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
16 February 2022.

Summary of data sources, assumptions, and prior distributions

Model inputs	Data sources, assumptions, rationale	Reference
Age and sex distribution of infections and fatalities from omicron variant	COVID-19 cases reported in Australia from to 19/11/2021 to 19/01/22 were used to provide estimates of age distribution for the omicron variant. While some of these cases and deaths were attributable to delta, the numbers would be too small to affect our assumptions about the age distribution of omicron cases and deaths. 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. Data sourced from Australian NINDSS. We made the above assumptions because cases and deaths on specific dates were not readily available from NNDSS. See Table A1.	1
Community transmission levels	Chance of infection over 2 months calculated for different levels of community transmission. See Table A3. 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 Australian NINDSS reports age and sex distribution of all COVID-19 cases in Australia up to 19 Jan 2022. We subtracted data from the Australian Government Department of Health Epidemiology Reports 32 and 43 reporting age and sex distribution of COVID-19 cases in Australia in 2020, and Jan to June 2021, respectively, to obtain age and sex distribution of cases from 6 June 2021 to 19 Jan 2022. Of these cases, those from 6 June to 8 Dec 2021 were considered as attributable to the delta variant, and those from 9 Dec 2021 to 19 Jan 2022 were selected to represent the omicron variant. We calculated relative risk of infection by age group and sex for the omicron variant by estimating the probability of infection in each age-sex group if overall probability of infection in the community was 1%. See Table A4 for final assumptions.	1,4
Vaccine effectiveness against	Vaccine doses / Time since last dose / Effectiveness against symptomatic infection	5,6

<table>
<tr><td>symptomatic infection for the omicron variant</td><td><table>
<tr><td>1 dose of AZ</td><td>3 weeks</td><td>21.8%</td></tr>
<tr><td>2 doses of AZ</td><td>0 to <2 months</td><td>38.3%</td></tr>
<tr><td>2 doses of AZ</td><td>2 to <4 months</td><td>20.8%</td></tr>
<tr><td>2 doses of AZ</td><td>4 to <6 months</td><td>1.9%</td></tr>
<tr><td>2 doses of AZ + Pfizer/Moderna booster*</td><td><2 months</td><td>58.3%</td></tr>
</table>
*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.</td><td></td></tr>
<tr><td>Vaccine effectiveness against death for the omicron variant</td><td><table>
<tr><th>Vaccine doses</th><th>Time since last dose</th><th>Effectiveness against death</th></tr>
<tr><td>1 dose of AZ</td><td>3 weeks</td><td>47.7%</td></tr>
<tr><td>2 doses of AZ</td><td>0 to <2 months</td><td>52.6%</td></tr>
<tr><td>2 doses of AZ</td><td>2 to <4 months</td><td>52.6%</td></tr>
<tr><td>2 doses of AZ</td><td>4 to <6 months</td><td>28.9%</td></tr>
<tr><td>2 doses of AZ + Pfizer/Moderna booster*</td><td><2 months</td><td>88.3%</td></tr>
</table>
*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.</td><td>5,7</td></tr>
<tr><td>TTS after AZ vaccine</td><td>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
For age ≥70 in model, used rate of 1.85 (average of rates for 70-79 and ≥80).
Estimated rate per 100,000 after 2nd dose of AZ vaccinations: 0.18 per 100,000 (no age specific rates available).</td><td>8–11</td></tr>
</table>

	Case fatality rate in Australia ~5% (noting that higher rates reported in UK ~18%).	

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 A5 for final assumptions.
	
	CVST data from Kristoffersen *et al*.
	• Age-specific rates per million population per year:
	  ○ Age <20: 10.8
	  ○ 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.
		12,13

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.
		14

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 A6 for final assumptions.	2,15–17
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) 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 A6 for final assumptions.	2,18
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 A7 for final assumptions.	19
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 $\leq$30 years.	20
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 A8 for final assumptions.	21
Risk of dying from SARS-CoV-2	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	21

<table>
<tr><td>infection-induced myocarditis</td><td>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 A8 for final assumptions.</td><td></td></tr>
<tr><td colspan="3">Prior distributions</td></tr>
<tr><td>Age distribution of Australian population</td><td>Australian Bureau of Statistics. National population estimates, December 2020. See Table A2.</td><td>2</td></tr>
<tr><td>Sex distribution of Australian population</td><td>50% male, 50% female.</td><td></td></tr>
<tr><td>Vaccine coverage in population</td><td><table><tr><th>Vaccine doses</th><th>% of population</th></tr><tr><td>No doses</td><td>5%</td></tr><tr><td>1 dose of AZ</td><td>5%</td></tr><tr><td>2 doses of AZ</td><td>20%</td></tr><tr><td>2 doses of AZ</td><td>20%</td></tr><tr><td>2 doses of AZ</td><td>20%</td></tr><tr><td>2 doses of AZ + Pfizer/Moderna booster</td><td>30%</td></tr></table></td><td></td></tr>
<tr><td>Community transmission at x% over 2 months*</td><td>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’.</td><td></td></tr>
<tr><td>Other assumptions</td><td>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.</td><td></td></tr>
</table>

NINDSS= National Interoperable Notifiable Diseases Surveillance System; 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. *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.

Appendix A. Model assumptions

Table A1. Distribution of SARS-CoV-2 infections and case fatality rate in Australia by age and sex for the omicron variant, January 2020 to 19/01/2022.

Sex	Male				Female			
Age group	Cases	% of cases in age group	Deaths	Case fatality	Cases	% of cases in age group	Deaths	Case fatality
12-19	51,086	11.03%	0	0%	57,259	11.77%	0	0%
20-29	152,975	33.04%	3	0.002%	159,300	32.75%	0	0%
30-39	95,893	20.71%	7	0.007%	97,387	20.02%	0	0%
40-49	60,907	13.16%	8	0.013%	66,802	13.73%	4	0.006%
50-59	49,613	10.72%	17	0.034%	54,008	11.10%	16	0.030%
60-69	30,505	6.59%	34	0.111%	29,942	6.15%	35	0.117%
≥70	22,006	4.75%	332	1.509%	21,779	4.48%	238	1.093%
Total	**462,985**	**100.00%**	**401**	**0.087%**	**486,477**	**100.00%**	**293**	**0.060%**

Sources:

Australian Government Department of Health. (2021). Coronavirus (COVID-19) case numbers and statistics – cases and deaths by age and sex. *Australian Government Department of Health.* Accessed 17 December 2021 from https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-case-numbers-and-statistics#covid19-summary-statistics. [1]

Table A2. Age distribution of Australian population, March 2021.

Age group	Population	% of total population
0-11	3,828,247	14.90%
12-19	2,438,423	9.49%
20-29	3,617,689	14.08%
30-39	3,757,954	14.63%
40-49	3,296,519	12.83%
50-59	3,120,900	12.15%
60-69	2,696,731	10.50%
≥70	2,936,879	11.43%
Total	**25,693,342**	**100.00%**

Source:

[a]Australian Bureau of Statistics. (2021). National, state and territory population. *Australian Bureau of Statistics.* Accessed 15 December 2021 from https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/mar-2021/31010do002_202103.xls. [2]

Table A3. 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 A4. Relative risk of infection by age group and sex for the SARS-CoV-2 omicron variant (chance of infection if overall probability of infection of 1% in all ages).

Age group	Male	Female
0-11	0.64%	0.63%
12-19	1.02%	1.16%
20-29	2.20%	2.29%
30-39	1.25%	1.25%
40-49	0.87%	0.94%
50-59	0.75%	0.82%
60-69	0.52%	0.51%
≥70	0.34%	0.34%
Overall	**0.98%**	**1.02%**

Sources:

Australian Government Department of Health. (2021). Coronavirus (COVID-19) case numbers and statistics – cases and deaths by age and sex. *Australian Government Department of Health.* Accessed 17 December 2021 from https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-case-numbers-and-statistics#covid19-summary-statistics. [1]

Australian Government Department of Health. (2021). Coronavirus disease 2019 (COVID-19) epidemiology reports, Australia, 2020-2021. *Australian Government Department of Health.* Accessed 17 December 2021 from https://www1.health.gov.au/internet/main/publishing.nsf/Content/novel_coronavirus_2019_ncov_weekly_epidemiology_reports_australia_2020.htm. [4]

Table A5. 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	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. [12]

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. [13]

Table A6. 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	53.92	39.64	1.62	1.69	3.00%	4.27%

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. [15]

[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. [18]

Table A7. 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	24	6
20-29	17	7
30-39	17	8
40-49	5	5
50-59	7	2
60-69	4	6
≥70	0	4

Source:

Therapeutic Goods Administration. (2021). COVID-19 vaccine weekly safety report – 09-12-2021. *Australian Government Department of Health.* Accessed 17 December 2021 from https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-12-2021. [19]

Table A8. 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	66,431	1314	1.98%	199	15.14%	74,800	1452	1.94%	183	12.60%
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]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. [21]

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2. Australian Bureau of Statistics. National, state and territory population, https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/mar-2021/31010do002_202103.xls.; 2021 [accessed December 2021].
3. Australian Technical Advisory Group on Immunisation. Weighing up the potential benefits and risk of harm from COVID-19 vaccine AstraZeneca, 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; 2021 [accessed December 2021].
4. Australian Government Department of Health. Coronavirus disease 2019 (COVID-19) epidemiology reports, Australia, 2020-2021, https://www1.health.gov.au/internet/main/publishing.nsf/Content/novel_coronavirus_2019_ncov_weekly_epidemiology_reports_australia_2020.htm; 2021 [accessed December 2021].
5. 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].
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