ABNMS Conference
16th Nov, 2022



# Implementing a risk-benefit calculator for COVID-19 Vaccine

https://corical.immunisationcoalition.org.au/

h.mayfield@uq.edu.au













Carissa Bonner

Risk communication



Sam Brown

Data collection & model validation



Colleen Lau

BN, public health expertise



John Litt

Data collection, public health expertise



Jane Sinclair

Data collection & BN modelling



**Kirsty Short** 

Data collection & virology



Kerrie Mengersen

BN modelling & statistics



Tina Moghaddam

Programming & interface



Ramona Muttucumaru

Data collection & BN modelling



Helen Mayfield

BN modelling & product management



Michael Waller

Statistics & model assumptions



Tej Shukla

**Paediatrics** 

# CoRiCAL is designed to help people make an **informed choice** about COVID-19 vaccinations

Uses Australian data where possible, and International data when local data not available



& COPY LINK

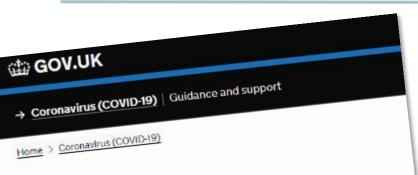
- SHARE

Dr Kirsty Short is one of the research leaders who developed the online COVID calculator dubbed CoRiCal. (Supplied)

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abc.net.au/news/qld-coronavirus-cov...

## The motivation behind Corical



# VEEP: Vaccine effectiveness table, 16 July 2021

Paper by the Vaccine Effectiveness Expert Panel (VEEP).

From: Scientific Advisory Group for Emergencies

Published 6 August 2021

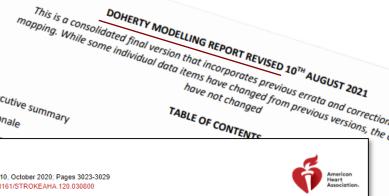
### Documents





Volume 51, Issue 10, October 2020; Pages 3023-3029 https://doi.org/10.1161/STROKEAHA.120.030800

Executive summary



CLINICAL AND POPULATION SCIENCES

#### Incidence and Mortality of Cerebral Venous Thrombosis in a Norwegian Population

Espen Saxhaug Kristoffersen, MD, PhD no, Charlotte Elena Harper, MD, Kjersti Grøtta Vetvik, MD, PhD, Svetozar Zarnovicky, MD, Jakob Møller Hansen, MD, PhD (10), and Kashif Waqar Faiz, MD, PhD (b)

rebral venous thrombosis (CVT). The

This is a consolidated final version that incorporates previous errota and correction that incorporates previous errota and correction that incorporates previous errota and correction individual data items have changed from newious versions, the

**EClinicalMedicine** 

cidence and

Research paper

Cerebral venous thrombosis and portal vein thrombosis: A retrospective cohort study of 537,913 COVID-19 cases

Maxime Taquer<sup>a,b,e</sup>, Masud Husain<sup>c,d</sup>, John R Geddes<sup>a,b</sup>, Sierra Luciano<sup>e</sup>, Paul J Harrison<sup>a,b</sup>

ABSTRACT

- Department of Psychology, University of Longova, Linguist, University Oxford Health NHS Foundation Trust, Oxford, United Kingdom
- ingulus remains new remainstance ericus, conjune, venusus narquioris Nagliodd Department of Clinical Neurosciences, University of Oxford, Oxford, United Kingdom Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom

ARTICLE INFO

deceived 8 June 2021 levised 14 July 2021 ccepted 15 July 2021

Background: There are concerns about a link between the ChAdOx1 nCoV-19 and Ad26.COV2.5 Vaccins against COVID-19 and cerebral venous thrombosis (CVT) and other thrombotic events. One key missing cor against substituting account versions terminating (s.v.) may also assume the contract of the risk-benefit analysis of using such vaccines is the risk of these severe thrombotic events follow

ing currents.

Methods: Using a retrospective cohort study based on electronic health records primarily in

13

Akershus

atients were ssification of



#### CoRiCal: Covid Risk Calculator

- CoRiCal is a tool to help people who are not sure about getting the COVID-19 vaccines. It tells you how the vaccine can reduce your chances of getting or dying
  from COVID-19. It also shows the chances of developing certain rare conditions from the vaccines.
- The benefits and risks of the vaccines vary because of many reasons. Some of these are: your age, your sex, how many vaccines you have had, which vaccine(s)
  you have had, and the number of COVID-19 cases in your community.
- The tool shows you what your chances are of getting sick based on your age and sex. It shows you the risk out of a million people, or a one in x chance. You can
  choose which way the results are displayed for each calculator by clicking on the tabs for 'Show risk per million people' or 'Show risk as a chance'.
- Note that the chances shown are only a rough guide. The tool shows the average chance for people who are the same sex and age as you. It does not use other
  factors, like any health problems you have, such as heart problems or diabetes. It also does not know if you live or work in a place with more COVID-19 cases,
  or if you have a job that puts you in contact with a lot of people. These things may change your chances of getting COVID-19 or dying from it.
- Even if there are not many cases in your community right now, this can change. The number of cases can go up quickly at any time. So when you make your
  decision about getting the COVID-19 vaccine, you should also think about possible cases in the future.
- . The Moderna vaccine has similar effectiveness as the Pfizer vaccine when used for the third (booster) dose,
- Last updated on 11/03/2022. Estimates based on an assumed distribution of 100% Omicron variant.

WHAT'S NEW!

#### Choose a risk calculator

First dose Pfizer - Omicron Variant, updated 11/03/2022

PFIZER CALCULATOR

First dose AstraZeneca - Omicron Variant, updated 11/03/2022

ASTRAZENECA CALCULATOR

#### View risk chart

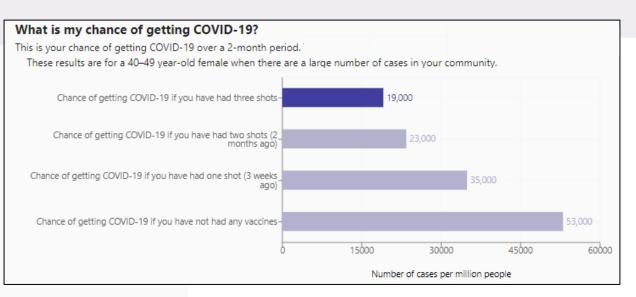
Risk of dying from COVID-19 based on age, sex, and vaccination status - 90% Omicron/10% Delta Variants, updated January 2022

**RISK CHART FOR DYING OF COVID-19** 

Risk of developing myocarditis from COVID-19 infection or vaccination based on age, sex, and vaccination status - updated October 2022

https://corical.immunisationcoalition.org.au/





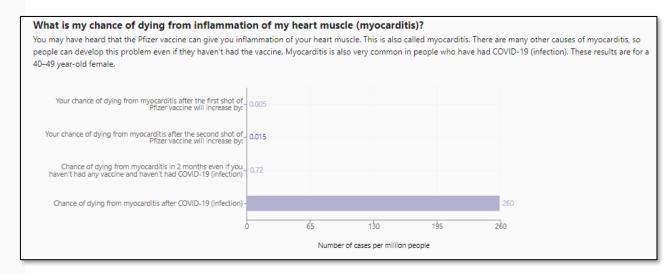
RISK CHART FOR DEVELOPING MYOCARDITIS

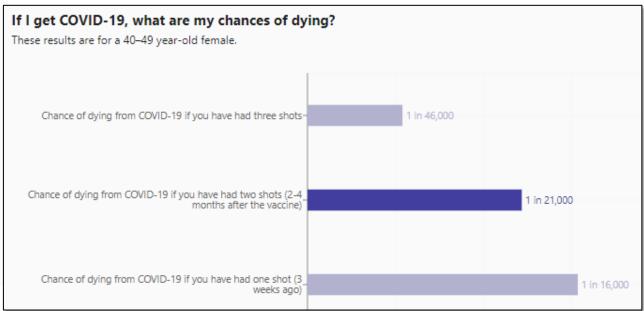
#### About you

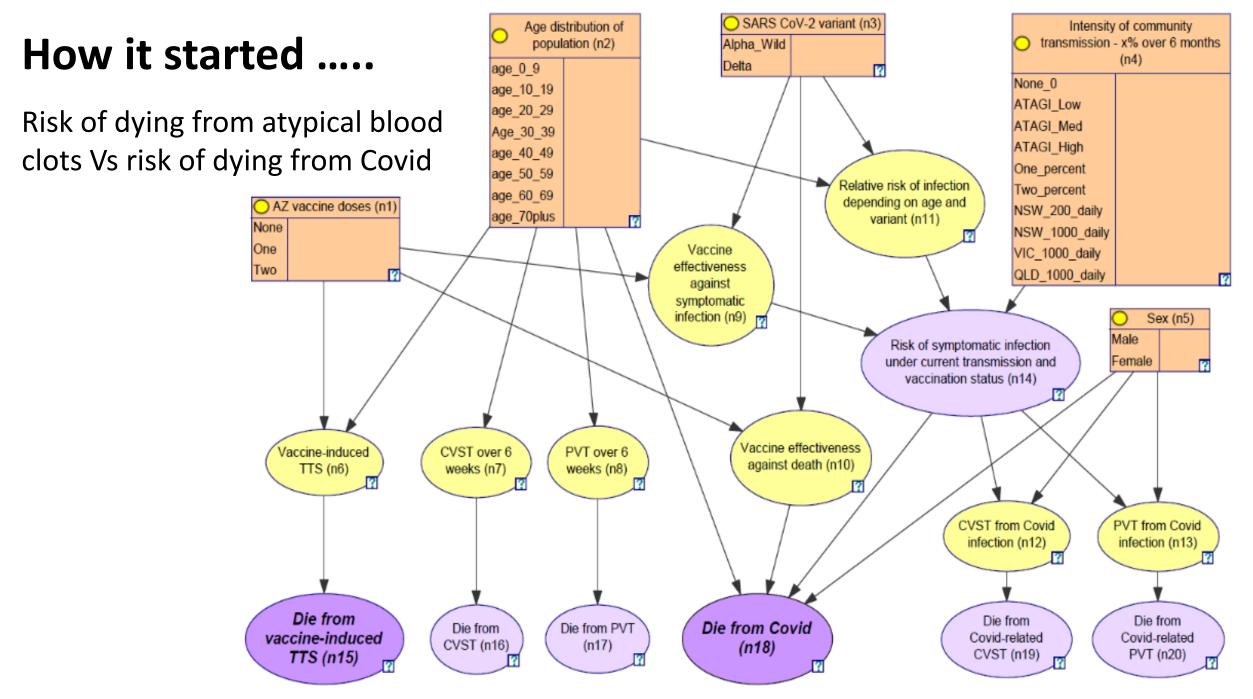
Enter your age, sex, and if you've had a vaccine to check your risks.

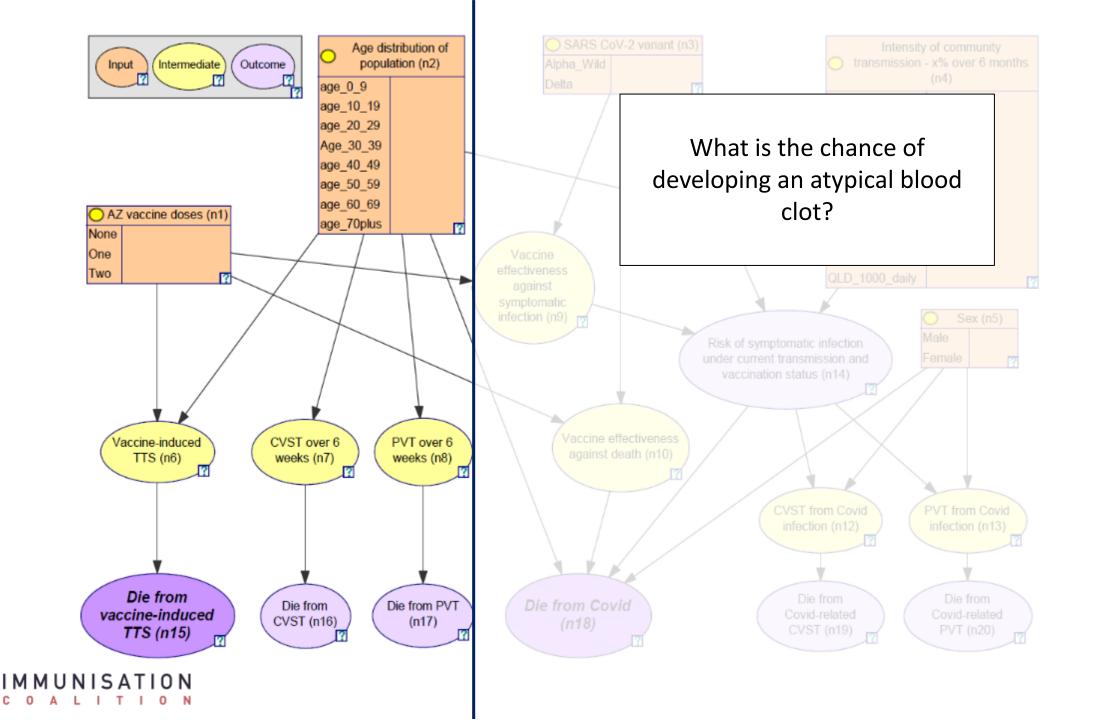
Age
Sex
○ Female ○ Male ○ Unspecified
Vaccine
We don't currently have estimates for people whose second or third shot is overdue
O None
One shot of Pfizer (3 weeks ago)
O Two shots of Pfizer
O Three shots of Pfizer
How many cases are there in your community?
A huge number of cases
10% chance of getting COVID-19 over 2 months – about the same as 13,600 cases per day in NS
A large number of cases
5% chance of getting COVID-19 over 2 months – about the same as 6,800 cases per day in NSW

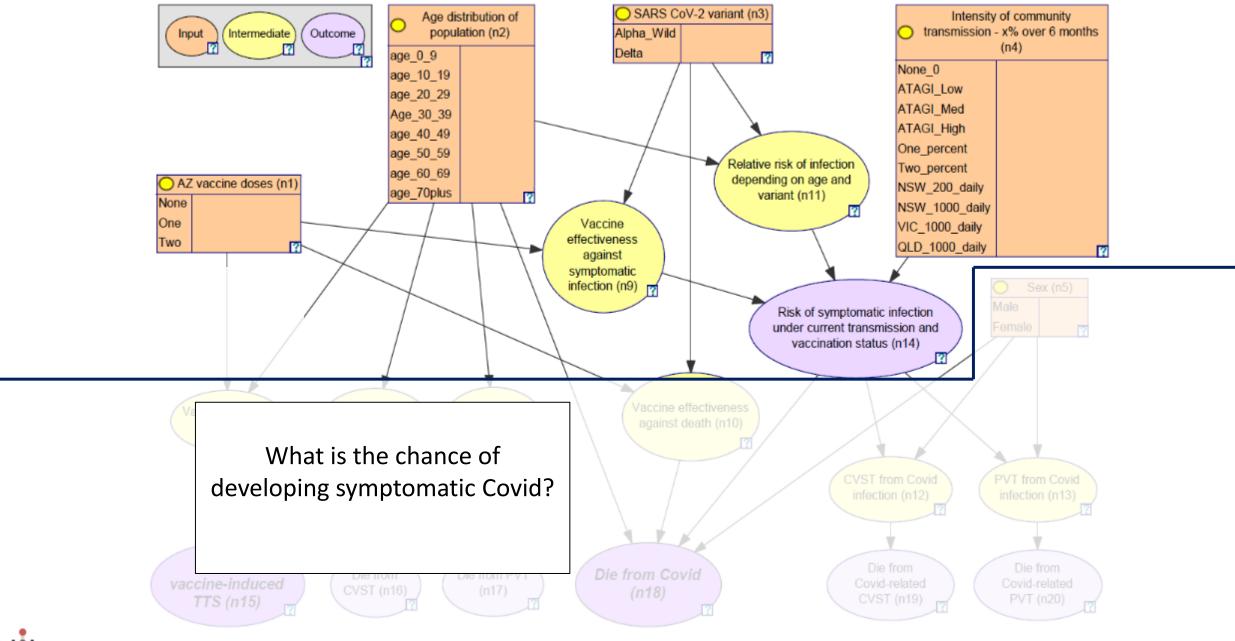
# Risks can be displayed in x per million, or 1 in x, with or without relative risks



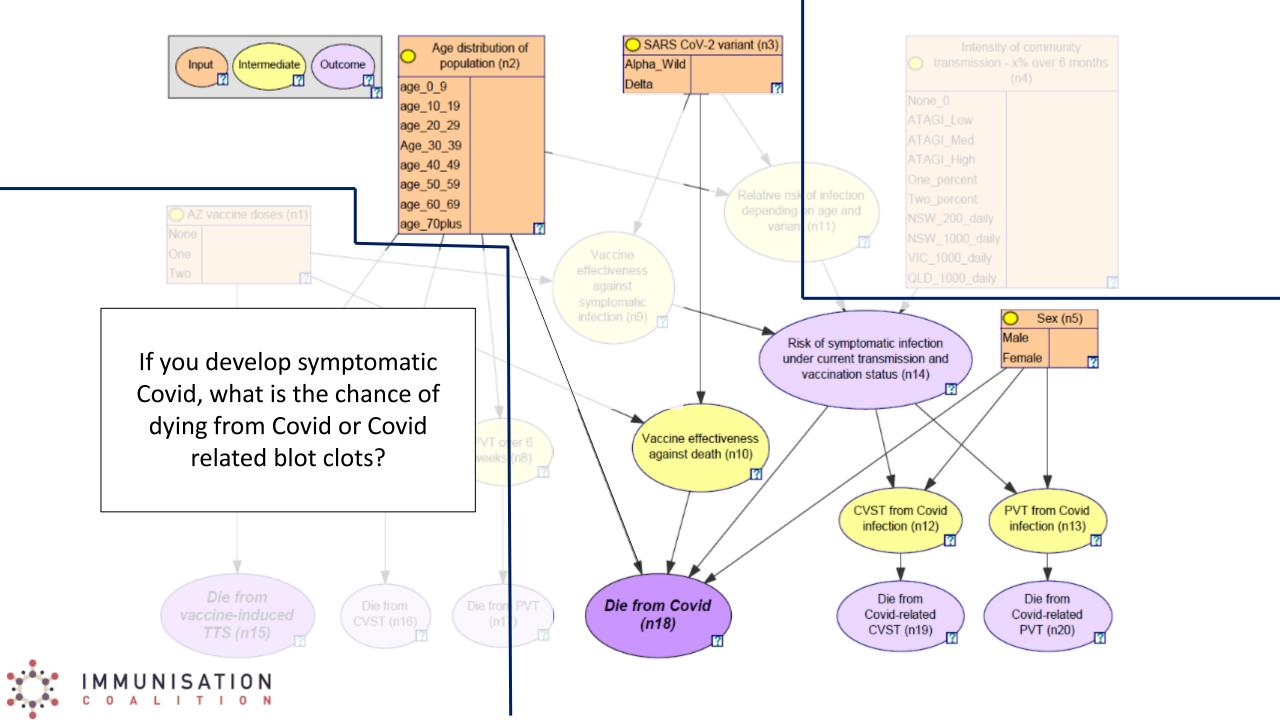


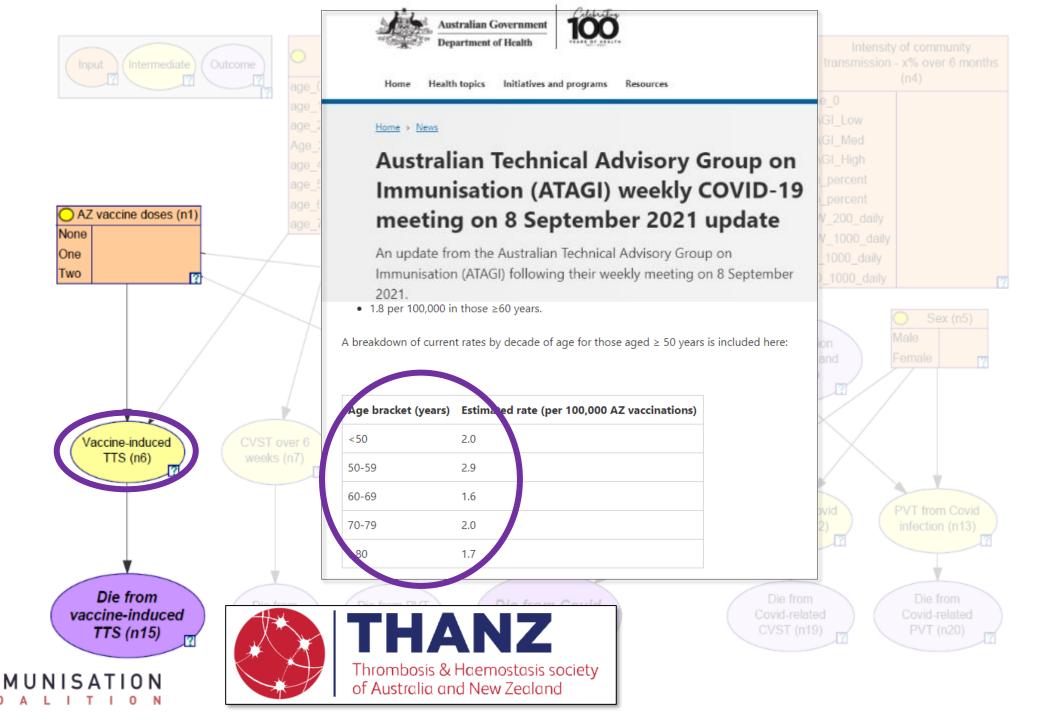


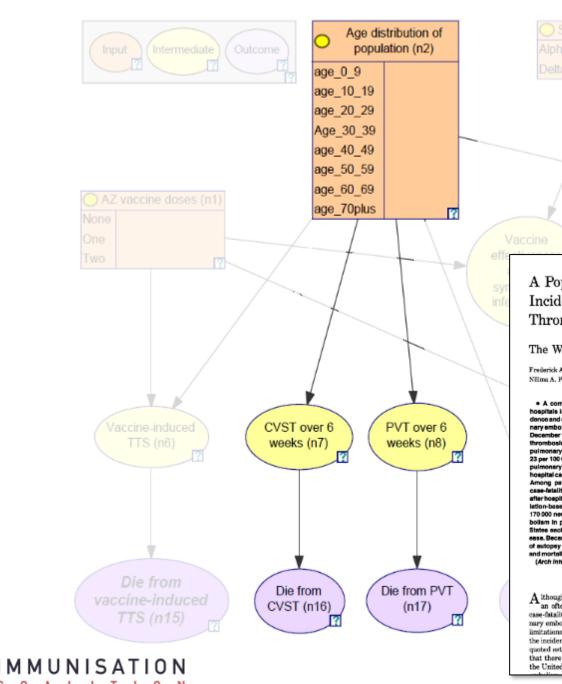












#### Stroke

Volume 51, Issue 10, October 2020; Pages 3023-3029 https://doi.org/10.1161/STROKEAHA.120.030800



#### **CLINICAL AND POPULATION SCIENCES**

## Incidence and Mortality of Cerebral Venous Thrombosis in a Norwegian Population

Espen Saxhaug Kristoffersen, MD, PhD ( ), Charlotte Elena Harper, MD, Kjersti Grøtta Vetvik, MD, PhD, Svetozar Zarnovicky, MD, Jakob Møller Hansen, MD, PhD ( ), and Kashif Waqar Faiz, MD, PhD ( )

#### A Population-Based Perspective of the Hospital Incidence and Case-Fatality Rates of Deep Vein Thrombosis and Pulmonary Embolism

The Worcester DVT Study

Frederick A. Anderson, Jr. PhD; H. Brownell Wheeler, MD; Robert J. Goldberg, PhD; David W. Hoemer, PhD; Nilma A. Putwardhan, MD; Borko-Javanovic, PhD; Ann Foreier, James E. Dalen, MD

. A community-wide study was conducted in 16 short-stay hospitals in metropolitan Worcester, Mass, to examine the incidence and case-fatality rates of deep vein thrombosis and pulmonary embolism in patients hospitalized between July 1, 1985, and December 31, 1986. The average annual incidence of deep vein thrombosis alone was 45 per 100 000, while the incidence of pulmonary embolism with or without deep vein thrombosis was 23 per 100 000. The incidence rates of deep vain thromboals and monary embolism increased exponentially with age. The inhospital case-fatality rate of venous thromboembolism was 12%. Among patients discharged from the hospital, the long-term case-fetality rates were 19%, 25%, and 30% at 1, 2, and 3 years after hospital discharge. Extrapolation of the data from this population-based study suggests that there are approximately 170 000 new cases of clinically recognized venous thromboemboilsm in patients treated in short-stay hospitals in the United States each year, and 99 000 hospitalizations for recurrent disease. Because of the silent nature of this disease and the low rate of autopey in the United States, the total incidence, prevalence, and mortality rates of venous thrombo (Arch Intern Med. 1991;151:933-938)

A lthough it is widely accepted that pulmonary embolism is an often preventable cause of death, the incidence and case-fatality rates of scute deep vein thrombosis and pulmonary embolism are uncertain. This uncertainty is due to the limitations of autopsy data and clinical diagnosis in estimating the incidence of vesuus thromboembolism. "The met widely quoted estimate of the prevalence of pulmonary embolism is that there are approximately 630 000 symptomatic cases in the United States each year." It is estimated that pulmonary

incidence and case-fatality rates of venous thromboembolism since this information can be used to assess the magnitude of this disease, its impact on survival, and the resources required for its prevention, diagnosis, and treatment.

The present report describes the findings of a communitywide study of venous thromboembolism conducted in 16 short-stay general bospitals in the Worcester, Mass, metropolitan area. We examined the incidence rates as well as the in-hospital and long-term case-fatality rates of all hospitalized patients in whom deep win thrombosis and/or pulmonary embolism was diagnosed.

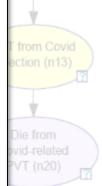
#### PATIENTS AND METHODS

The study population constituted all patients discharged during an ill-marth period, from July 1, 1985, to December 31, 1986, with a diagnosis of acute deep vein thrombosis and/or polimonary embolism from 19 central Massachusetta baspitude that provide abort-term care residents of the Warcester Standard Metropolitan Statistical Area (1985 population, 379 553; The number of short-stay bods in the 18 study baspitule ranged from 18 to 578; the 16 hospitule comprised 10 nonteaching hospitals and six teaching bospitals, including a major academic boath center.

Medical records were individually reviewed and validated based on the property dispances effected from the International Classification of Diseases Ninth Recisions (CD+CM) codes for acute deep vein thrombesis—45.1.1, 451.19, 451.2, 551.8, 451.8, 451.8, 451.9, 571.9, 671.3, 451.9, 671.8, 671.0, 671.4, 671.0, 671.4, 671.0, 992.2 and codes for pulmenary embelism—415.1, 650.9, 995.7. Up neight baseful discharge dispressis rodes were searched for each record. Some of these codes are not specific for venous thromboembolism, perticularly the 900 series. Therefore, while all records with the shore codes were reviewed in a systematic manner, data were collected only from records that included a written beopital discharge discharges the charge of the complex of the control of the contr

cerebral venous thrombosis (CVT). The /100 000/y, but more recent studies have s study was to explore the incidence and

on-based study conducted at Akershus otal Norwegian population. Patients were relevant International Classification of



#### DOHERTY MODELLING REPORT REVISED 10TH AUGUST 2021

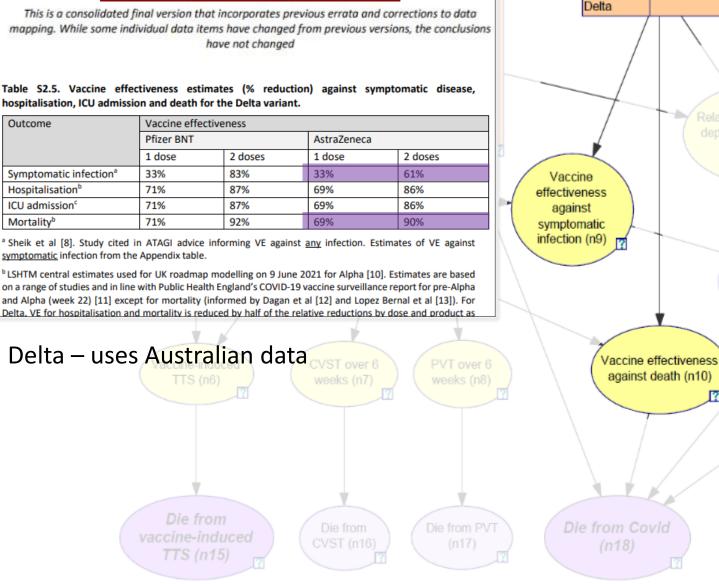
This is a consolidated final version that incorporates previous errata and corrections to data mapping. While some individual data items have changed from previous versions, the conclusions have not changed

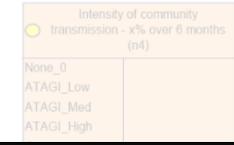
hospitalisation, ICU admission and death for the Delta variant.

Outcome	Vaccine effectiveness				
	Pfizer BNT		AstraZeneca		
	1 dose 2 doses		1 dose	2 doses	
Symptomatic infection <sup>a</sup>	33%	83%	33%	61%	
Hospitalisation <sup>b</sup>	71%	87%	69%	86%	
ICU admission <sup>c</sup>	71%	87%	69%	86%	
Mortality <sup>b</sup>	71%	92%	69%	90%	

symptomatic infection from the Appendix table.

<sup>&</sup>lt;sup>b</sup> LSHTM central estimates used for UK roadmap modelling on 9 June 2021 for Alpha [10]. Estimates are based on a range of studies and in line with Public Health England's COVID-19 vaccine surveillance report for pre-Alpha and Alpha (week 22) [11] except for mortality (informed by Dagan et al [12] and Lopez Bernal et al [13]). For Delta, VE for hospitalisation and mortality is reduced by half of the relative reductions by dose and product as







SARS CoV-2 variant (n3)

Alpha\_Wild

#### Alpha – uses UK data

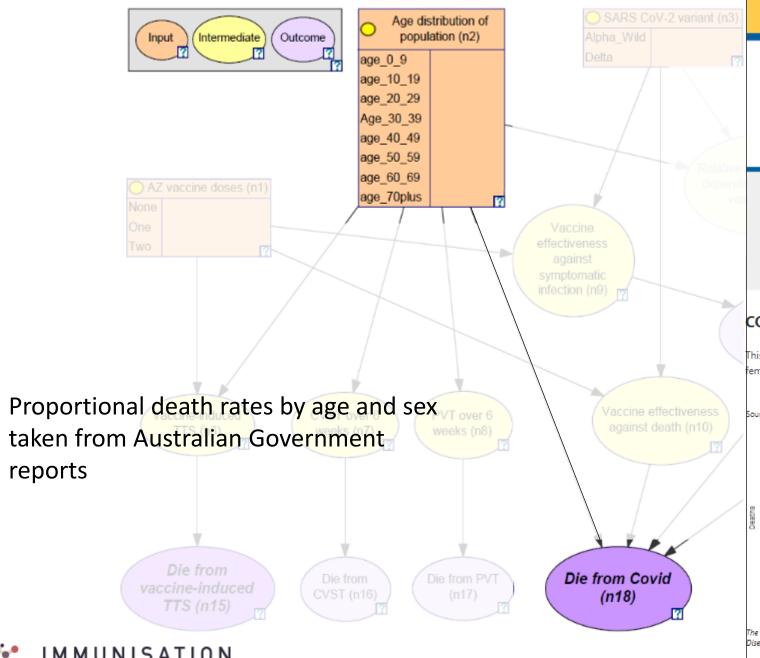
#### → Coronavirus (COVID-19) | Guidance and support

This product captures data agreed by a consensus of experts on one and two dose vaccine effectiveness. Effectiveness is measured against infection, sympto variants in circulation within the UK.

High Confidence	Evidence from studies is consistent and	Medium Confidence	Evidence is emerging but may be inconsistent requires further analysis
rigi contocice	comprehensive	mediani comeence	Entertie is enterging out may be inconsistent requires rotates analysis

		Alpha (B.1.1.7 - Kent)					
Vaccine Product	Dose Regime	Real World Data					
		infection	Symptomatic	Severe	Transmission		
Oxford/AstraZeneca (Non-replicating viral vector)	1st Dose	60-70%, Source 1 61%, Source 4	55-70%, Source 1 49%, Source 2 71%, Source 4	7 15% [hospitalisation], 75-80% (mortality), Source 1	35-50%, Source 1		
AZD1222	2nd Dose	79%, Source 4	65-90%, Source 1 75%, Source 2 97%, Source 4	80-95% (hospitalisation), Source 1	Insufficient data		
Pfaer-BioNTech (RNA)	1st Dose	55-70%, Source 1 66%, Source 4	48%, Source 2 78%, Source 4	75-85% (hospitalisation), 75-80% (mortality), Source 1 64% (hospitalisation), Source 6	45-50%, Source 1		
BNT162P5	2nd Dose	70-90%, Source 1 80%, Source 4 92%, Source 5	85-90%, Source 1 94%, Source 2 95%, Source 4 97%, Source 5	90-95% (hospitalisation), 95-99% (mortality), Source 1 97% (hospitalisation), 97% (mortality), Source 5 94% (hospitalisation), Source 6	Insufficient data		
Moderna (RNA) mRNA-1273	1st Dose	58%, Source 7	Insufficient data	Insufficient data	Insufficient data		







04 October 2021 Coronavirus (COVID-19) health alert



Health topics

Initiatives and programs

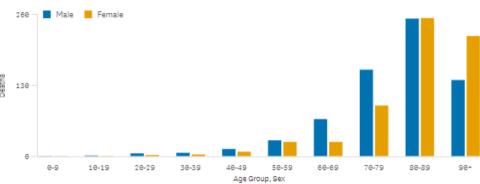
News > Health alerts > Coronavirus (COVID-19) health alert

### Coronavirus (COVID-19) case numbers and statistics

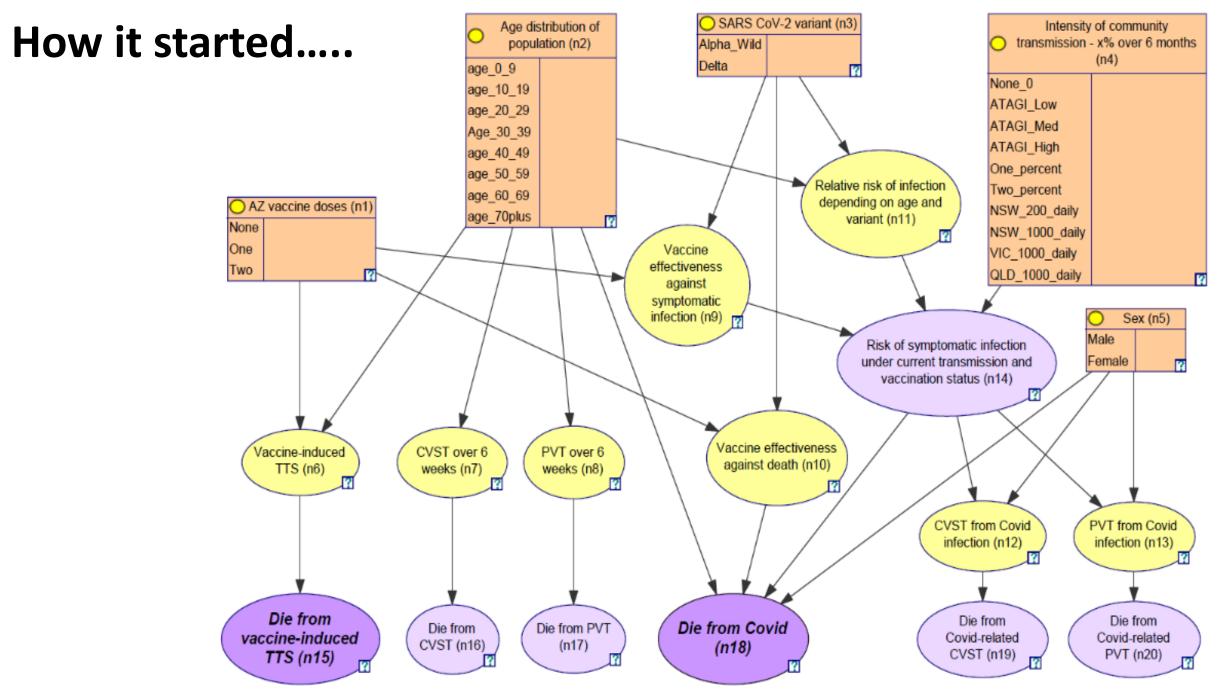
#### COVID-19 deaths by age group and sex

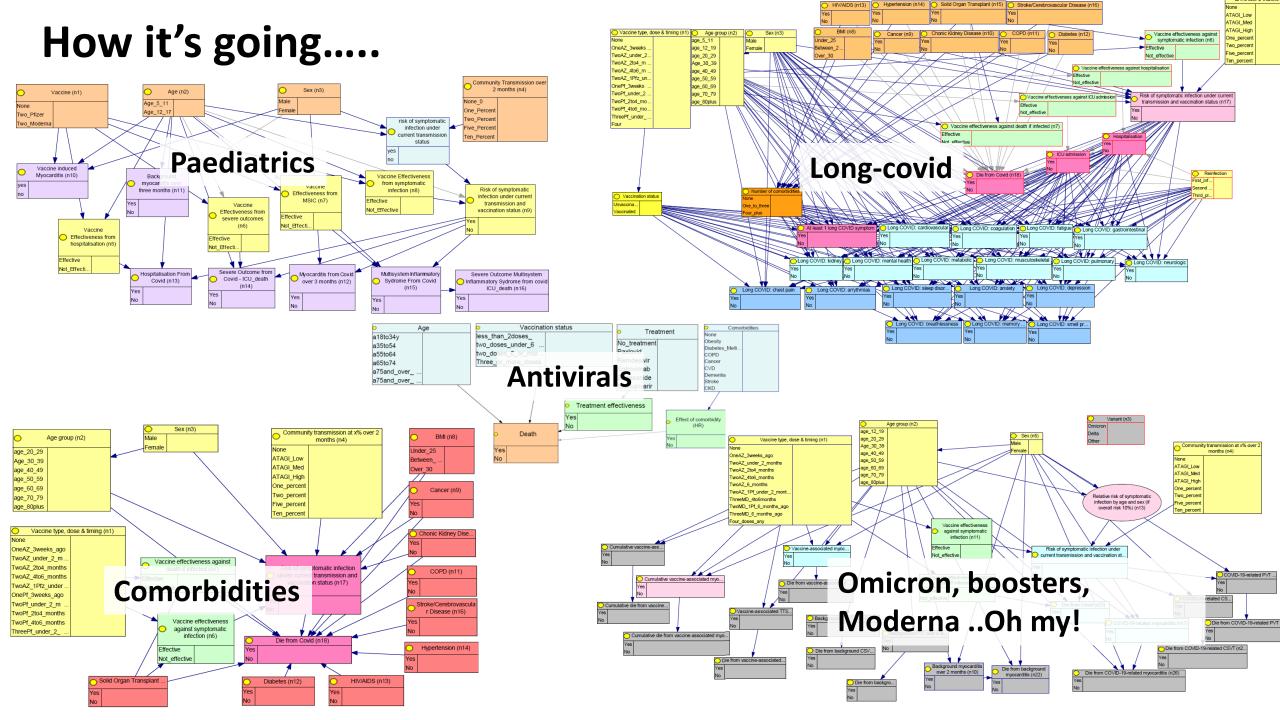
This graph shows the number of COVID-19 associated deaths in Australia for males and females by age group since the first case was reported.

Source: NINDSS data 4/10/2021



The total number of deaths in this chart may be less than what is reported due to delays in notification to the National Interoperable Notifiable Disease Surveillance System (NINDSS) or where the case's age or sex are unknown.







### COVID-19 hospitalisations and deaths in NSW up to 4pm 03 November 2022

809

people in hospital

17

people in ICU

24

lives lost in the past 7 days\*

#### COVID-19 cases and deaths reported in NSW

Time	Cases confirmed by PCR	Cases confirmed by RAT	Total
Cases this week	6,851	5,599	12,450
Cases last week	5,591	4,459	10,050
Total cases (since beginning of pandemic)	1,952,760	1,608,786	3,561,546
Total deaths (since beginning of pandemic)			5.454

COVID-19 deaths

7 days	Total
14	2,288

#### Queensland COVID-19 statistics



#### Changes to reporting

Routine reporting of COVID-19 statistics, including case numbers, hospitalisations and deaths now occurs weekly.

As part part of the Queensland Government's shift from the emergency response phase of the COVID-19 pandemic to living with COVID-19, information relating to testing, and the location, age and gender of cases has been removed.

The next weekly report will be on Friday 11 November.

Case, hospitalisation and death data as at midnight 1 November 2022. Vaccination data as at 26 October 2022. Refer to data caveats.

New cases (7d)

1,668,438 105 Cases (total)

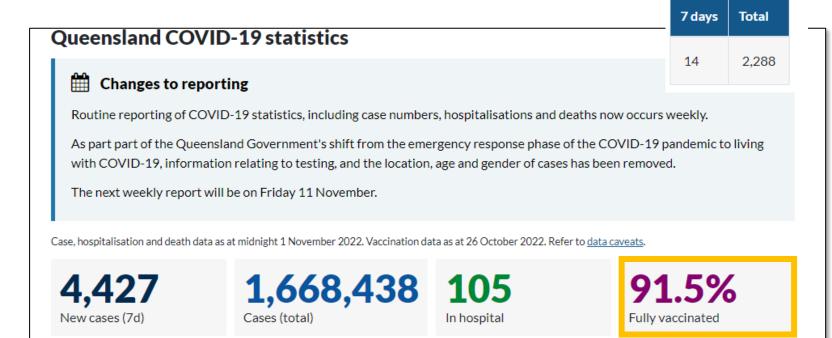
In hospital

91.5%

Fully vaccinated

# Most Australians are already vaccinated though?

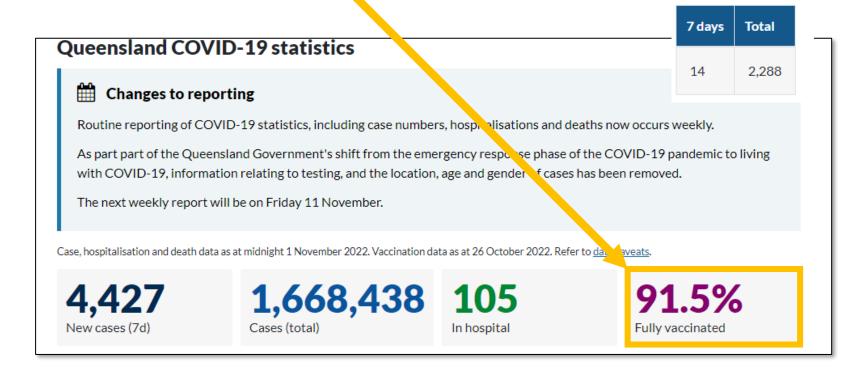
#### COVID-19 deaths



# Most Australians are already vaccinated though?

## People who have had 2 shots

#### COVID-19 deaths



# Most Australians are already vaccinated though?

- Conflicting information on the risks and benefits of vaccination remains prominent
- Boosters will become relevant as new variants emerge



for healthy under 50s

settled science and policy orthodoxy on pandemic management with Covid, we are on the cusp of

Having overturned 100 years of

If not paused and stopped, this will affect every Australian, to the detriment of public health. Let's look at the practical implications of this in relation to the

people. Denmark and Norway have banned Covid vaccines for healthy under-50s/65s. On Sepember 30, Sweden announced an end to vaccine recommendations for 12 to 17-year-olds from Novemper L. All three have excellent public alth infrastructure and aggress-

Yet our own Therapeutic Goods Administration has approved vac-

For children, the risk of severe illness or death from Covid is very slight – while the **risks of serious reactions to vaccines** are higher

rious underlying conditions. An article in Vaccine suggests that, for added risks of serious adverse the reduced risk of hospitalisation. In a follow-up note, two of the authors note that the manufacturers' clinical trials showed 125 adverse events per 100,000 vaccinated people, while preventing between 22 to

Another study in preprint by US, Canadian and British scientists estimates that to prevent one Covid

For children, the risk of severe illness or death from Covid is very slight - while the risks of serious reactions to vaccines are higher

in 18 to 29-yearto 30,000 of them oosted. But for every one

Another new study of almost 900,000 children aged five to 11 in North Carolina, in the New England Journal of Medicine, adds to concerns that vaccines don't just

53 per cent at the end of May this also vaccinated, effectiveness had fallen to zero by May. The likely, al-

diologist who initially promoted the Covid vaccines on TV to help overcome public hesitancy. When his fit and healthy 73-year-old dad died of a sudden heart attack six months after a second Pfizer dose he spent six months analysing the data around vaccines. He now describes this as "perhaps the greatest miscarriage of medical science we

He notes that Pfizer's own trial showed slightly more deaths in the treatment than in the placebo arm and no statistically significant reduction in all-cause mortality

ing trend of rising excess mortalia

among under-l British data, the risk of my 27,000: nearly

I have more confidence in my consultant's advise based on training and qualification [..] free of pressures to conform to the zeitgeist from bureaucrats and regulators, the latter often with compromising links to industry

British consultant the net harm-benefit balance to ar cardiologist Aseem Malhotra indeterminate degree.

The number needed to vaccinate to Centre in February mapped falling prevent just one Covid death confidence in medical scientiagainst the Delta variant reflects since 2020. Malhotra argues th the steep age-segregated risk prothe rollout of vaccines under eme files, from 230 for over-80s to gency-use authorisation withou 93,000 for 18 to 29-year-olds. access to the raw data, the grown evidence of harms, and the resor Against this, the risk of myocarditis mandates whose major impact anges in different studies from one boost manufacturers' profits "have in 6000 to one in 2700 for 12 to 27highlighted modern medicine's year-old males, once again demonworst failings on an epic scale, with additional catastrophic harms to

article in the Journal of trust in public health'

Pfizer's own trial showed slightly more deaths

in the treatment than in the placebo, and no

significant reduction in all-cause mortality

A poll by the Pew Research

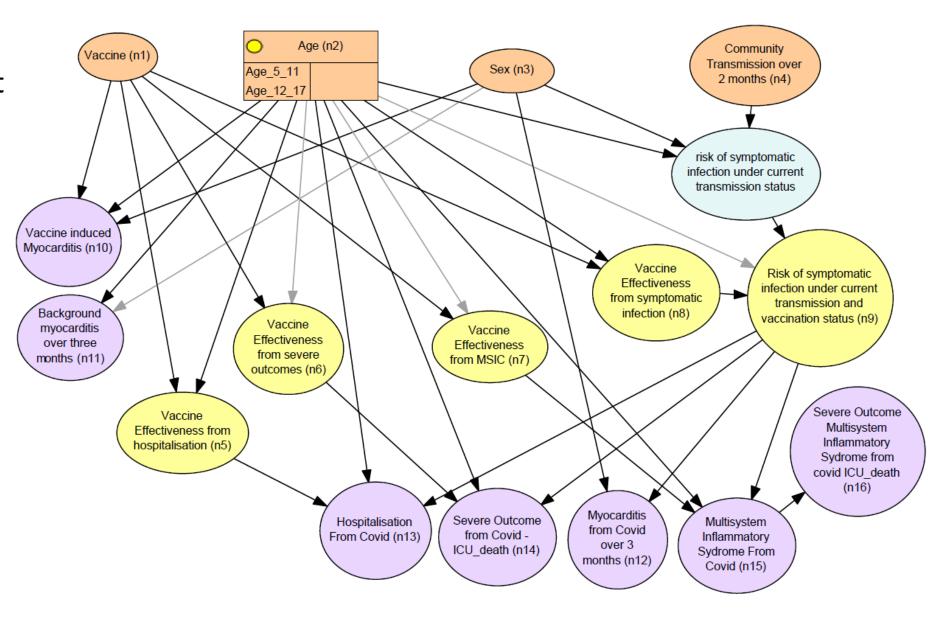
knowledge of my medical history free of pressures to conform to the zeitgeist from bureaucrats and regulators, the latter often with compromising links to industry

eritus ralian Crawford cy and a secretary-

## CoRiCAL Kids

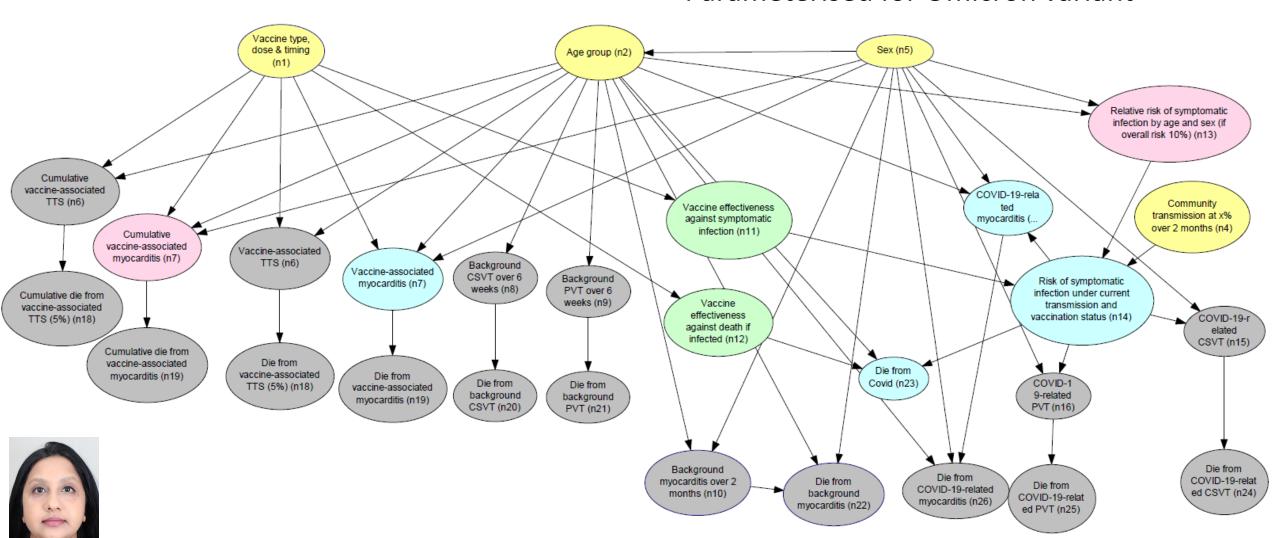
- Under 18s have different risks from COVID-19
- Death is from COVID-19 is very rare
- Paediatric model focuses on risk of hospitalisation and severe outcomes
- Results pending





## Moderna and boosters

- Combines original AZ and Pfizer models for easier updating
- Added Moderna and boosters
- Parameterised for Omicron variant



# Myocarditis risk charts



Risk of myocarditis after mRNA COVID-19 vaccination vs after COVID-19 infection Estimated cases of myocarditis by age, sex and vaccination status Australia, October 2022







Cases of myocarditis per million vaccine doses							
		Pfizer COVID	)-19 vaccine	Moderna COV	ID-19 vaccine		
Gender	Age group (years)	Post first dose	Post second or third dose	Post first dose	Post second or third dose	Post COVID-19 infection	Estimated myocarditis cases per million post COVID-19 vaccination or infection
	5-11	≤10	≤10	Insuff. data	Insuff. data	176	10 or less
	12-17	32	134	57	236	590	10.1 to 50
Male	18-29	23	94	56	232	637	50.1 to 100
	30-39	≤10	32	12	50	630	100.1 to 300
	40+	≤10	≤10	≤10	13	630	More than 300
	5-11	≤10	≤10	Insuff. data	Insuff. data	81	
	12-17	15	28	27	50	357	
Female	18-29	15	28	26	48	195	
	30-39	≤10	≤10	≤10	≤10	363	
	40+	≤10	≤10	≤10	11	363	

<sup>\*\*\*</sup>IMPORTANT NOTES\*\*\*

• Chart demonstrates risk of myocarditis following COVID-19 mRNA vaccination or infection. However, causality is not certain - i.e. rates above are inclusive of background myocarditis, which may be due to other causes.

culations are based on population-level data and do not take into account individual risk factors including a past history of myocarditis following COVIDaccine or infection

e to limitations in data availability, the risk of myocarditis following third doses of vaccine is assumed to approximate that following second doses.

The to limitations in data availability, the risk of myocarditis following vaccination with Moderna COVID-19 vaccine in children aged 5 to 11 years can not stimated.

of myocarditis post COVID-19 infection assumes rates are consistent for all variants

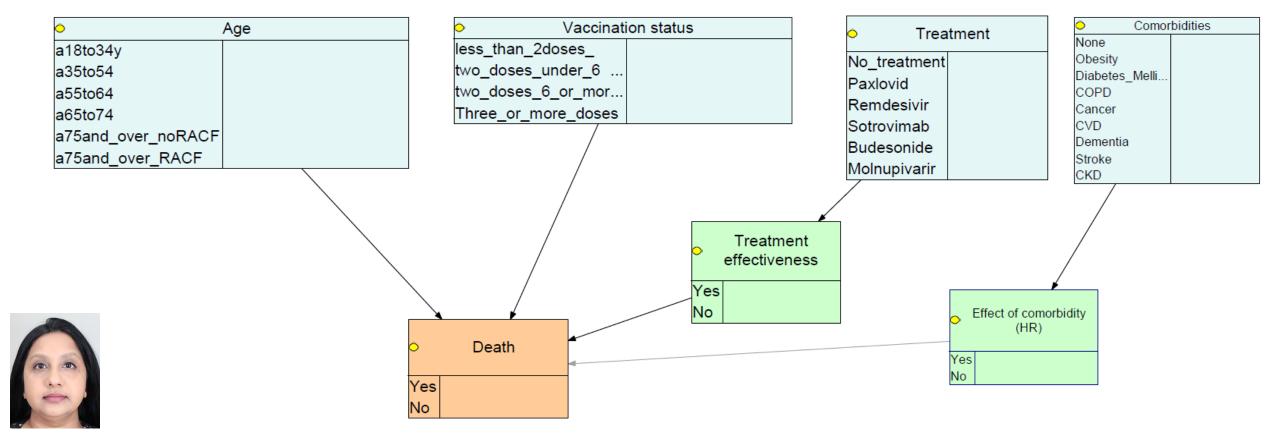
Estimates based on CoRiCal (COVID-19 Risk Calculator):

https://corical.immunisationcoalition.org.au.

Questions and feedback to:
corical.feedback@immunisationcoalition.org.au

## Antiviral treatments

- Antiviral treatments can be given once a patient is infected
- They can reduce the risk of death, particularly in high risk patients
- Effectiveness in each case should be considered when prioritising who to treat



# Long COVID

- Persistent, recurring or new symptoms that cannot be attributed to other diagnoses more than 12 weeks post-SARS-CoV-2 infection
- We estimate presence of symptoms at 6 months
- Between <5% to >80% of recovered COVID-19 patients.
- Vaccination is effective at reducing long COVID
- Important to avoid reinfection, as this will increase risk substantially



- Current transmission rates
- Age / sex
- Vaccination status
- Comorbidities
- Number of previous SARS-CoV-2 infections



#### **Main outcomes**

- Hospitalisation from COVID-19,
- ICU admission from COVID-19,
- presence of at least one long COVID symptom at 6 months post-infection.



## Comorbidities

- Comorbidities are associated with increased risk of infection/death
- Risk estimates for multiple permutations of comorbidities
- Comorbidities increase benefit of vaccination compared to individuals living without comorbidities





## Risk communication

## How can we present CoRiCAL to help people understand?

## STUDY 1

Iterative end user testing of revised versions (e.g. simplified language to grade 8 reading level) using "think aloud" interviews with GPs and patients

## STUDY 2

Tests different combinations of risk formats to identify the optimal combination for consumer decision making about COVID-19 vaccination

## STUDY 3



Evaluate current CoRiCal tool against government information and a layered version that includes audio-visual explanations of rare outcomes to meet the varying health literacy needs of the Australian population.

Watch this space....

https://corical.immunisationcoalition.org.au/

