Evidence table

COVID-19 vaccines

4 April 2023

This is the final version of the living evidence table on COVID-19 vaccines. This evidence table was last updated in March 2023. This table is no longer a 'living' document and the information within it is not updated on a regular basis.

Background

There are four main types of COVID-19 vaccines and over <u>240 candidate vaccines</u> in development. This table includes information on vaccines that have published phase 3 trial data in the peer reviewed literature and are <u>provisionally approved</u> by the Australian Government Therapeutic Goods Administration (TGA). It focuses on information related to efficacy and safety. Data is included on these vaccines from additional publications. Studies that capture outcomes in real world settings are tabulated under effectiveness. Approximates of the vaccine effectiveness relative to time since last dose is derived from an ongoing <u>systematic review</u> and dataset prepared by the International Vaccine Access Center at Johns Hopkins Bloomberg School of Public Health, World Health Organization (WHO), and Coalition for Epidemic Preparedness Innovations (CEPI). Safety data is derived from the TGA <u>COVID-19 vaccine safety reports</u> and <u>AusVaxSafety</u> – an Australian national survey on COVID-19 vaccine safety.

The <u>TGA</u> recognise the following vaccines for the purpose of travel to Australia:

- Coronavac (Sinovac)
- Covidshield (AstraZeneca Serum Institute of India)
- BBIBP-CorV for people aged 18 60 years of age (Sinopharm China)
- Covaxin (Bharat Biotech)
- Sputnik V (Gamaleya Research Institute)

	Comirnaty (Pfizer/BioNTech) BNT162b2	Vaxzevria (Oxford/AstraZeneca) AZD1 222	Spikevax (Moderna) mRNA- 1273	Janssen Ad26.COV2.S	Novavax NVX-CoV2373
Phase 3 trial publication	<u>The New England Journal of</u> <u>Medicine (1)</u> <u>The New England Journal of</u> <u>Medicine (2)</u>	<u>The Lancet (3)</u> <u>The Lancet (4)</u>	<u>The New England</u> <u>Journal of Medicine</u>	The New England Journal of Medicine	<u>The New England</u> Journal of Medicine (1) The New England Journal of Medicine (2)
Vaccine type	mRNA (nucleic acid)	Viral vector	mRNA (nucleic acid)	Viral vector	Protein subunit
Dosing schedule from phase 3 trial	Two 30µg doses; Dose interval 21 days	Two doses (5x10 ¹⁰ viral particles); Dose interval 28 days	Two 100µg doses; Dose interval 28 days	One dose (5x10 ¹⁰ viral particles)	Two 5µg doses; Dose interval 21 days
Efficacy - various endpoints					
SARS-CoV-2 infection	14 to 20 days after Dose 1: 46%* ≥7 days after Dose 2: 92%* (2)	55.7%* (3) 54.1%* (4)	89.6%*	Not yet available	Not yet available
Asymptomatic infection	14 to 20 days after Dose 1: 29% (estimated)* ≥7 days after Dose 2: 90% (estimated)* (2)	LD/SD (initial half dose) 58.9% /SD/SD (full dose) recipients 3.8% Total combined 27.3%*1 (3) COV002 UK study participants only: LD/SD 49.3%* / SD/SD 2.0%* Total combined 22.2%* (4)	Not yet available	At day 71 days: 65.5%*	Not yet available
COVID-19 symptomatic disease	95.0% (1) 14 to 20 days after Dose 1: 57%* ≥7 days after Dose 2: 94%*(2)	70.4% (this varies from 62.1– 90.0% based on schedule used) (3)	94.1%	≥14 days after dose: 66.9% ≥28 days after dose: 66.5%	89.7% (1) 90.4% (2)



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		LD/SD 80.7%* / SD/SD 63.1%* 66.7% (overall efficacy >14 days after second dose)* (4) <u>76%</u> (2 doses administered 4 weeks apart)^ <u>85%</u> for ages ≥65 years^			
Severe COVID- 19	 88.9% after Dose 1* (1) 14 to 20 days after Dose 1: 62%* >7 days after Dose 2: 92%* (2) For hospitalisation: 14 to 20 days after Dose 1: 74%* ≥7 days after Dose 2: 87%* (2) 	100%*⊦ (3) 100% (US Phase 3 trial; 2 Doses administered 4 weeks apart)^	100%*	 ≥14 days after dose: 76.7% ≥28 days after dose: 85.4% For hospitalisation: ≥14 days after dose: 93.1%* ≥28 days after dose: 100%* 	100%*⊦ (No hospitalizations or cases of severe infection were reported among the 10 cases in the vaccine group) (1) 100%*⊦ (No hospitalizations or cases of severe infection were reported among the 14 cases in the vaccine group) (2)
Mortality	14 to 20 days after Dose 1: 72% (estimated)* (2)	Not yet available	Not yet available	≥28 days after dose: <u>82.8</u> %, with protection sustained through at least 6 months after administration.	Not yet available
Transmission l	Reduction in PCR positivity in contacts of index cases who received 2 doses versus non- vaccinated: adjusted rates	Reduction in PCR positivity in contacts of index cases who received 2 doses versus non-vaccinated: adjusted rates	Not yet available	Not yet available	Not yet available



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	ratio <u>0.32</u> for Alpha and 0.5 for Delta	ratio <u>0.48</u> for Alpha and 0.76 for Delta			
Effectiveness and duration	<u>Severe disease</u>	<u>Severe disease</u>	<u>Severe disease</u>	Severe disease	Direct evidence on efficacy against the
('real world' data; Omicron	Primary 0.5 to <3m: ~70%	Primary 0.5 to <3m: ~65%	Primary 0.5 to <3m: ∼60%	Primary 0.5 to <3m: ~25%	Omicron variant is not yet available.
variant)	Primary 3 to <6m: ~65%	Primary 3 to <6m: ~60%	Primary 3 to <6m:	Primary 3 to <6m: ~35%	
	Primary >6m: ~55%	Primary >6m: ~50%	~70%	Primary >6m: ~50%	
	First booster 0.5 to < 3m: ~85%	First booster (either with Comirnaty or Spikevax) 0.5 to	Primary >6m: ~55%	Booster 0.5 to <3m :	
	First booster 3 to < 6m: ~75%	<3m: ~85%	Sim: ~85%	~75%	
	First booster ≥ 6m: ~35%	Comirnaty or Spikevax) 3 to	First booster 3 to $< 6m$:		
	Second booster 0.5 to < 3m: ~50%	Sumptomotio discoso	~00%	~70%	
	Second booster 3 to < 6m: $\sim 30\%$	$\frac{30\%}{2}$	< 3m: ~80%	Booster 0.5 to <3m: ~50%	
	Symptomatic disease	Primary 3 to <6m; <0%	Symptomatic disease	Any infection	
	Primary 0.5 to <3m: ~60%	Primary >6m: <0%	Primary 0.5 to <3m: ∼55%	Primary 0.5 to $<3m$:	
	Primary 3 to <6m: ~25%	Findary 2011. <070	Primary 3 to <6m	~60%	
	Primary >6m: ~15%	Comirnaty or Spikevax) 0.5 to	~20%	Primary 3 to <6m: ~40%	
	FIRST DOOSTER U.5 TO <3M: ~65%			Primary >6m: ~40%	



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First booster 3 to <6m: ~50%	First booster (either with	Primary >6m: ~10%		
First booster ≥ 6m: ~5%	<6m: ~25%	First booster 0.5 to <3m: ~60%		
Second booster 0.5 to < 3m: ~40%	Any infection			
Second booster 3 to < 6m: ~10%	Primary 0.5 to <3m: ~50%	∼25%		
Any infection	Primary 3 to <6m: ~50%	Second booster 0.5 to <3m: ~65%		
Primary 0.5 to <3m: ~50%	Primary >6m: ~0%	Any infection		
Primary 3 to <6m: ~20%	First booster (with Comirnaty) 0.5 to <3m: ~45%	Primary 0.5 to <3m:		
Primary >6m: ~15%		~40%		
Booster 0.5 to <3m: ~55%		Primary 3 to <6m: ~30%		
Booster 3 to <6m: ~30%		Primary >6m: ~15%		
		First booster 0.5 to <3m: ~65%		
		First booster 3 to <6m: ~20%		
		Second booster 0.5 to < 3m: ~60%		



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			Second booster 3 to < 6m: ~25%		
Effectiveness of the second booster dose relative to the first booster dose ('real world' data; Omicron variant)	Death ~35%-90% (any mRNA vaccine as a second booster) Severe disease ~30%-90% (any mRNA vaccine as a second booster) Symptomatic disease ~30%-90% (any mRNA vaccine as a second booster) Any infection ~0%-80%	Not yet available	Death ~35%-90% (any mRNA vaccine as a second booster) <u>Severe disease</u> ~30%-90% (any mRNA vaccine as a second booster) <u>Symptomatic disease</u> ~30%-90% (any mRNA vaccine as a second booster) <u>Any infection</u> ~0%-80%	Not yet available.	Not yet available.
Safety	Commonly reported <u>adverse</u> <u>events</u> after the dose two include local reaction, fatigue, headache, and muscle or joint pain. They are generally mild and short-lived. <u>Myocarditis</u> is more commonly reported after the second dose in	Commonly reported <u>adverse</u> <u>events</u> after the dose two include fatigue, local reaction, headache, and muscle or joint pain. They are generally mild and short-lived.	Commonly reported <u>adverse</u> <u>events</u> after the dose two include fatigue, local reaction, headache, and muscle or joint pain. They are	Initial assessment determined acceptable safety profile. <u>WHO</u> estimates that approximately 2 cases per million doses administered globally	Commonly reported <u>adverse</u> <u>events</u> after the dose two include local reaction, fatigue, headache, and muscle or joint pain.



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12-17 year-old boys (14 cases per 100,000 Comirnaty doses) and men under 30 (9 cases per 100,000 Comirnaty doses). <u>Pericarditis</u> is reported in about 2 in every 100,000 people who receive	Thrombocytopenia syndrome (TTS) reported in about 2 in every 100,000 people Immune thrombocytopenia (ITP) and Guillain-Barre	generally mild and short-lived. <u>Myocarditis</u> is more commonly reported after the second dose in 12–17-year-old boys	experience TTS. No TTS cases have been recorded after a <u>second</u> or <u>subsequent dose</u> . The overall estimated observed to expected	They are generally mild and short-lived. <u>Pericarditis</u> is reported in about 13 in every 100,000 doses, most commonly in males aged
an mRNA vaccine. The rate of reporting of myocarditis and pericarditis is less than 1 in every 100,000 people after a <u>booster (either a third or fourth)</u> dose	Syndrome (GBS) reported in about one in every 100,000 people TGA has found <u>no</u> <u>evidence</u> of increased risk by anaphylaxis	(24 cases per 100,000 Spikevax doses) and men under 30 (23 cases per 100,000 Spikevax doses).	rate ratio for presumptive Guillain-Barre Syndrome was <u>4.18</u> , corresponding to an absolute rate increase of 6.36 per 100 000 person-years.	18-49 years old
The most common adverse events reported to the TGA following a booster dose are headache, swollen lymph nodes, chest pain, fatigue and muscle pain.		in about 2 in every 100,000 people who receive an mRNA vaccine.		
		myocarditis and pericarditis is less than 1 in every 100,000 people after a <u>booster</u> (either a third or fourth) dose.		
		The most common adverse events reported to the TGA following a booster dose are headache,		



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			swollen lymph nodes, chest pain, fatigue and muscle pain.		
Storage	-80°C and -60°C - <u>20±5°C for up to 2 weeks</u> within the shelf life when stored at -90 to - 60°C <u>2°C to 8°C</u> for unopened thawed vials up to 31 days.^	2°C to 8°C	-25°C and -15°C	2°C to 8°C: Unopened for up to 4.5 months. 2°C to 8°C: Opened up to 6 hours. Freezer at <u>-25°C to -</u> <u>15°C</u> : Up to 24 months to the expiry date.	2°C to 8°C
Study participants	43,548 enrolled, 43,448 received injections (randomly assigned 1:1 ratio) (1) 596,618 vaccine recipients matched 1:1 ratio to controls. (2)	 23 848 enrolled, 11 636 included in interim primary efficacy analysis (randomly assigned 1:1 ratio) (3) 17178 participants included in the efficacy analysis after a further month of data collection from original Lancet article* (4) 	30,420 enrolled (randomly assigned 1:1 ratio)	44,325 enrolled, 43,783 received vaccine or placebo (randomly assigned 1:1 ratio)	 15,187 enrolled, 15,139 underwent randomisation (randomly assigned 1:1 ratio) 14,039 participants met the criteria for the perprotocol efficacy population
Study population	49% female, 35% obese, 21% at least one coexisting condition. Majority White (83%). Median age 52 years; 42% older than 55y (1) Participants from Clalit Health Services data, which insures 4.7 million patients (53% of the population). (2)	Majority aged 18–55 years (86.7% in UK; 89.9% in Brazil cohort). 60.5% female. Majority White (91.4% in UK; 66.6% in Brazil)	47.3% female, mean age 51.4 years; 24.8% were 65 years of age or older. Majority White (79.2%)	45.0% female, median age 52 years; 33.5% were 60 years of age or older. Majority White (58.7%). Latin America 40.9%; South Africa 15.0%; US 44.1%	45.0% female, median age 52 years; 33.5% were 60 years of age or older. Majority White (58.7%). Latin America 40.9%; South Africa 15.0%; US 44.1%



Notes

* Preliminary data, not fully established, in some cases small numbers or short follow up, or based on previous data; interpret with caution.

- ^ Commentary, grey literature, pre peer review or news.
- 1 Asymptomatic/unreported symptoms. Efficacy estimated by study by pooling all cases and applying to entire cohort of sub studies; interpret with caution.
- + Onward transmission in a vaccinated individual.
- +This figure was not reported in the paper but was included on the same basis of the Moderna results for severe COVID-19.
- LD/SD = low dose/standard dose and SD/SD = standard dose

Where multiple studies are available on an outcome, not all studies are hyperlinked. Those that are more recent, published in peer reviewed journals and are higher on the evidence hierarchy are generally linked.

Living evidence tables include some links to low quality sources and an assessment of the original source has not been undertaken. Sources are monitored regularly but due to rapidly emerging information, tables may not always reflect the most current evidence. The tables are not peer reviewed, and inclusion does not imply official recommendation nor endorsement of NSW Health.

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