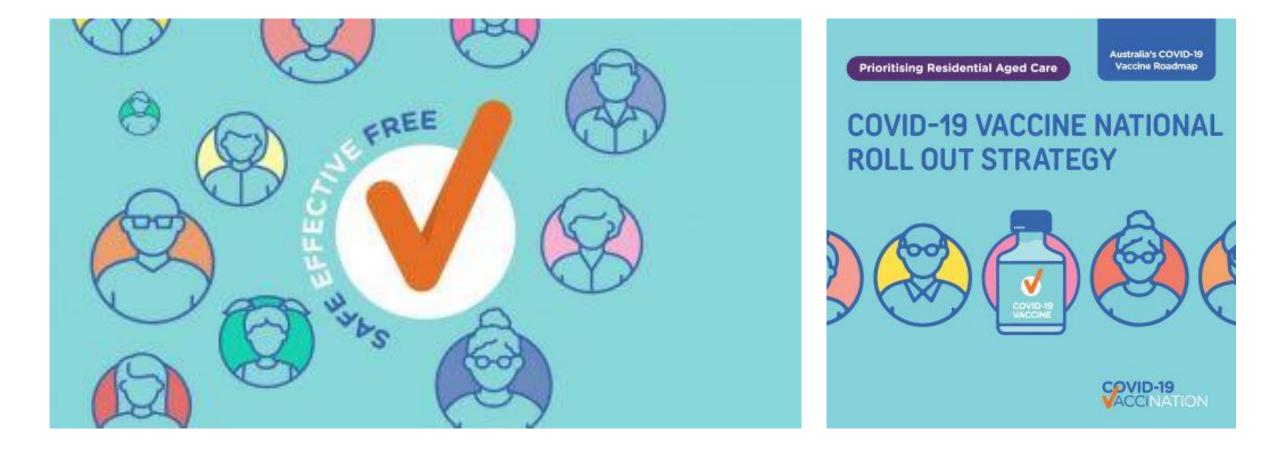


Dominic Raab blasts Russia over fake news claims Oxford Covid vaccine could... DOMINIC Raab yesterday tore into Russia's campaign to discredit the Oxford coronavirus vaccine. Moscow is flooding social media with posts pretending th... & thesun.co.uk

Vaccine communication and confidence



Vaccine communication and confidence



Summary: Why What Who How When



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 are required and must be guided by clear aims, ethical principles and the evidence.

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

We all have a critical role to play

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