Risk-benefit analysis of the AstraZeneca COVID-19 vaccine and Pfizer booster in Australia during the SARS-CoV-2 omicron wave using an adaptable Bayesian network modelling framework
28 February 2022.

Summary of data sources, assumptions, and prior distributions

Model inputs	Data sources, assumptions, rationale	Reference
Age distribution of infections and fatalities from omicron variant	Data from New South Wales (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. We assumed cases in 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 were made up 80% of the numbers reported for ages 10-19. See Table S1.	1
Community transmission levels	Chance of infection over 2 months calculated for different levels of community transmission. See Table S2. Definitions of low, medium, and high transmission as defined by ATAGI document 'Weighing up the potential benefits and risk of harm from COVID-19 Vaccine AstraZeneca'. Low – similar to first wave in Australia (equivalent to 0.05% of population infected over 6 months). Medium – similar to second wave in VIC in 2020 (equivalent to 0.045% of population infected over 6 months). High – similar to Europe in January 2021 (equivalent to 5.76% of population infected over 6 months). Also included transmission scenarios equivalent to: zero transmission; 1%, 2%, 5% and 10% chance of infection over 2 months; other transmission levels can be added to model.	2, 3
Relative risk of symptomatic infection by age and sex	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. We assumed cases in this time-period were attributable to the omicron variant. We calculated relative risk of infection by age group and sex for the omicron variant 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 off data from NSW is applicable also to the rest of Australia. See Table S3 for final assumptions.	1
Vaccine effectiveness against symptomatic infection for the omicron variant	Vaccine doses / Time since last dose / Effectiveness against symptomatic infection 1 dose of AZ / 3 weeks / 21.8% 2 doses of AZ / 0 to <2 months / 38.3% 2 doses of AZ / 2 to <4 months / 20.8%	4,5

	2 doses of AZ — 4 to <6 months — 1.9% 2 doses of AZ + Pfizer/Moderna booster* — <2 months — 58.3% *Studies showed that vaccine effectiveness after a Moderna booster was slightly better than after a Pfizer booster. For simplicity, we assumed the same vaccine effectiveness after booster with either mRNA vaccine, using data for Pfizer booster.	
Vaccine effectiveness against death for the omicron variant	Vaccine doses — Time since last dose — Effectiveness against death 1 dose of AZ — 3 weeks — 47.7% 2 doses of AZ — 0 to <2 months — 52.6% 2 doses of AZ — 2 to <4 months — 52.6% 2 doses of AZ — 4 to <6 months — 28.9% 2 doses of AZ + Pfizer/Moderna booster* — <2 months — 88.3% *Studies showed that vaccine effectiveness after a Moderna booster was slightly better than after a Pfizer booster. For simplicity, we assumed the same vaccine effectiveness after booster with either mRNA vaccine, using data for Pfizer booster.	4,6
TTS after AZ vaccine	Model uses data reported by ATAGI update following weekly COVID-19 meeting on 25/8/2021. Estimated rate per 100,000 1st dose of AZ vaccinations: • Age <50: 2.5 • Age 50-59: 2.7 • Age 60-69: 1.6 • Age 70-79: 2.1 • Age ≥80: 1.6 Estimated rate per 100,000 after 2nd dose of AZ vaccinations: 0.18 per 100,000 (no age specific rates available). Case fatality rate in Australia ~5% (noting that higher rates reported in UK ~18%).	7–10
Background rates of atypical venous thrombotic disorders	Background rates (in population not infected with and not vaccinated for COVID-19) of atypical venous thrombotic disorder (CVST and PVT) over 6 weeks were calculated for each age group to provide a comparison with chance of TTS after AZ vaccine. See Table S4 for final assumptions. CVST data from Kristoffersen *et al*. • Age-specific rates per million population per year: ○ Age <20: 10.8	11,12

	- Age 20-49: 18.0 - Age 50-69: 21.1 - Age ≥70: 20.7 - Case fatality of 7% for all age groups. - Assumed equal rates in males and females. PVT data from Ageno *et al*. - Age-specific rates per million population per year: - Age <20: 0 - Age 20-29: 5.5 - Age 30-39: 7.25 - Age 40-49: 15.75 - Age 50-59: 25.5 - Age 60-69: 49.5 - Age ≥70: 55.125 - Case fatality of 27.2% for all age groups. - Assumed equal rates in males and females.	
Atypical venous thrombotic disorders associated with COVID-19 infection	Rates of CVST and PVT in COVID-19 cases from a retrospective cohort study using data primarily from the USA. CVST: - Cases per million COVID-19 infections: - Male: 28.87 - Female: 54.20 - Case fatality 17.4% for both sexes. - Assumed same rates for all age groups. PVT: - Cases per million COVID-19 infections: - Male: 483 - Female: 318 - Case fatality 19.9% for both sexes. - Assumed same rates for all age groups.	13
Risk of developing (background) myocarditis	2021 multinational network cohort study by Li et al., 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. We assumed that 65% of reported myopericarditis cases were myocarditis, based on proportions from other 2021 studies by Barda et al. and Su, that differentiate between them post-vaccination. 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. See Table S5 for final assumptions.	2,14–16
Risk of dying from (background) myocarditis	2007 study by Kytö et al. reports incidence of fatal myocarditis in Finland per 100,000 person-years by age group and sex as total risk, 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)	2,17

	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. See Table S5 for final assumptions.	
Risk of developing Pfizer/Moderna vaccine-associated myocarditis	There is currently limited data on the risk of myocarditis when mRNA vaccines are used as a booster for those who received the AZ vaccine for their primary course. i.e. AZ-AZ-Pfizer or AZ-AZ-Moderna. The model assumes the same risk of myocarditis as the first dose of Pfizer vaccine in those who received Pfizer for their primary course. TGA reports rates of myocarditis from the Pfizer vaccine per 100,000 doses in Australia, from all doses and second doses. From this we calculated rates from first doses. See Table S6 for final assumptions.	18
Risk of dying from Pfizer/Moderna vaccine-associated myocarditis	Case fatality rate from mRNA vaccine-associated myocarditis has not been reported widely, in part due to very low numbers. Data from CDC VAERS reported 1195 myocarditis cases after mRNA vaccination in those aged under 30 years, of which two likely died from myocarditis, giving a case fatality rate of 0.167% (2/1195). We assumed the same case fatality rate for Pfizer and Moderna COVID-19 vaccines, and the same case fatality rate in those aged ≦30 years.	19
Risk of developing SARS-CoV-2 infection-induced myocarditis	Study reports that 5.0% of patients with COVID-19 developed new-onset myocarditis 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. The study used a live database, so the data from the original patient cohort in the study were no longer available; the patient data provided through personal communication was from an updated cohort and showed a lower total prevalence of myocarditis (~2.3%). See Table S7 for final assumptions.	20
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. 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 S7 for final assumptions.	20
Prior distributions*		
Age distribution of Australian population	Distribution based on Australian Bureau of Statistics national population estimates from June 2021. See Table S8. 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 can be added into the model in future updates.	21
Sex distribution of Australian population	Distribution of 49% male and 51% female based on Australian Bureau of Statistics national population estimates from June 2021. See Table S8.	21
Vaccine coverage in population	Vaccine doses / % of population No doses / 5% 1 dose of AZ / 5%	22

	2 doses of AZ 2 doses of AZ 2 doses of AZ 2 doses of AZ + Pfizer/Moderna booster	20% 20% 20% 30%	
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'.		
Other assumptions	There is currently no evidence that the Pfizer vaccine causes TTS above background rates. There is currently no evidence that the AZ vaccine causes myocarditis above background rates.		

*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.
NSW= New South Wales; ATAGI=Australian Technical Advisory Group on Immunisation; TTS=Thrombosis and Thromobcytopenia Syndrome; CVST=Cerebral venous sinus thrombosis; PVT=Portal vein thrombosis; TGA=Therapeutic Goods Administration; CDC=Centers for Disease Control and Prevention, USA; VAERS=Vaccine Adverse Event Reporting System.

Supplementary Materials – Model assumptions

Table A1. 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	Cases	% of cases in age group	Deaths	Case fatality
12-19	12,061	12.32%	0	0.000%
20-29	26,733	27.31%	0	0.002%
30-39	20,692	21.14%	1	0.005%
40-49	14,870	15.19%	3	0.018%
50-59	11,416	11.66%	7	0.057%
60-69	7,069	7.22%	18	0.254%
70-79	3,315	3.39%	44	1.324%
≥80	1742	1.78%	125	7.187%
Total	**97,898**	**100.00%**	**198**	**1.106%**

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]. [1]

Table A2. 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 [9]. 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. [2]

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. [3]

Table A3. 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	**0.90%**	**0.93%**

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]. [1]

Table A4. Estimated background incidence and fatality of atypical blood clots (CVST and PVT combined) over 6 weeks (in populations who have not received AZ vaccine and not diagnosed with COVID-19).

Age group	Incidence of atypical blood clots (CVST and PVT) over 6 weeks (per million)	Fatality rates from atypical blood clots (CVST and PVT) over 6 weeks (per million)	Overall case fatality rate from atypical blood clots (CVST and PVT)
12-19	0.383	0.027	7.00%
20-29	0.834	0.098	11.73%
30-39	0.896	0.115	12.80%
40-49	1.198	0.197	16.43%
50-59	1.654	0.299	18.05%
60-69	2.507	0.530	21.16%
70-79	2.692	0.584	21.69%
≥80	2.692	0.584	21.69%

Sources:
Espen Saxhaug Kristoffersen, et al. Incidence and Mortality of Cerebral Venous Thrombosis in a Norwegian Population Stroke, 51 (10) (2020), pp. 3023-3029. [11]
W. Ageno, et al. Incidence rates and case fatality rates of portal vein thrombosis and Budd-Chiari Syndrome Thromb Haemost, 117 (4) (2017), pp. 794-800. [12]

Table A5. 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. [2]

[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. doi: 10.1101/2021.03.25.21254315. [14]

[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. doi: 10.1093/aje/kwk076. [17]

Table A6. Estimated rates of myocarditis cases per 1,000,000 Pfizer COVID-19 vaccine first doses in Australia by age and sex.

Age (years)	Male	Female
12-19	19	4
20-29	11	2
30-39	11	7
40-49	2	3
50-59	7	2
60-69	2	4
70-79	0	0
≥80	0	0

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. [18]

Table A7. 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.

Age (years)	Male					Female				
	COVID-19 cases	Myocarditis cases	Incidence	Deaths	Case fatality	COVID-19 cases	Myocarditis cases	Incidence	Deaths	Case fatality
12-19	1106	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**	**3.66%**	**366**	**5.86%**	**417,606**	**9618**	**2.21%**	**305**	**4.77%**

[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]In the dataset available, 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. doi: 10.1111/eci.13679. [20]

Table A8. 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. [21]

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