IMMUNISATION
COALITION

Dr Hazel Clothier

Lead Epidemiologist,
Epi-Informatics, Centre for Health Analytics Murdoch Childrens Research Institute

Determining risk factors and benefits of vaccination: a guide to immunisers

1:35 pm

Determining Risks and Benefits of Vaccination: A Guide for Immunisers

Hazel Clothier

Epi-Informatics, Centre for Health Analytics

SAEFVIC Victoria

Global Vaccine Data Network

8th IC Influenza

June 2024

Centre for Health Analytics

Determining Risks and Benefits of Vaccination: A Guide for Immunisers Anyone

Hazel Clothier

Epi-Informatics, Centre for Health Analytics

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Centre for Health Analytics

Determining Benefit-Risk of Vaccination

Considerations

Vaccine vigilance (safety)

Finding the balance

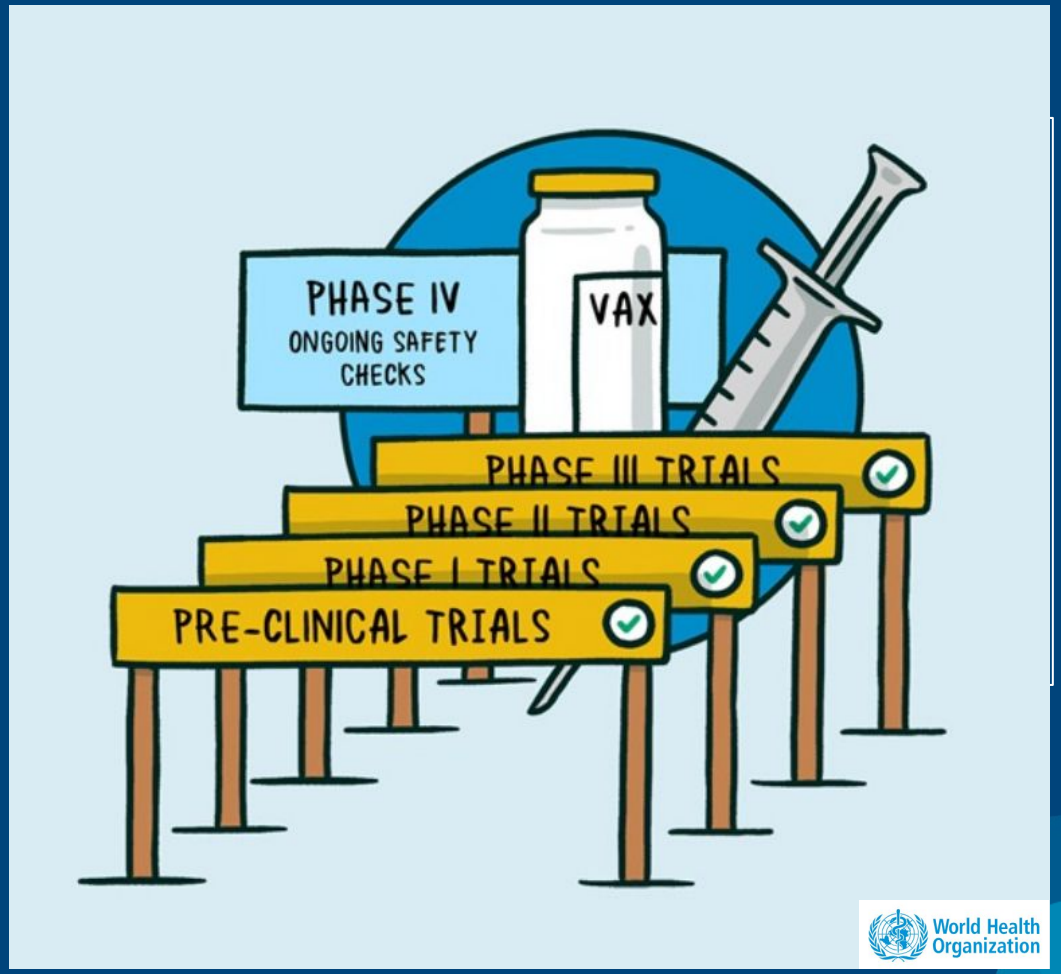
- ADEM
- Myocarditis
- Thromboembolic
- Children & Adolescents
- Long COVID

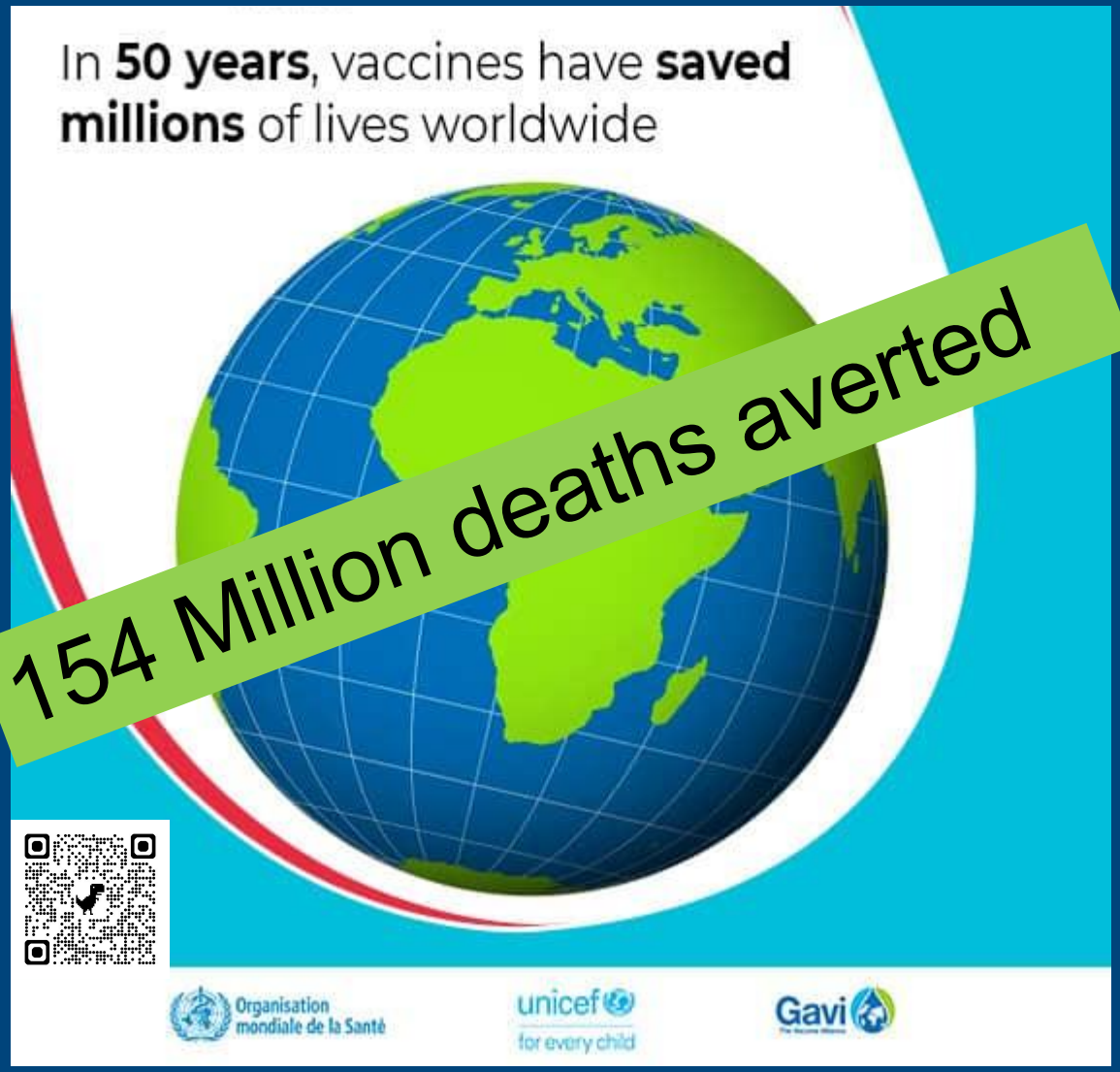
Infodemic / noise

Determining Benefit-Risk of Vaccination

1. Does it work?
2. Do I need it?
3. Is it safe (for me)?

….. How do I know?



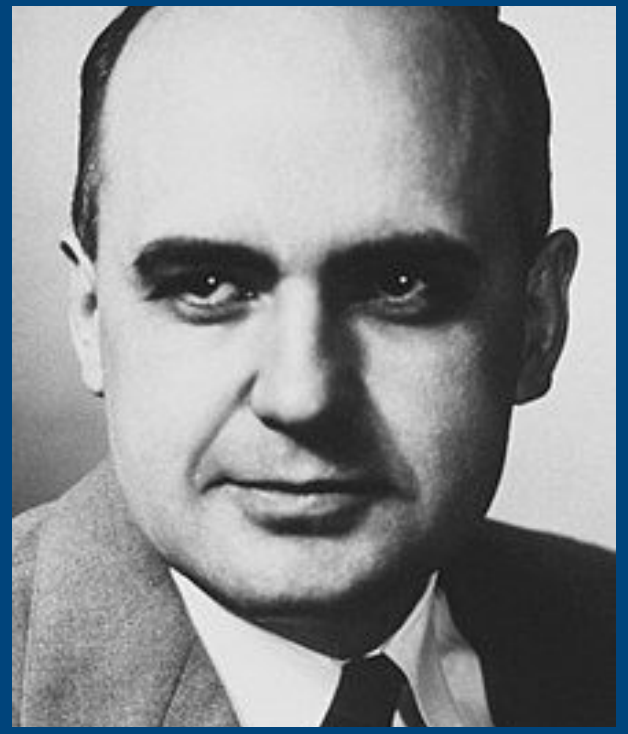


14 pathogens (ie, diphtheria, *Haemophilus influenzae* type B, hepatitis B, Japanese encephalitis, measles, meningitis A, pertussis, invasive pneumococcal disease, poliomyelitis, rotavirus, rubella, tetanus, tuberculosis, and yellow fever

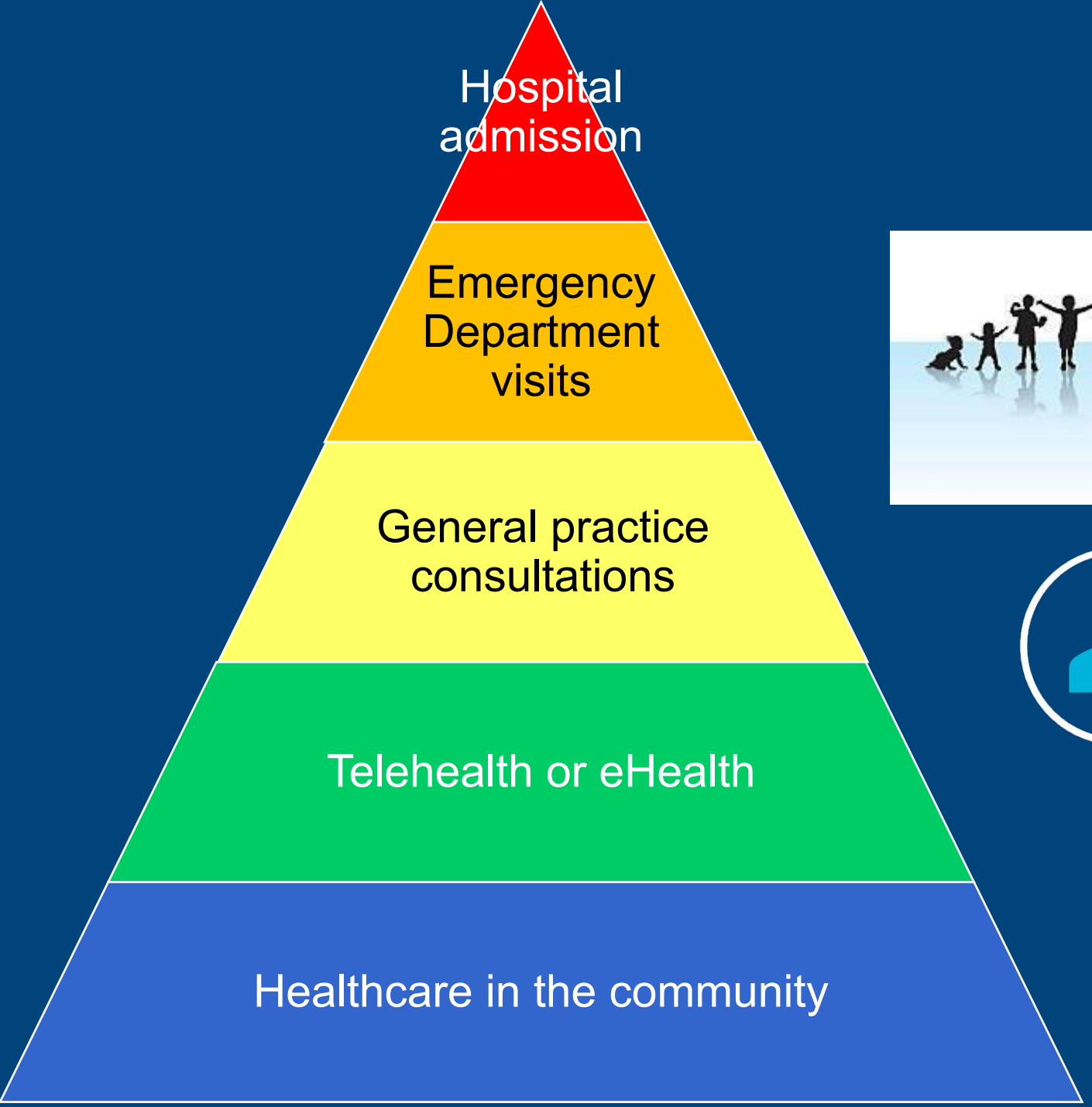
Determining Risks and Benefits of Vaccination

“I never breathe a sigh of relief until the first 3 million doses have been delivered”

Maurice Hilleman



Determining Risks and Benefits of Vaccination

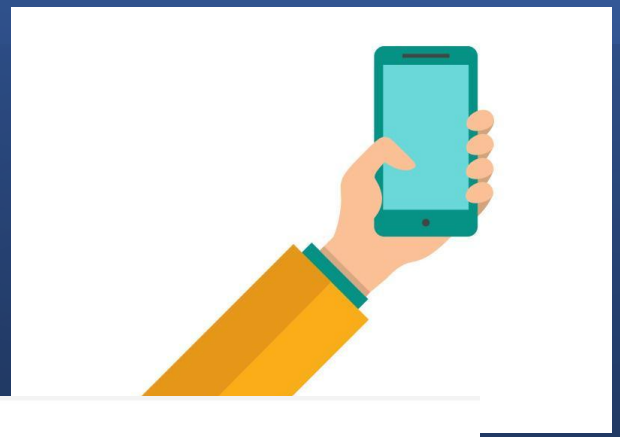

Hospital admission
Emergency Department visits
General practice consultations
Telehealth or eHealth
Healthcare in the community

Comprehensive vaccine safety surveillance

Detect & Investigate

- ✔ Very rare events
- ✔ Increase in common events
- ✔ Cryptic events
- ✔ Community concerns
- ✔ Spurious rumours
- ✘ Personal risk / risk factors
- ✘ Platform, Antigen, Brand, batch…

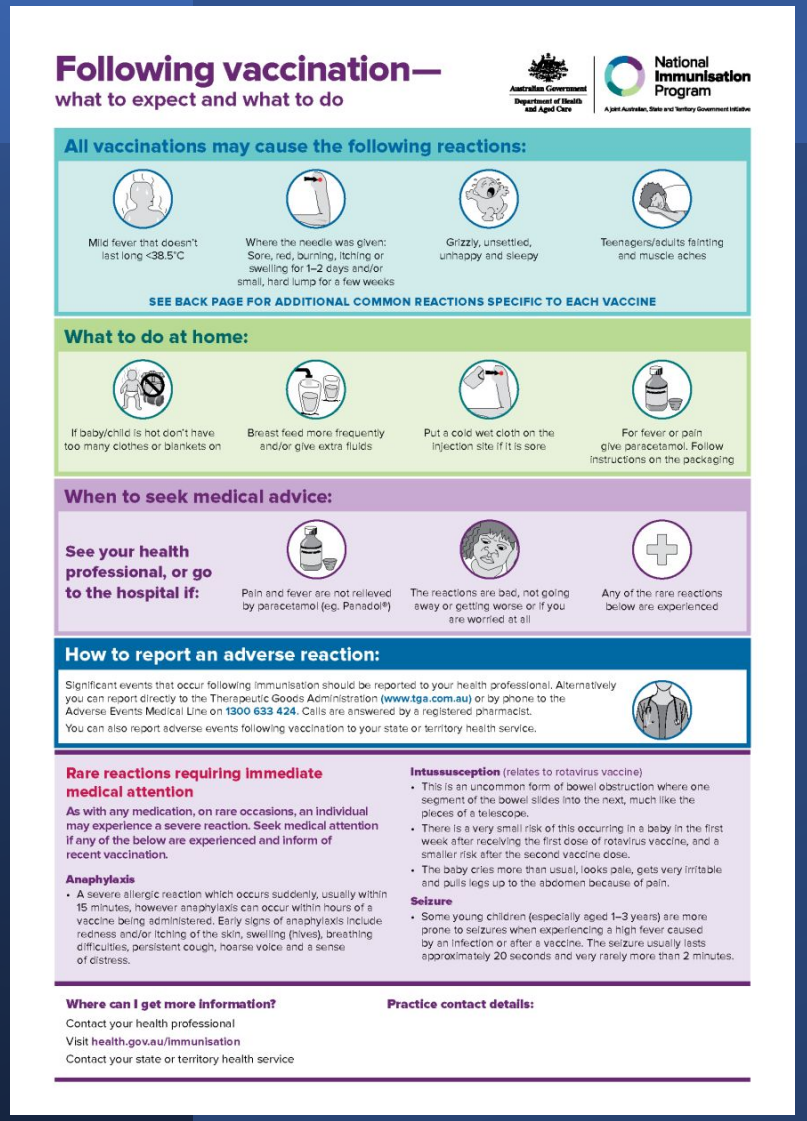
Traditional surveillance



AusVaxSafety
An NCIRS led collaboration

SAEFVIC

PAEDS Paediatric Active Enhanced Disease Surveillance
An NCIRS led collaboration



Following vaccination—
what to expect and what to do

Australian Government Department of Health and Aged Care | National Immunisation Program
A joint Australian, State and Territory Government initiative

All vaccinations may cause the following reactions:

- Mild fever that doesn't last long <38.5°C
- Where the needle was given: Sore, red, burning, itching or swelling for 1–2 days and/or small, hard lump for a few weeks
- Grizzly, unsettled, unhappy and sleepy
- Teenagers/adults fainting and muscle aches

SEE BACK PAGE FOR ADDITIONAL COMMON REACTIONS SPECIFIC TO EACH VACCINE

What to do at home:

- If baby/child is hot don't have too many clothes or blankets on
- Breast feed more frequently and/or give extra fluids
- Put a cold wet cloth on the injection site if it is sore
- For fever or pain give paracetamol. Follow instructions on the packaging

When to seek medical advice:

See your health professional, or go to the hospital if:

- Pain and fever are not relieved by paracetamol (eg. Panadol®)
- The reactions are bad, not going away or getting worse or if you are worried at all
- Any of the rare reactions below are experienced

How to report an adverse reaction:

Significant events that occur following immunisation should be reported to your health professional. Alternatively you can report directly to the Therapeutic Goods Administration (www.tga.com.au) or by phone to the Adverse Events Medical Line on 1300 633 424. Calls are answered by a registered pharmacist.
You can also report adverse events following vaccination to your state or territory health service.

Rare reactions requiring immediate medical attention

As with any medication, on rare occasions, an individual may experience a severe reaction. Seek medical attention if any of the below are experienced and inform of recent vaccination.

Anephylaxis

- A severe allergic reaction which occurs suddenly, usually within 15 minutes, however anaphylaxis can occur within hours of a vaccine being administered. Early signs of anaphylaxis include redness and/or itching of the skin, swelling (hives), breathing difficulties, persistent cough, hoarse voice and a sense of distress.

Intussusception (relates to rotavirus vaccine)

- This is an uncommon form of bowel obstruction where one segment of the bowel slides into the next, much like the pieces of a telescope.
- There is a very small risk of this occurring in a baby in the first week after receiving the first dose of rotavirus vaccine, and a smaller risk after the second vaccine dose.
- The baby cries more than usual, looks pale, gets very irritable and pulls legs up to the abdomen because of pain.

Seizure

- Some young children (especially aged 1–3 years) are more prone to seizures when experiencing a high fever caused by an infection or after a vaccine. The seizure usually lasts approximately 20 seconds and very rarely more than 2 minutes.

Where can I get more information?
Contact your health professional
Visit health.gov.au/immunisation
Contact your state or territory health service

Practice contact details:

Using Big data for Real World Evidence

Using Big data for Real World Evidence

CDC VSD Vaccine Safety Datalink

VACCINE SAFETY HEALTH LINK VSHL

VAC4EU

Global Vaccine Data Network®

Linked data

Collaborations

Social media

Comprehensive vaccine safety surveillance

Detect & Investigate

- ✔ Very rare events
- ✔ Increase in common events
- ✔ Cryptic events
- ✔ Community concerns
- ✔ Spurious rumours
- ✔ By demographic/risk factors
- ✔ Platform, Antigen, Brand, batch…

Real world data

- ✔ All levels of healthcare
- ✔ Accessible & near real-time data
- ✔ Natural language processing (NLP)
- ✔ Community concerns & sentiment
- ✔ Population inclusive
- ✔ Cost effective

Global Vaccine Data Network®

Collaborating on vaccine safety and effectiveness studies using health data from around the world.

The GVDN® uses big data to assess vaccine safety and effectiveness across large and diverse populations around the world and over time.

The Global Vaccine Data Network™ is a multinational collaboration ready to conduct globally coordinated epidemiological studies on the safety and effectiveness of vaccines, including COVID-19 vaccines.

6 Continents

26 Countries

31 Sites

>300 Million People

Multinational **cohort of 99 million** vaccinated persons….

Neurological conditions

		GBS		TRM		BP		ADEM	
Dose	Vaccine	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI	OE Ratio	95%CI
1	ChAdOx1	2.49	(2.15,2.87)	1.91	(1.22,2.84)	0.98	(0.88,1.08)	2.23	(1.15,3.90)
	BNT162b2	0.90	(0.79,1.03)	0.74	(0.53,1.02)	1.05	(1.00,1.11)	1.28	(0.77,2.00)
	mRNA-1273	0.95	(0.65,1.34)	1.50	(0.77,2.62)	1.25	(1.11,1.39)	3.78	(1.52,7.78)
2	ChAdOx1	0.73	(0.54,0.96)	0.58	(0.21,1.26)	0.95	(0.85,1.06)	1.63	(0.70,3.21)
	BNT162b2	0.69	(0.60,0.79)	0.84	(0.62,1.11)	0.93	(0.88,0.97)	0.54	(0.23,1.06)
	mRNA-1273	0.84	(0.60,1.15)	1.27	(0.69,2.12)	1.02	(0.91,1.13)	1.21	(0.25,3.55)
3	ChAdOx1	3.99	(0.48,14.41)	0		0.75	(0.20,1.92)	0	
	BNT162b2	0.66	(0.54,0.79)	1.02	(0.68,1.46)	0.81	(0.76,0.87)	0.82	(0.30,1.79)
	mRNA-1273	0.68	(0.45,1.00)	0.92	(0.40,1.81)	0.83	(0.74,0.94)	0.64	(0.02,3.58)
4	BNT162b2	0.87	(0.56,1.29)	1.05	(0.39,2.29)	1.14	(0.99,1.29)	2.26	(0.06,12.62)
	mRNA-1273	0.88	(0.32,1.92)	1.25	(0.15,4.50)	1.08	(0.83,1.38)	0	

AESI: GBS= Guillain-Barré syndrome, TRM= Transverse myelitis, BP= Facial (Bell's) palsy, ADEM= Acute disseminated encepha
GSZ= Generalised seizures
Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of India (ChAdOx1

OE Ratio

Observed vs Expected

Faksova *et al*

Global Vaccine Data Network®

Multinational **cohort of 99 million** vaccinated persons….

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Absolute risk

- ADEM 0.78
- TM 1.82

per million doses of ChAdOx1 (Astrazeneca)

Faksova *et al*

Morgan *et al*

VACCINE SAFETY HEALTH LINK
VSHL

Multinational **cohort of 99 million** vaccinated persons….

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Absolute risk

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per million doses of ChAdOx1 (Astrazeneca)

Weighed against well established protective benefits of vaccination against COVID-19 disease and its complications *(including ADEM with COVID-19 infection)*

VACCINE SAFETY HEALTH LINK
VSHL

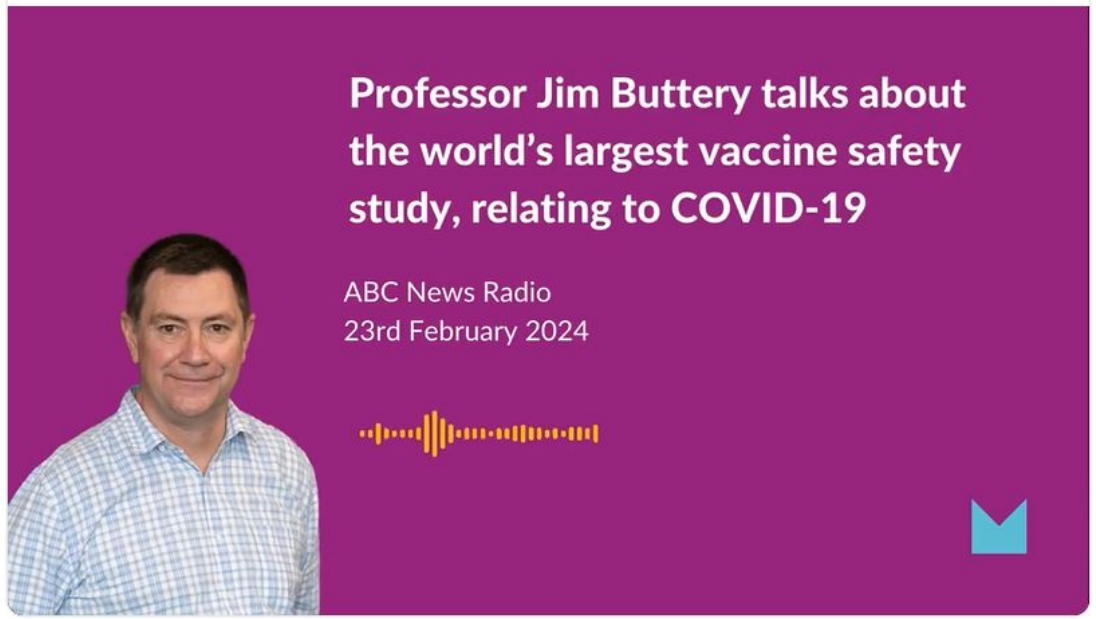
Two very rare Covid vaccine side-effects detected in global study of 99 million

Results confirm how uncommon known complications are as researchers confirm benefits from vaccines still 'vastly outweigh the risks'

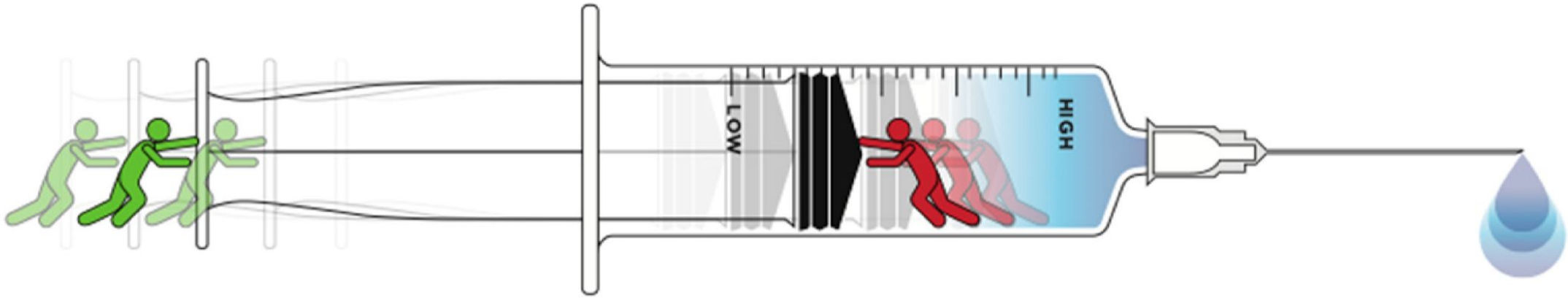
> By making the data dashboards publicly available, we are able to support greater transparency, and stronger communications to the health sector and public.

Associate Professor Helen Petousis-Harris
Co-Director, Global Vaccine Data Network
hosted at University of Auckland

"It demonstrates to the community that we now have the ability to look for very rare adverse events and either rule them out...or demonstrate that, yes, there is an association."



….. **increasing public trust in vaccines** needs reshaping medicine’s cultural environment **to communicate better the risks and benefits of vaccines**

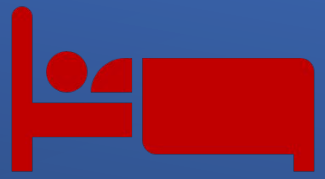


START OF THE VACCINATION CAMPAIGN

TIME

- High perception of the disease severity
- Proof of vaccine safety as more people get vaccinated without relevant side effects
- First cases of vaccine severe side effects amplified by mass- and social-media
- Doubts about safety and effectiveness of the different types of vaccines
- Decreased disease severity perception due to the achievement of a high level of immunization coverage
- Misleading messages about the vaccine effectiveness in preventing infection and surge of cases among vaccinated people
- General demotivation toward preventative measures due to pandemic fatigue
- Routinization of the vaccine with the return to pre-pandemic life

G Alderotti *et al.* Communicating with patients about COVID-19 Vaccination: A Qualitative Study on Vaccinators in Tuscany Region, Italy. Vaccines 2023




Benefit > Risk

Guillain Barre syndrome

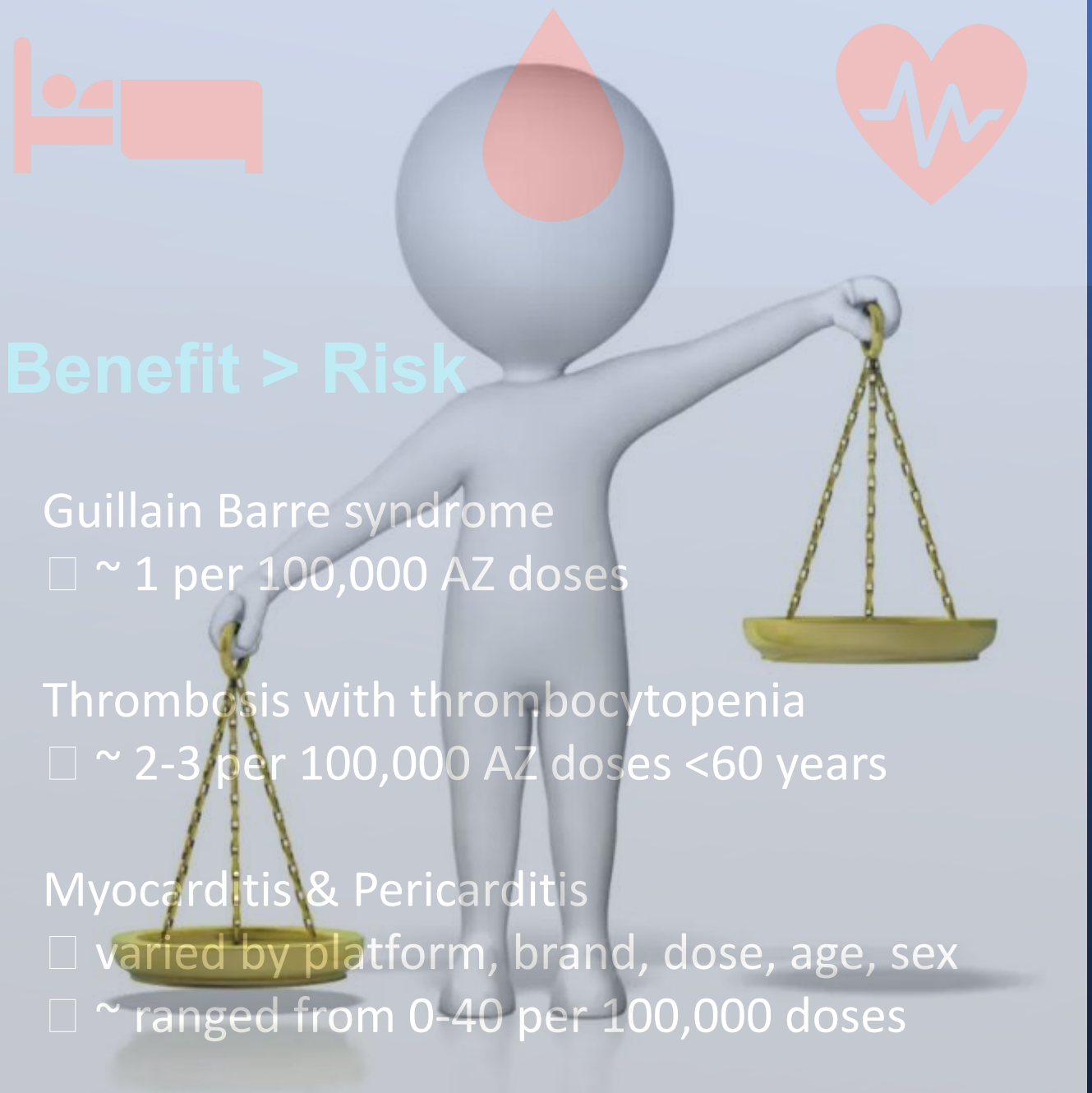
- ~ 1 per 100,000 AZ doses

Thrombosis with thrombocytopenia

- ~ 2-3 per 100,000 AZ doses <60 years

Myocarditis & Pericarditis

- varied by platform, brand, dose, age, sex
- ~ ranges from 0-40 per 100,000 doses



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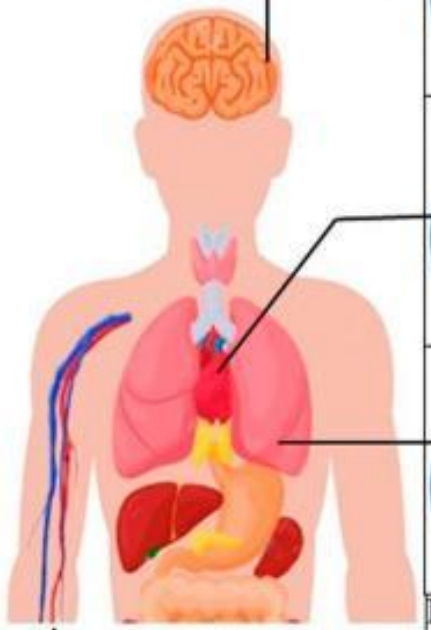
vaccines

Review

An Update on Complications Associated with SARS-CoV-2 Infection and COVID-19 Vaccination

Purvita Chowdhury [1], Shinjini Bhattacharya [1], Bhaskarjyoti Gogoi [2] and Sachin Kumar [1,*]

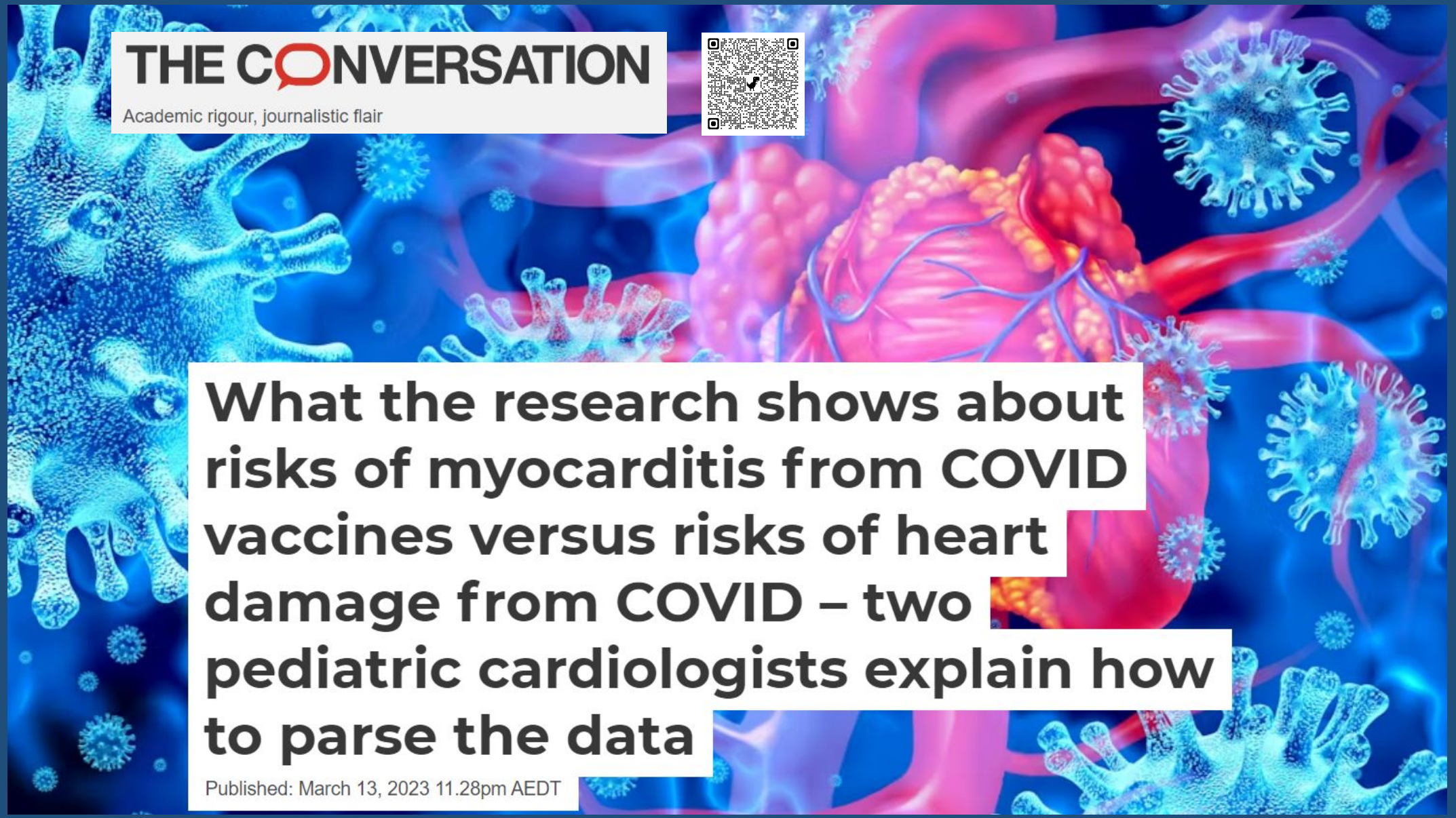


	Acute phase Complications	Long term Complications	COVID-19 Vaccine Complications
Neurological	• Encephalopathy • Guillain Barre syndrome	• Neuro-inflammation • Loss of smell • Loss of taste • Guillain Barre syndrome	• Bells palsy • Guillain Barre syndrome
Cardiological	• Arrhythmias • Myocardial injury • Hearth failure • Shock	• Abnormal echocardiography • Myocarditis • Postural tachycardia syndrome	• Myocarditis • Pericarditis
Pulmonary	• Acute respiratory distress syndrome • Mechanical ventilation	• Dyspnea • Oxygen dependance • Fibrotic lung disease • Pulmonary function test disorder	--
Hematological	• Venous thromboembolism • Pulmonary embolism • Limb ischemia • Acute stroke	• Thrombosis	• Thrombocytopenia • Thrombosis

Table 4. Measures of the Effect of Vaccinations and SARS-CoV-2 Infections Presented as Excess Events Per 1 Million Exposed

	Excess myocarditis events per 1 000 000 exposed (95% CI)								
	Main analysis	Age <40 y	Age ≥40 y	Women	Men	Age <40 y		Age ≥40 y	
						Women	Men	Women	Men
BNT162b2									
First dose	2 (1–3)	2 (1–3)	…	2 (1–3)	3 (1–4)	…	4 (2–6)	3 (0–4)	…
Second dose	2 (1–3)	5 (4–5)	…	…	6 (4–7)	…	11 (9–13)	…	…
Booster dose	2 (1–3)	…	2 (2–3)	1 (0–2)	3 (2–4)	…	…	2 (1–3)	3 (2–4)
mRNA-1273									
First dose	…	7 (3–9)	…	…	10 (1–14)	…	14 (5–17)	…	…
Second dose	34 (32–35)	43 (41–44)	…	7 (2–9)	73 (70–76)	7 (1–9)	97 (91–99)	…	…
Booster dose	1 (0–2)	…	1 (1–2)	…	3 (1–3)	…	…	…	3 (1–3)
SARS-CoV-2									
Positive test (before vaccine)	35 (34–36)	10 (9–11)	63 (62–64)	28 (27–29)	50 (48–51)	8 (6–8)	16 (12–18)	51 (49–52)	85 (82–87)
Positive test (vaccinated)	23 (21–24)	…	39 (38–40)	17 (16–19)	34 (30–36)	7 (3–8)	…	26 (24–27)	61 (58–63)

Patone *et. al.* *2022*



What the research shows about risks of myocarditis from COVID vaccines versus risks of heart damage from COVID – two pediatric cardiologists explain how to parse the data

Published: March 13, 2023 11.28pm AEDT

Heart

Cardiac risk factors and prevention
Original research

12 March 2024

The role of COVID-19 vaccines in preventing post-COVID-19 thromboembolic and cardiovascular complications

Núria Mercadé-Besora [1, 2, 3], Xintong Li [1], Raivo Kolde [4], Nhung TH Trinh [5], Maria T Sanchez-Santos [1], Wai Yi Man [1], Elena Roel [3], Carlen Reyes [3], Antonella Delmestri [1], Hedvig M E Nordeng [6, 7], Anneli Uusküla [8], Talita Duarte-Salles [3, 9], Clara Prats [2], Daniel Prieto-Alhambra [1, 9], Annika M Jödicke [1], Martí Català [1]

10.17 M Vaccinated

10.36 M Un-vaccinated

Heart

Cardiac risk factors and prevention

Original research

The role of COVID-19 vaccines in preventing post-COVID-19 thromboembolic and cardiovascular complications

WHAT THIS STUDY ADDS

- COVID-19 vaccination reduced the risk of heart failure, venous thromboembolism and arterial thrombosis/thromboembolism in the acute (30 days) and post-acute (31 to 365 days) phase following SARS-CoV-2 infection. This effect was stronger in the acute phase.

a substantial reduction of risk (45–81%) for thromboembolic and cardiac events in the acute phase

10.17 M Vaccinated

10.36 M Un-vaccinated

Reduced risk

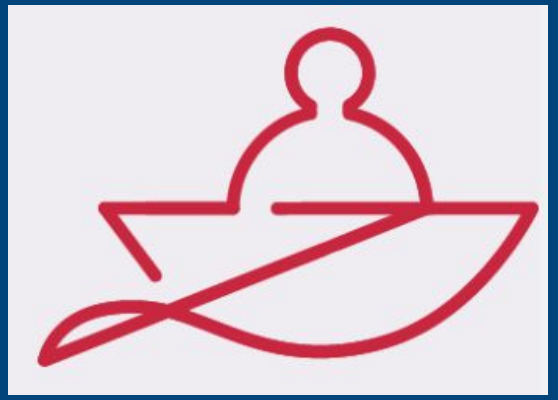
45-81%

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

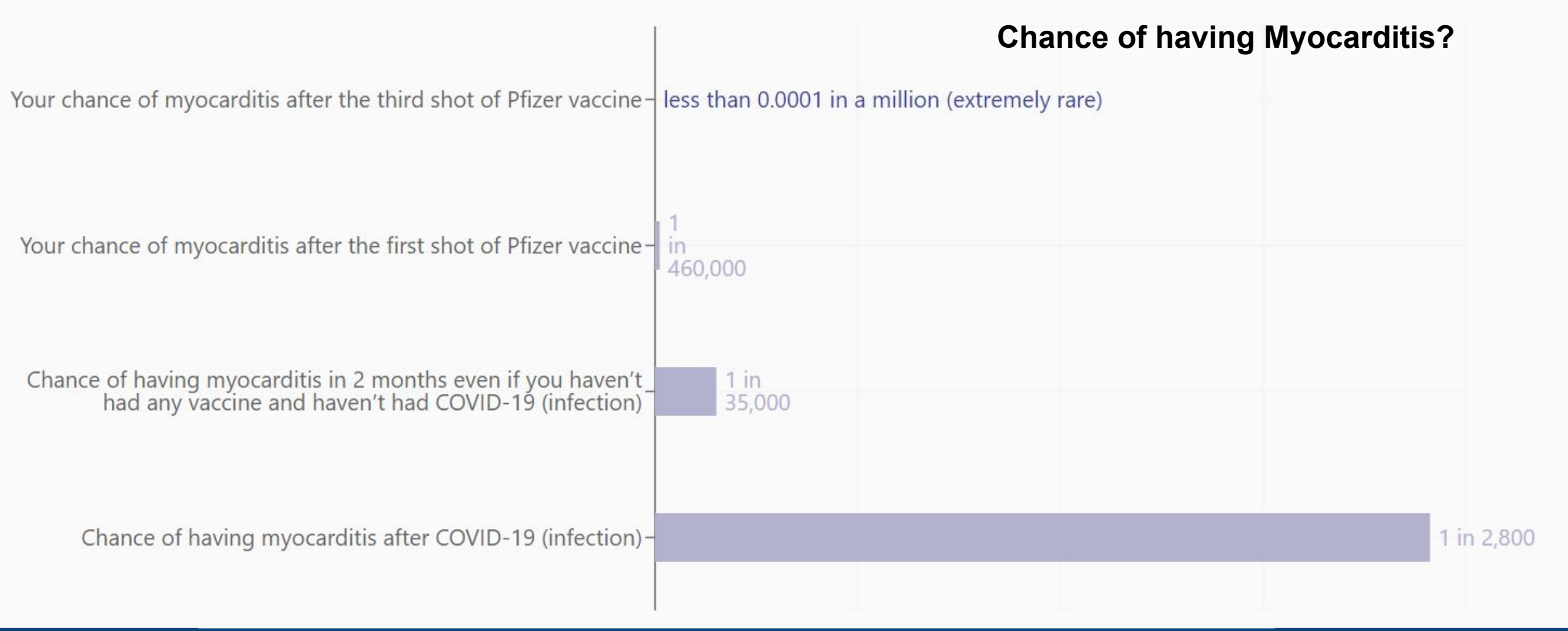
IMMUNISATION COALITION

CoRiCal: COVID-19 Risk Calculator

- ? Which COVID-19 vaccine
- ? Sex & Age
- ? How many doses (1-3)
- ? Timing since last dose
- ? Community cases (Not many Huge)

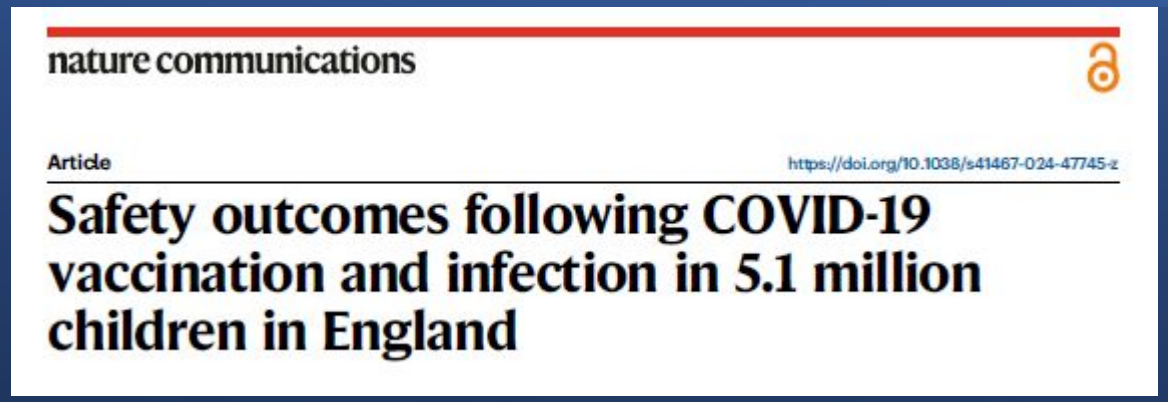


These results are for a 50–59 year-old female when there are a large number of cases in your community.



CoRiCal

Benefit- Risk in Children?



Copland *et al*

27 May 2024

COVID-19 severe illness = low

But… MISC-C, Long COVID…

And… School absence, overall wellbeing & health

Investigated 12 pre-defined conditions

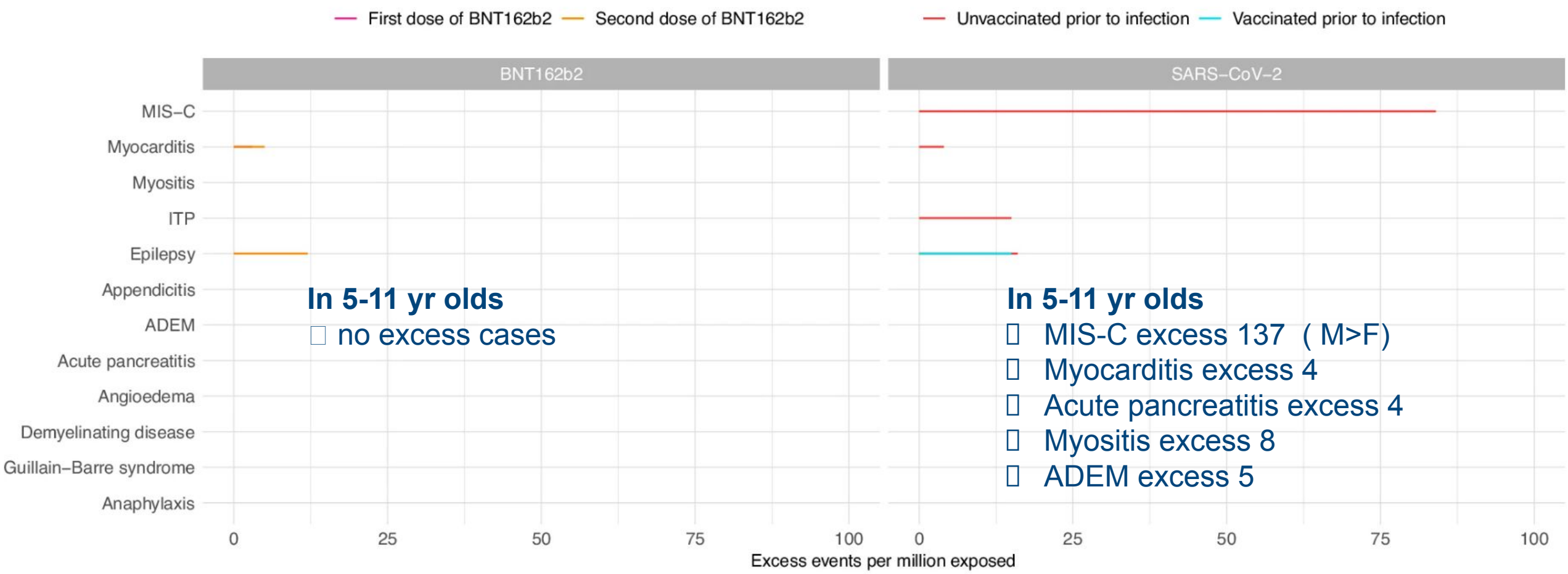
Incidence as hospital admissions <6 weeks of exposure

Compare vaccination vs not vaccinated before infection

Myocarditis
MIS-C
Thrombocytopenia (ITP)
Epilepsy
Acute pancreatitis
ADEM
Guillain-Barre syndrome
Demyelinating disease
Myositis
Angioedema
Anaphylaxis

Risk of serious outcomes post BNT COVID-19 vaccination (dose 1 or 2) or COVID-19 infection (prior to vaccination) in adolescents aged 12-17 years

From: Safety outcomes following COVID-19 vaccination and infection in 5.1 million children in England



In 5-11 yr olds

- no excess cases

In 5-11 yr olds

- MIS-C excess 137 (M>F)
- Myocarditis excess 4
- Acute pancreatitis excess 4
- Myositis excess 8
- ADEM excess 5

Epilepsy* authors suggest likely due to inclusion of pre-existing epilepsy not excluded by the studies available data for washout period

Benefit- Risk in Children?

- 5-11yr olds No increased risk of AESI post vaccination
- 12-17yr olds Increased myocarditis post Pfizer dose 1 or 2 & epilepsy and demyelinating disease (F) post Pfizer dose 2
- 5-17 yr olds Unvaccinated prior to COVID infection had increased risk of hospitalization from 7 of the AESI, incl MIS-C and myocarditis
- 5-17yr olds risk of safety outcomes from COVID-19 infection were largely absent if had received at least 1 COVID-19 vaccine dose prior to infection

Vaccination Benefit > Risk in children & adolescents aged 5-17 years

nature reviews microbiology

https://doi.org/10.1038/s41579-022-00846-2

Review article

13 January 2023

Long COVID: major findings, mechanisms and recommendations

Hannah E. Davis[1], Lisa McCorkell[2], Julia Moore Vogel[3] & Eric J. Topol[3]

Abstract

Long COVID is an often debilitating illness that occurs in at least 10% of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. More than 200 symptoms have been identified with impacts on multiple organ systems. At least 65 million individuals worldwide are estimated to have long COVID, with cases increasing daily. Biomedical research has made substantial progress in identifying various pathophysiological changes and risk factors and in characterizing the illness; further, similarities with other viral-onset illnesses such as myalgic encephalomyelitis/chronic fatigue syndrome and postural orthostatic tachycardia syndrome have laid the groundwork for research in the field. In this Review, we explore the current literature and highlight key findings, the overlap with other conditions, the variable onset of symptoms, long COVID in children and the impact of vaccinations. Although these key findings are critical to understanding long COVID, current diagnostic and treatment options are insufficient, and clinical trials must be prioritized that address leading hypotheses. Additionally, to strengthen long COVID research, future studies must account for biases and SARS-CoV-2 testing issues, build on viral-onset research, be inclusive of marginalized populations and meaningfully engage patients throughout the research process.

Sections

Introduction

Major findings

Diagnostic tools and treatments

Impact of vaccines, variants and reinfections

Challenges and recommendations

Conclusions

nature reviews microbiology

https://doi.org/10.1038/s41579-022-00846-2

Review article

Check for updates

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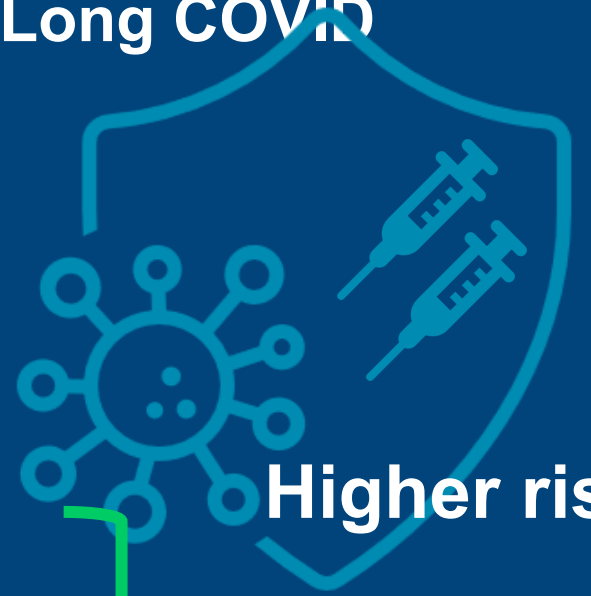
Sections

Introduction

Major findings

~10% of severe cases

Long COVID



Higher risk

Females
Hypertension
Heart disease
Smoking
Obesity
Diabetes
Depression

Medical News in Brief

February 14, 2024

https://jamanetwork.com/journals/jama/fullarticle/2815350

Millions of US Children Experience Range of Long COVID Effects

JAMA Internal Medicine | Original Investigation

Risk Factors Associated With Post–COVID-19 Condition

A Systematic Review and Meta-analysis

Original research

BMJ Public Health

Excess mortality across countries in the Western World since the COVID-19 pandemic: 'Our World in Data' estimates of January 2020 to December 2022

3 June 2024

Saskia Mostert [1,2] Marcel Hoogland,[3] Minke Huibers,[2] Gertjan Kaspers[1,2]

Herald Sun

We're for you

7 June 2024

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1 38m ago

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Academic rigour, journalistic flair

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Published: June 7, 2024 4.13am AEST

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Merryn Johns

3 mins read · June 7, 2024 06:36 am

News Corp Australia Network

Benefit-Risk: Piecing it together

Efficacy

Clinical trials

Benefit-Risk: Piecing it together

Efficacy

Clinical trials

Effectiveness

Individual
Population/herd
Long lasting
Level of protection

Safety

Clinical trials
Post-licensure surveillance

- Frequency
- Severity
- Permanence

Benefit-Risk: Piecing it together

Efficacy
Clinical trials

Effectiveness
Individual
Population/herd
Long lasting
Level of protection

Benefit-risk
Population level
Individual

Safety
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