Risk-benefit analysis of the Pfizer COVID-19 vaccine in Australia for the Omicron variant using an adaptable Bayesian network modelling framework
28 February 2022.

Summary of data sources, assumptions, and prior distributions

Model inputs	Data sources, assumptions, rationale (references)
Vaccine effectiveness (VE) against symptomatic infection	VE against Omicron variant: 1 dose [1] • Source: Data from Andrews et al. Effectiveness of COVID-19 vaccines against the Omicron (B1.1.529) variant of concern. Study from UK based on 581 Omicron cases between 27/11/2021 and 6/12/2021. • Assumptions: Study reported VE at 4+ weeks after first dose. Our model assumed the same effectiveness for 3 weeks after first dose. 2 and 3 doses [2] • Source: UK Health Security Agency COVID-19 vaccine surveillance report. Week 2, 13 January 2022. Figure 6b. • Assumptions: Study reported VE at different time points to those used in our model. For VE after two doses, our model used average of reported VE at 2-4 and 5-9 weeks to estimate VE at 0 to <2 months; average of VE at 10-14 and 15-19 weeks to estimate VE at 2 to <4 months; and average of VE at 20-24 and 25+ weeks to estimate VE at 4 to <6 months. For VE after 3 doses at <2 months, our model used average of reported VE at 1, 2-4, and 5-9 weeks after third dose. Data in Figure 6b were not provided as exact numbers in the report, so numbers were estimated using Plot Digitiser [3]. See Table S1 for summary of final assumptions.
Vaccine effectiveness against death	VE against Omicron variant: 1 dose [2] • Limited data were available for VE against death after one dose. • We assumed that the ratio of VE against death after dose 1: dose 2 was the same as the ratio of VE against hospitalisation after dose 1: dose 2 (0.91) from in the above report. 2 and 3 doses • Sources: [4] Report from Imperial College on 'The value of vaccine booster doses to mitigate the global impact of the Omicron SARS-CoV-2 variant'. Table 2. [2] UK Health Security Agency COVID-19 vaccine surveillance report. Week 2, 13 January 2022. Table 1. • Assumptions: Study (a) reported VE at different time points to those used in our model. For VE after two doses, our model used data 90 days post-dose 2 to estimate VE at 2 to <4 months; 180 days post-dose 2 to estimate VE at 4 to <6 months; and 90 days post-booster to estimate VE at <2 months post-booster. Report did not include VE at 0 to <2 months; model assumed the same as VE at 2 to <4 months. See Table S2 for summary of final assumptions.
Relative risk of symptomatic	Data from New South Wales (NSW) COVID-19 weekly surveillance reports shows age and sex distributions (separately) of COVID-19 cases in NSW from 26/11/2021 to 05/02/2022, and also reports the proportion of these cases that occurred in the unvaccinated population [5]. We assumed cases during this time-period were attributable to the Omicron variant. We calculated relative risk of infection by age group and sex for the Omicron variant

infection by age and sex	in the unvaccinated population by estimating the probability of infection in each age-sex group if overall probability of infection in the community was 1%. Relative risk for the unvaccinated population as opposed to the total population was used to isolate the effects of age and sex from the effects of vaccination, which are accounted for separately in the 'Vaccine effectiveness' nodes. We assumed the relative risk estimated based on data from NSW is applicable also to the rest of Australia. See Table S3 for final assumptions.
Risk of symptomatic infection under current transmission and vaccination status	Definitions of low, medium, and high transmission as defined by Australian Technical Advisory Group on Immunisation (ATAGI) [6]. Low – similar to first wave in Australia (equivalent to 0.016% of population infected over 2 months). Medium – similar to second wave in Victoria, Australia in 2020 (equivalent to 0.149% of population infected over 2 months). High – similar to Europe in January 2021 (equivalent to 1.920% of population infected over 2 months). We also included transmission scenarios equivalent to: zero transmission; 1%, 2%, 5% and 10% chance of infection over 2 months. See Table S4 for final assumptions.
Age distribution of infections and fatalities from Omicron variant	Data from NSW COVID-19 weekly surveillance reports shows the age distribution of COVID-19 cases and deaths in NSW from 26/11/2021 to 05/02/2022, and also reports the proportion of these cases and deaths that occurred in the unvaccinated population [5]. We assumed cases during this time-period were attributable to the Omicron variant. We calculated estimates of age distribution of cases and deaths for the Omicron variant in the unvaccinated population. Distributions for the unvaccinated population as opposed to the total population were used to isolate the effects of age from the effects of vaccination, which are accounted for separately in the 'Vaccine effectiveness' nodes. We assumed the estimates based off data from NSW are applicable also to the rest of Australia. When converting estimates into the age categories used in the model, we assumed that number of cases and deaths for 12-19 year-olds accounted for 80% of the numbers reported for ages 10-19. See Table S5 for final assumptions.
Risk of getting (background) myocarditis	Multinational network cohort study from Australia, France, Germany, Japan, Netherlands, Spain, the UK and the USA reports background incidence of myocarditis and pericarditis per 100,000 person-years by age group and sex [7]. We assumed that 65% of reported myopericarditis cases were myocarditis, based on proportions from other studies that differentiate between them post-vaccination [8,9]. We converted incidence to probability of infection per person over 2 months. To convert reported age groups into those used in the model, calculations were based on age distribution of the Australian population [10]. See Table S6 for final assumptions.
Risk of dying from (background) myocarditis	Study reports incidence of fatal myocarditis in Finland per 100,000 person-years by age group and sex as total risk [11], but not as case fatality rate. We converted incidence per 100,000 person-years to probability per person over 2 months (in the general population), then used these values for each age-sex subgroup as the numerator and the respective values for node 'Risk of getting (background) myocarditis' as the denominator to calculate case fatality rate. When converting reported age groups to the age groups used in our model, calculations were based on the age distribution of the Australian population [10]. See Table S6 for final assumptions.
Risk of getting Pfizer COVID-19 vaccine-associated myocarditis	Therapeutic Goods Administration (TGA) reports rates of myocarditis from the Pfizer COVID-19 vaccine per 100,000 doses in Australia, from all doses and second doses [12]. From this we calculated rates from first doses. At the time of writing (28/02/2022), the only data available for the third dose in Australia estimated a rate of less than 10 reported myocarditis cases per million people receiving a third dose. As this information was very limited, we assumed the same rate of vaccine-associated myocarditis as the second dose. This assumption was based on data from Israel reporting that rates of Pfizer COVID-19 vaccine-induced myocarditis from the third dose was higher than after the first dose but lower than after the second dose [13]. To provide a conservative estimate and avoid underestimating the potential risk of myocarditis after the third dose, we assumed the same rates as the second dose, i.e. the 'worst case scenario'. See Table S7 for final assumptions.
Risk of dying from Pfizer COVID-19	Case fatality rate from mRNA vaccine-associated myocarditis has not been reported widely, in part due to very low numbers. By August 2021, USA Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) [14] reported 1195 myocarditis cases after mRNA vaccination (dose number not specified) in those aged under 30 years, of which two likely died from myocarditis, giving a case fatality rate of

vaccine-associated myocarditis	0.167% (2/1195). We assumed the same case fatality rate for Pfizer and other mRNA COVID-19 vaccines, and the same case fatality rate in those aged ≥30 years.
Risk of getting SARS-CoV-2 infection-induced myocarditis	Study reports that 5.0% of patients with COVID-19 developed new-onset myocarditis [15] based on electronic medical records in TriNetX, a global federated health research network. Published data were insufficient to stratify by age and sex. Age-sex breakdown of the patient cohort with COVID-19 and related myocarditis cases were provided by the authors through personal communication. Exact dataset from the original patient cohort in the study were no longer available because of the revolving database; the patient data provided through personal communication was from an updated cohort and showed a lower total prevalence of myocarditis (~2.3%). See Table S8 for final assumptions.
Risk of dying from SARS-CoV-2 infection-induced myocarditis	Study reports a six-month all-cause mortality of 3.9% in COVID-19 patients with myocarditis, assuming that deaths were attributable to myocarditis [15]. Published data were insufficient to stratify by age and sex. Age-sex breakdown of the myocarditis cases and deaths were provided by the authors through personal communication. Data provided through personal communication were based on electronic medical records in TriNetX, reported with patient counts ≥10 rounded up to 10 to safeguard protected healthcare data. The case fatality rate for age-sex subgroups with 10 deaths was thus assumed to be <1.00%, with a value of 1.00% used in the model to assume the worst-case scenario. For males aged 12-19 and 20-29 years, there were zero deaths out of 152 and 661 cases of myocarditis, respectively. To avoid using a 0% case fatality rate in the model, we assumed that 12-19 and 20-29 year-old males had the same case fatality rate as 30-39 year-old males (1.00%). We believe this is a reasonable assumption because in females there was no significant difference in case fatality rate between ages 12-19 and 20-29 years and 30-39 years. See Table S8 for final assumptions.
Prior distributions*	
Age distribution of population	Distribution based on Australian Bureau of Statistics national population estimates from June 2021 [16]. See Table S9 for final assumptions. Note age group 0-11 years was excluded from this version of the model as they were not yet eligible for vaccination in Australia at time of model development. This age group will be added into the model in future updates.
Sex distribution of population	Distribution of 49% male and 51% female based on Australian Bureau of Statistics national population estimates from June 2021 [16]. See Table S9 for final assumptions.
Pfizer vaccine coverage in population	Assumed 5% had no doses, 5% had one dose only, 60% had two doses only, 30% had three doses for ages ≥12 years. These approximations were based on vaccine coverage data from Australian Government Department of Health COVID-19 vaccination data on 3 Jan 2022 [17], and our estimates of how coverage will increase over the coming months.
Community transmission at x% over 2 months	Chance of infection (x%) over 2 months, based on different levels of community transmission. Priors set to even distribution between categories, assuming that community transmission level will be selected when using the CoRiCal tool or running public health-level scenario analyses. See explanation above under 'Risk of symptomatic infection under current transmission and vaccination status'.

*Note that prior distributions do not affect results of scenario analysis but enables the model to provide population-level estimates. Assumptions can be changed as the situation evolves.

Supplementary Materials

Table S1. Pfizer COVID-19 vaccine effectiveness against symptomatic infection with SARS-CoV-2 Omicron variant.

1 dose[a]	2 doses (last dose 0 to <2 months ago)[b]	2 doses (last dose 2 to <4 months ago)[b]	2 doses (last dose 4 to <6 months ago)[b]	3 doses (<2 months post 3rd dose)[b]
34.2%	55.9%	21.6%	12.0%	64.0%

Sources:

[a]UK Health Security Agency. COVID-19 vaccine surveillance report – Week 2, 13 January 2022, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1047814/Vaccine-surveillance-report-week-2-2022.pdf; 2022 [accessed January 2022]. [2]

[b]Andrews N, Stowe J, Kirsebom F, Toffa S, Rickeard T, Gallagher E, et al. Effectiveness of COVID-19 vaccines against the Omicron (B.1.1.529) variant of concern. medRxiv 2021. https://doi.org/10.1101/2021.12.14.21267615. [1]

SourceForge. Plot Digitizer, http://plotdigitizer.sourceforge.net/; 2015 [accessed January 2022]. [3]

Table S2. Pfizer COVID-19 vaccine effectiveness against death with SARS-CoV-2 Omicron variant.

1 dose[a]	2 doses (last dose 0 to <2 months ago)[b]	2 doses (last dose 2 to <4 months ago)[b]	2 doses (last dose 4 to <6 months ago)[b]	3 doses (<2 months post 3rd dose)[b]
66.7%	73.6%	73.6%	50.4%	88.3%

Sources:

[a]UK Health Security Agency. COVID-19 vaccine surveillance report – Week 2, 13 January 2022, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1047814/Vaccine-surveillance-report-week-2-2022.pdf; 2022 [accessed January 2022]. [2]

[b]Hogan AB, Wu SL, Doohan P, Watson OJ, Winskill P, Charles G, et al. Imperial College COVID-19 Response Team Report 48: the value of vaccine booster doses to mitigate the global impact of the Omicron SARS-CoV-2 variant, https://spiral.imperial.ac.uk/bitstream/10044/1/93034/13/2021-12-16%20COVID19%20Report%2048.pdf; 2021 [accessed January 2022]. [4]

Table S3. Relative probability of infection by age group and sex in the unvaccinated population for the Omicron variant (chance of infection in each age-sex group if overall probability of infection of 1%).

Age group (years)	Male	Female
0-11	0.82%	0.85%
12-19	1.11%	1.16%
20-29	1.74%	1.81%
30-39	1.24%	1.29%
40-49	1.02%	1.06%
50-59	0.82%	0.85%
60-69	0.58%	0.61%
70-79	0.38%	0.40%
≥80	0.36%	0.37%
Overall	**0.98%**	**1.02%**

Sources:

NSW Health. COVID-19 weekly surveillance in NSW – Epidemiological week 5, ending 5 February 2022, https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20220223.pdf; 2022 [accessed February 2022]. [5]

Table S4. Probability of infection (over 2 months) based on different intensities of community transmission.

Intensity of community transmission	Cases per 100,000 over 16 weeks*	Cases per million over 2 months	Estimated % of population infected over 2 months	Equivalent to cases/day in Australia[a]
Zero	0	0	0.000%	0
Low*	29	157	0.016%	58
Medium*	275	1,490	0.149%	543
High*	3,544	19,197	1.920%	6998
1% chance of infection over 2 months		10,000	1.000%	3645
2% chance of infection over 2 months		20,000	2.000%	7290
5% chance of infection over 2 months		50,000	5.000%	18,225
10% chance of infection over 2 months		10,0000	10.000%	36,450

***** Definitions of low, medium, and high transmission (cases per 100,000 over 16 weeks) as defined by [6]. Low: similar to first wave in Australia. Medium: similar to second wave in VIC. High: similar to Europe in January 2021.

[a]Based on Australian population of 21.87 million. [10]

Source:

Australian Technical Advisory Group on Immunisation. (2021). Weighing up the potential benefits and risk of harm from COVID-19 vaccine AstraZeneca. *Australian Government Department of Health.* Accessed 17 December 2021 from https://www.health.gov.au/sites/default/files/documents/2021/06/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca_2.pdf. [6]

Table S5. Estimated cases, deaths, and case fatality rate of COVID-19 in the unvaccinated population in NSW by age for the Omicron variant, 26/11/2021 to 05/02/2022.

Age group	Estimated cases	% of cases in age group	Estimated deaths	Case fatality
12-19	12,061	12.32%	0.00	0.000%
20-29	26,733	27.31%	0.42	0.002%
30-39	20,692	21.14%	1.06	0.005%
40-49	14,870	15.19%	2.74	0.018%
50-59	11,416	11.66%	6.54	0.057%
60-69	7,069	7.22%	17.94	0.254%
70-79	3,315	3.39%	43.91	1.324%
≥80	1742	1.78%	125.17	7.187%
Total	**97,898**	**100.00%**	**197.79**	**0.202%**

Sources:

NSW Health. COVID-19 weekly surveillance in NSW – Epidemiological week 5, ending 5 February 2022, https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20220223.pdf; 2022 [accessed February 2022]. [5]

Table S6. Estimated background incidence and fatality of myocarditis over 2 months (in populations who have not received the Pfizer COVID-19 vaccine and have not been diagnosed with COVID-19).

	Incidence of myocarditis over 2 months (per million population)[b]		Incidence of fatal myocarditis over 2 months (per million population)[c]		Case fatality rates from myocarditis	
Age (years)[a]	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
12-19	18.96	10.02	0.25	0.25	1.34%	2.45%
20-29	40.08	17.33	0.48	0.30	1.21%	1.73%
30-39	40.08	20.58	0.92	0.44	2.29%	2.15%
40-49	40.08	23.83	1.33	0.73	3.31%	3.04%
50-59	44.42	28.71	1.14	0.88	2.57%	3.05%
60-69	50.92	35.75	1.26	1.04	2.47%	2.91%
70-79	55.79	40.08	1.63	1.61	2.93%	4.01%
≥80	51.45	39.54	1.57	1.95	3.04%	4.93%

Sources:

[a]Australian Bureau of Statistics. (2021). National, state and territory population. *Australian Bureau of Statistics.* Accessed 17 December 2021 from https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/latest-release. [10]

[b]Li, X., Ostropolets, A., Makadia, R., Shoaibi, A., Rao, G., Sena, A.G., et al. (2021). Characterising the background incidence rates of adverse events of special interest COVID-19 vaccines in eight countries: multinational network cohort study. *The BMJ* 2021(373):n1435. https://doi.org/10.1101/2021.03.25.21254315. [7]

[c]Kytö, V., Saraste, A., Voipio-Pulkki, L., and Saukko, P. (2007). Incidence of fatal myocarditis: a population-based study in Finland. American Journal of Epidemiology 165(5):570–574. https://doi.org/10.1093/aje/kwk076. [11]

Table S7. Estimated rates of myocarditis cases per million Pfizer COVID-19 vaccine doses in Australia by age and sex.

	First dose		Second dose		Third dose[a]	
Age (years)	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
12-19	19	4	98	23	98	23
20-29	11	2	67	20	67	20
30-39	11	7	19	5	19	5
40-49	2	3	12	9	12	9
50-59	7	2	1	4	1	4
60-69	2	4	0	0	0	0
70-79	0	0	0	4	0	4
≥80	0	0	0	4	0	4

[a]Assumed the same rates as after second dose because no data were available for rates after third dose.

Source:

Therapeutic Goods Administration. (2022). COVID-19 vaccine weekly safety report – 24-02-2022. *Australian Government Department of Health.* Accessed 28 February 2022 from https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-24-02-2022. [12]

Table S8. COVID-19-related myocarditis cases, deaths, and case fatality rate in ages ≥12 years by age and sex, up to 6 months post-myocarditis diagnosis.

	Male					Female				
Age (years)	COVID-19 cases	Myocarditis cases	Incidence	Deaths	Case fatality	COVID-19 cases	Myocarditis cases	Incidence	Deaths	Case fatality
12-19	1,106	152	13.74%	0[a]	<1.00%	12,291	204	1.66%	≤10[b]	<1.00%
20-29	31,758	661	2.08%	0[a]	<1.00%	54,404	1321	2.43%	≤10[b]	<1.00%
30-39	43,723	1025	2.34%	≤10[b]	<1.00%	76,988	1849	2.40%	≤10[b]	<1.00%
40-49	41,971	1044	2.49%	18	1.72%	65,273	1690	2.59%	≤10[b]	<1.00%
50-59	51,473	1242	2.41%	44	3.54%	68,627	1644	2.40%	23	1.40%
60-69	57,880	1286	2.22%	95	7.39%	65,223	1458	2.24%	59	4.05%
70-79	42,493	841	1.98%	95	11.30%	43,531	773	1.78%	56	7.24%
≥80	23,938	473	1.98%	104	21.99%	31,269	679	2.17%	127	18.70%
Total	**294,342**	**6724**	**2.28%**	**366**	**5.44%**	**417,606**	**9618**	**2.30%**	**305**	**3.17%**

[a]For males aged 12-19 and 20-29 years, there were zero deaths out of 152 and 661 cases of myocarditis, respectively. To avoid using a 0% case fatality rate in the model, we assumed that 12-19 and 20-29 year old males had the same case fatality rate as 30-39 year old males (1.00%).

[b]Patient counts of ≤10 were rounded up to 10 to safeguard protected healthcare data. Related case fatality rates were thus assumed to be <1.00%., with a value of 1.00% used in the model to assume the worst-case scenario.

Source:

Personal communication from authors regarding patient cohort described in: Buckley, B.J.R., et al. (2021). Prevalence and clinical outcomes of myocarditis and pericarditis in 718,365 COVID-19 patients. *European Journal of Clinical Investigation* 51(11):e13669. https://doi.org/10.1111/eci.13679. [15]

Table S9. Age and sex distribution of Australian population of ages ≥12 years, June 2021.

Age (years)	Male		Female	
	Population	% of male population	Population	% of female population
12-19	1,255,966	11.6%	1,189,548	10.7%
20-29	1,771,900	16.4%	1,704,813	15.3%
30-39	1,864,350	17.3%	1,916,238	17.2%
40-49	1,632,718	15.1%	1,662,299	14.9%
50-59	1,534,788	14.2%	1,608,873	14.5%
60-69	1,326,260	12.3%	1,411,617	12.7%
70-79	945,920	8.8%	1,006,711	9.0%
≥80	465,333	4.3%	632,939	5.7%
Total	**10,797,235**	**100.0%**	**11,133,038**	**100.0%**

Source:

[a]Australian Bureau of Statistics. (2021). National, state and territory population. *Australian Bureau of Statistics*. Accessed 28 February 2022 from https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/jun-2021/31010do002_202106.xlsx. [16]

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