# “So you think you have had a vaccine reaction”

Prof Nick Wood
Associate Director, Clinical Research and Services,
Senior Staff Specialist NCIRS

NCIRS National Centre for Immunisation Research and Surveillance

THE UNIVERSITY OF SYDNEY

# Acknowledgement of Country

## The Aboriginal artwork was produced by Samantha Williams, a proud Wiradjuri woman from Narrandera, NSW

The artwork adorns a range of NCIRS communications materials, including printed and web-based media. The artwork's design represents our communities in the centre, from our home to the wider community. The symbols around the circle represent the people, both men and women; this could be anyone from mothers, fathers and grandparents to young men and women. It is our responsibility to keep our mob healthy. We need to educate our younger generation and communities about the importance of immunisations and how they keep us protected. The lines going out from the circle represent our journeys, jobs, relocation and impacts we have made along the way. Many Aboriginal and Torres Strait Islander families may relocate from one community to another. We have mob all over, but no matter where we go the story is the same – we need to protect our mob – so the smaller circles represent herd immunity across our communities, and the people that this has an impact on – our elders, our babies and our people who cannot be immunised.

# Take home messages

- Vaccine safety surveillance and reporting = essential role of primary health care

- Your input has national and international significance
  - Supports confidence and coverage
  - Understanding the risk
  - Define treatment and outcomes
  - Research

- Especially important when new vaccines introduced or used more widely
  - Shingrix
  - RSV
  - Japanese encephalitis
  - Vaxelis

# Vaccine side effect versus adverse event (AEFI)

## 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 doctor or immunisation provider, or go to hospital if:**

Pain and fever are not relieved by paracetamol (eg. Panadol®)

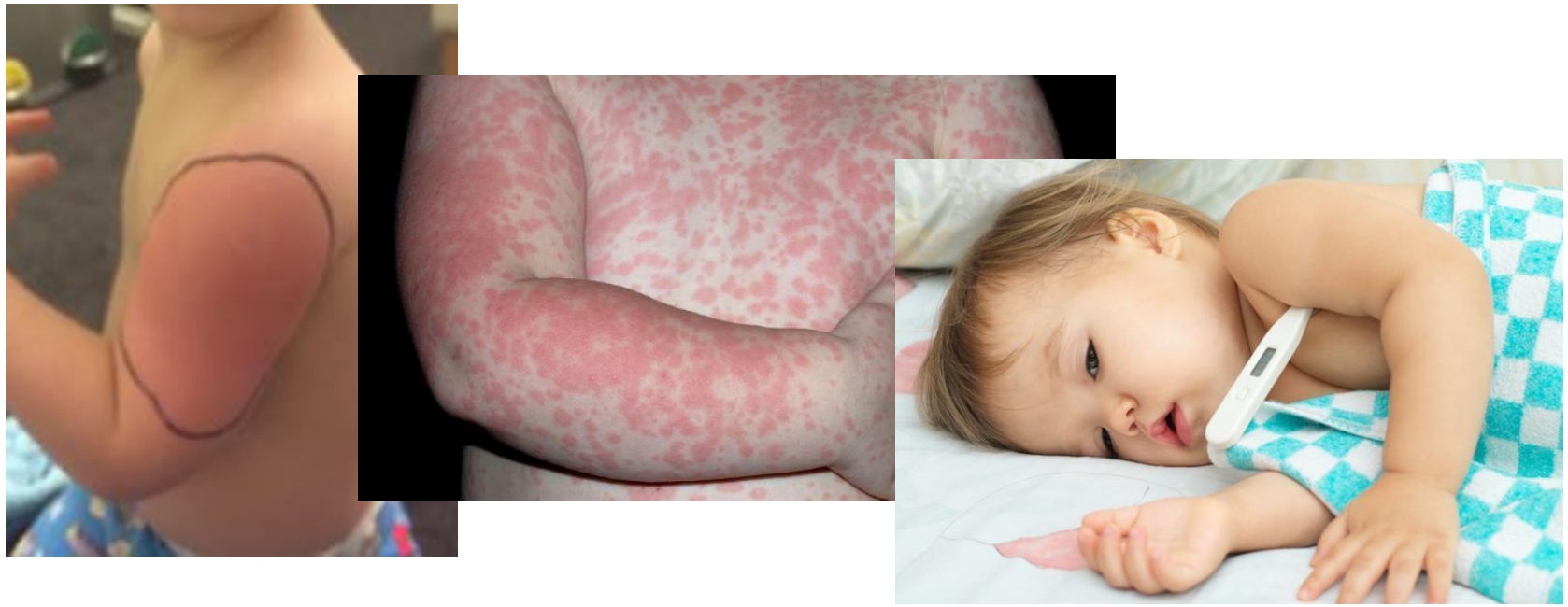
The reactions are bad, not going away or getting worse or if you are worried at all

Any of the rare reactions below are experienced

https://www.health.gov.au/sites/default/files/2023-06/following-vaccination-what-to-expect-and-what-to-do.pdf

# Adverse Event Following Immunisation

**‘any untoward medical occurrence which follows immunisation and which <u>does not necessarily have a causal relationship</u> with the usage of the vaccine’**



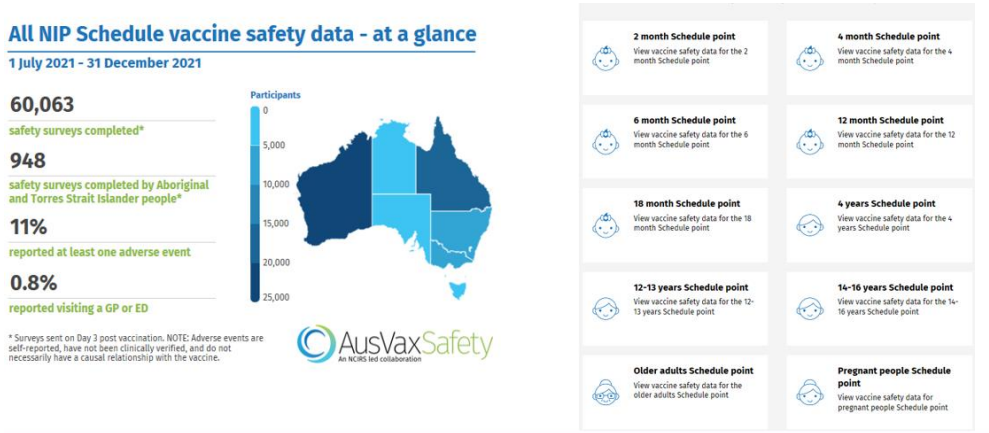
http://www.who.int/vaccine_safety/en/

# WHO Classification of AEFI

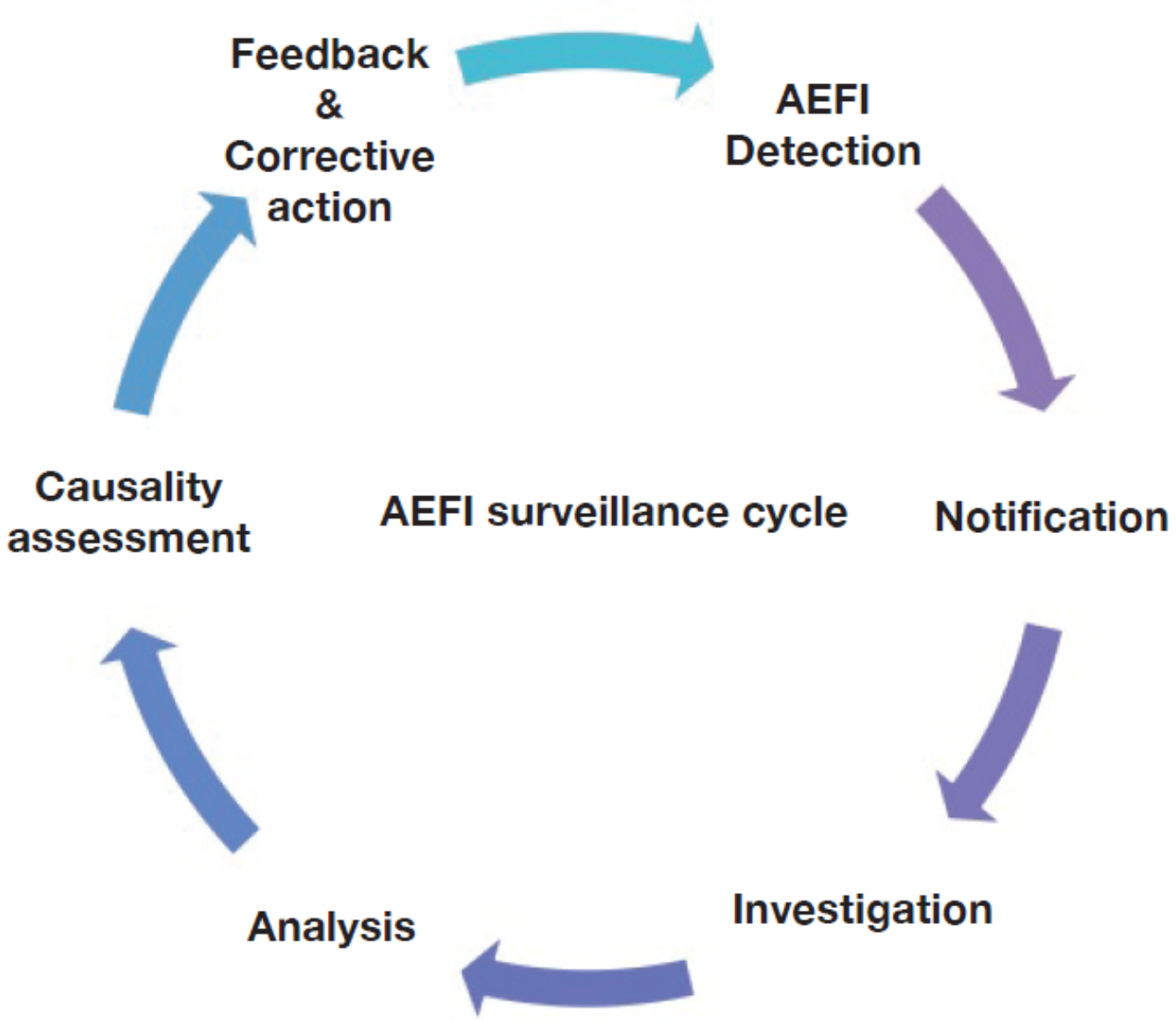
| | |
|---|---|
| Vaccine product related | • Febrile seizures with CSL Fluvax in 2010 |
| Vaccine quality defect related | • Manufacturing error |
| Immunisation error related | • Live vaccine in immunocompromised patient |
| Immunisation anxiety related | • Fainting with HPV vaccine in school program |
| Coincidental | • Fall off a bike after vaccination |

# AEFI system should contain …..

- Passive – also called spontaneous reporting
- Active surveillance
  - Especially useful for new vaccines
- Clinical services to assess and manage
- Data linkage capability
- Communication to providers and public
- Expert advisory group

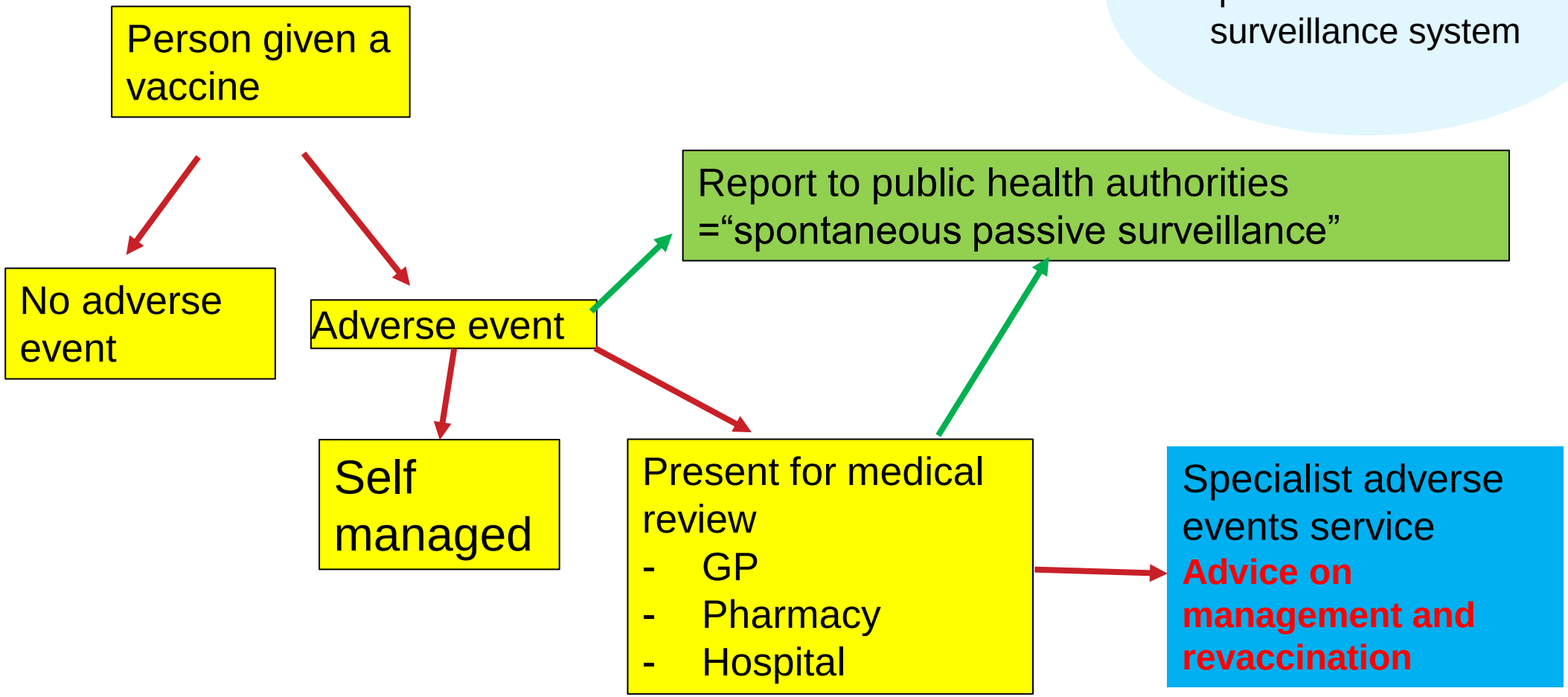


# WHO Vaccine safety surveillance cycle

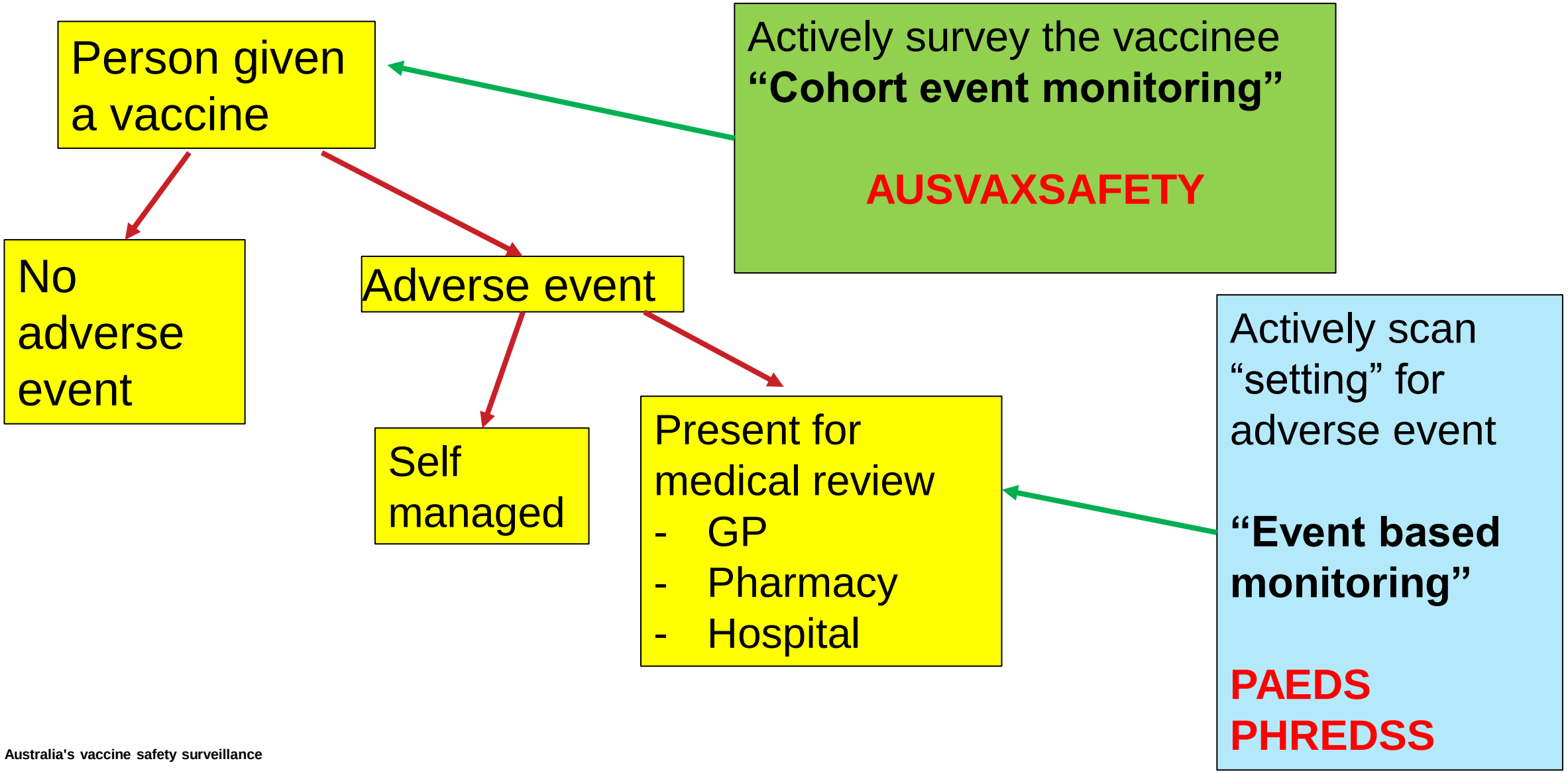


# AEFI Notification and management

Single harmonised "passive and active" surveillance system

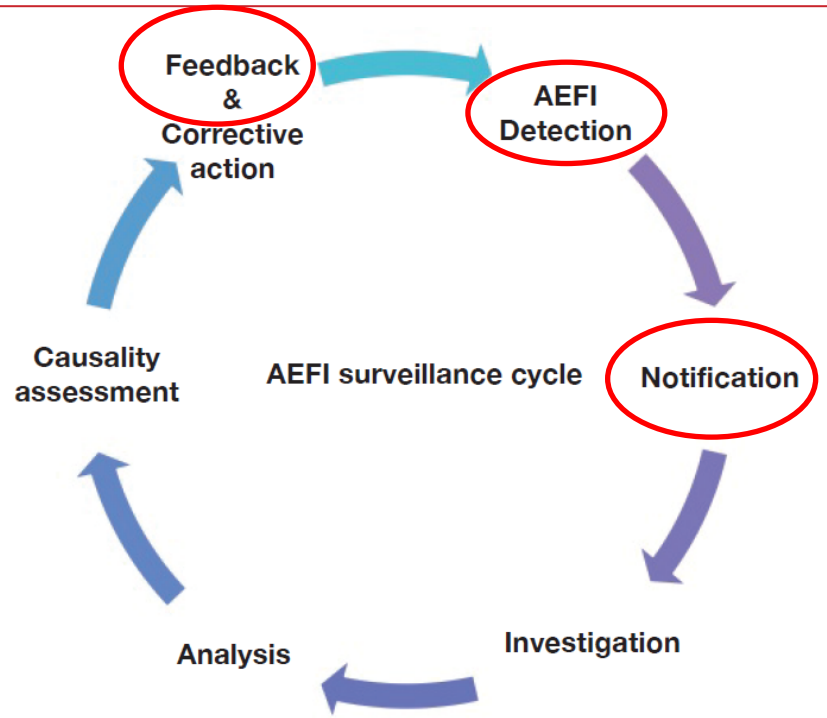


# Active surveillance



# So what is your role in primary healthcare?

- AEFI detection and notification PLUS
- Management of immediate adverse event
  - Anaphylaxis
  - HHE
- Advising on receipt of “next” dose




- Answering questions about long term outcomes of an adverse event
  - For person
  - ? family members

# Reporting an AEFI in NSW

## How do I report an AEFI?

- Report all uncommon, serious or unexpected AEFI or any event felt to be significant following immunisation to your local public health unit.

To report a suspected AEFI, please download the **National Adverse Events Following Immunisation (AEFI) Reporting Form** and contact your local Public Health Unit on 1300 066 055.

Australian Government
Department of Health
Therapeutic Goods Administration

**TGA use only**

Date report received:

Notification ID:

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

### National Adverse Events Following Immunisation (AEFI) reporting form

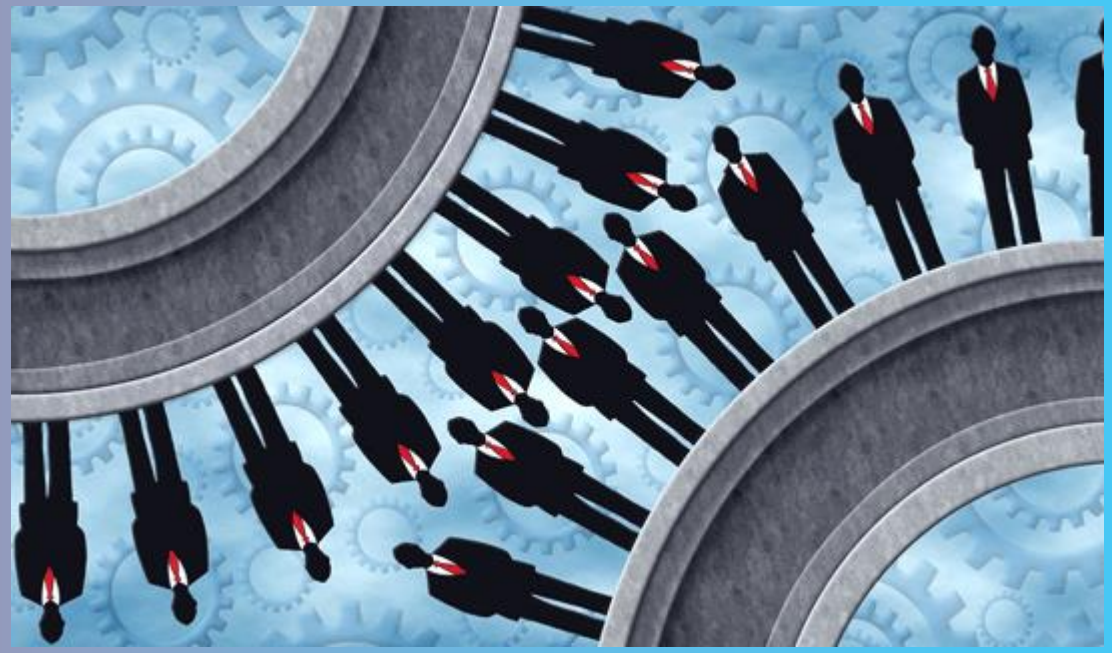
| **Vaccinated person's details** | | | | | | |
|---|---|---|---|---|---|---|
| **Personal details** | | | | | | |
| Surname: | | | First name: | | | |
| Sex: | Unknown | Date of Birth: | | **or** Age: | Years | Months |

AEFIs are notifiable conditions under the NSW Public Health Act (2010).

# What happens to your report?

# and

# Why is it important?



# AEFI process in NSW

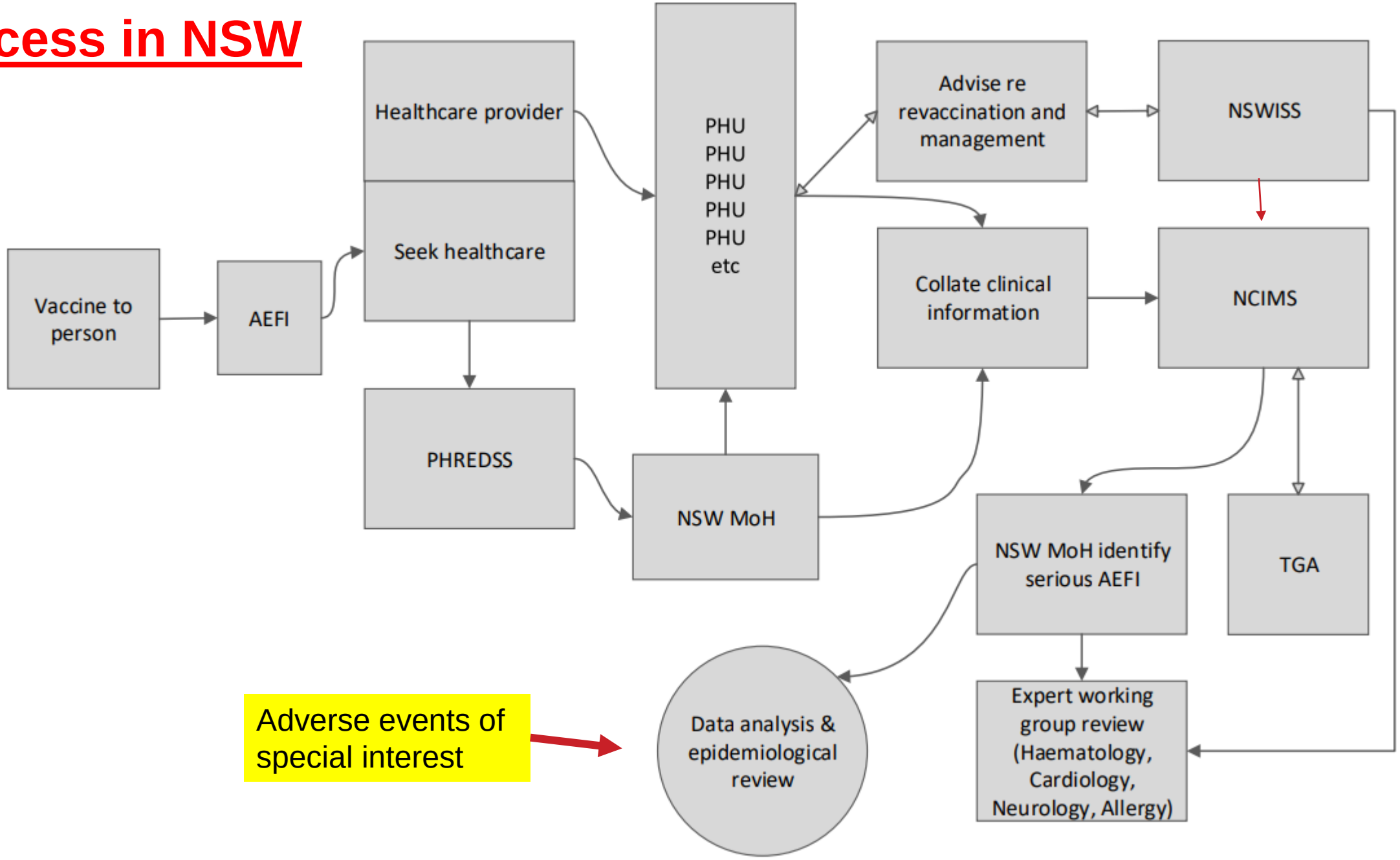
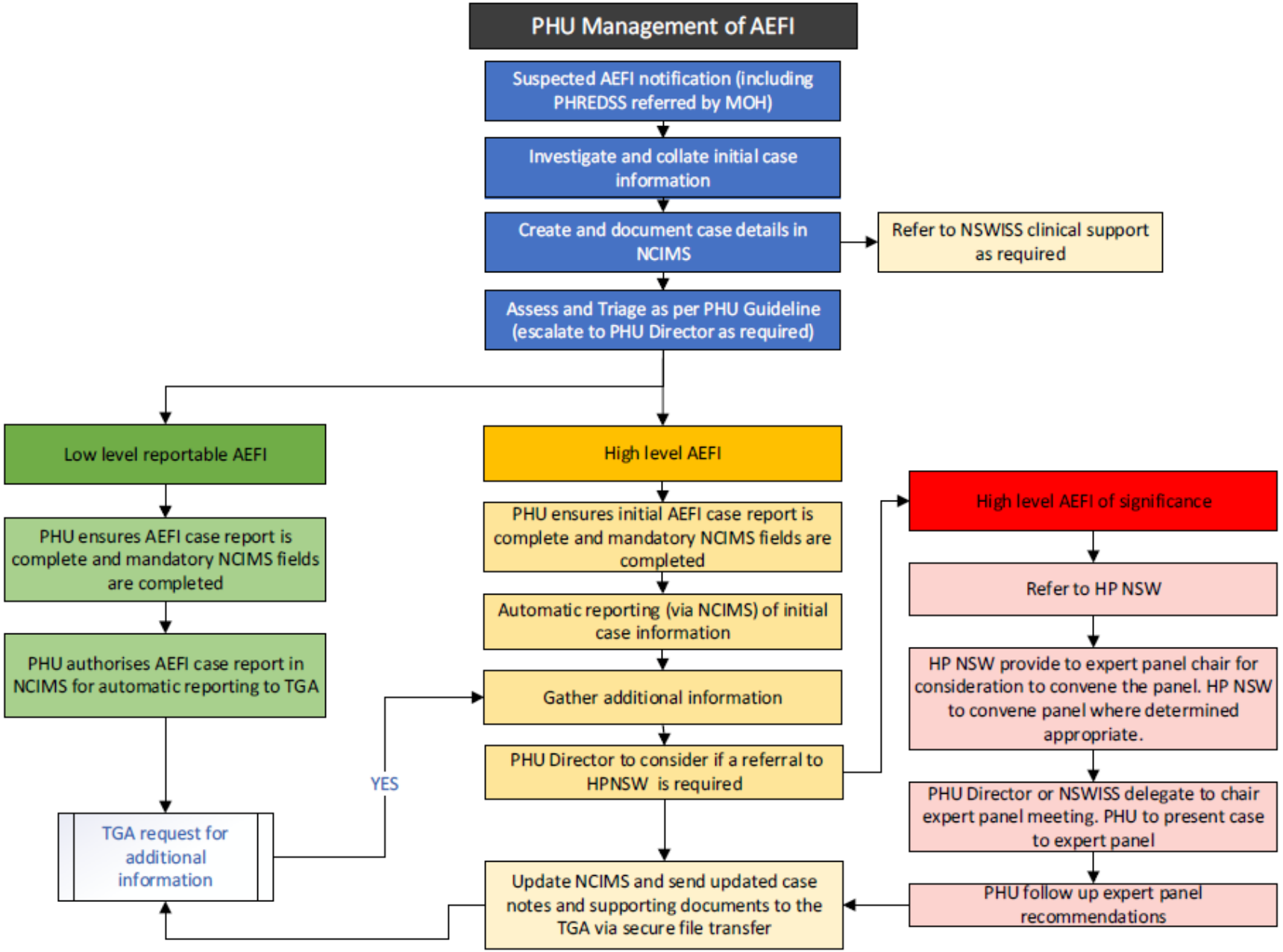
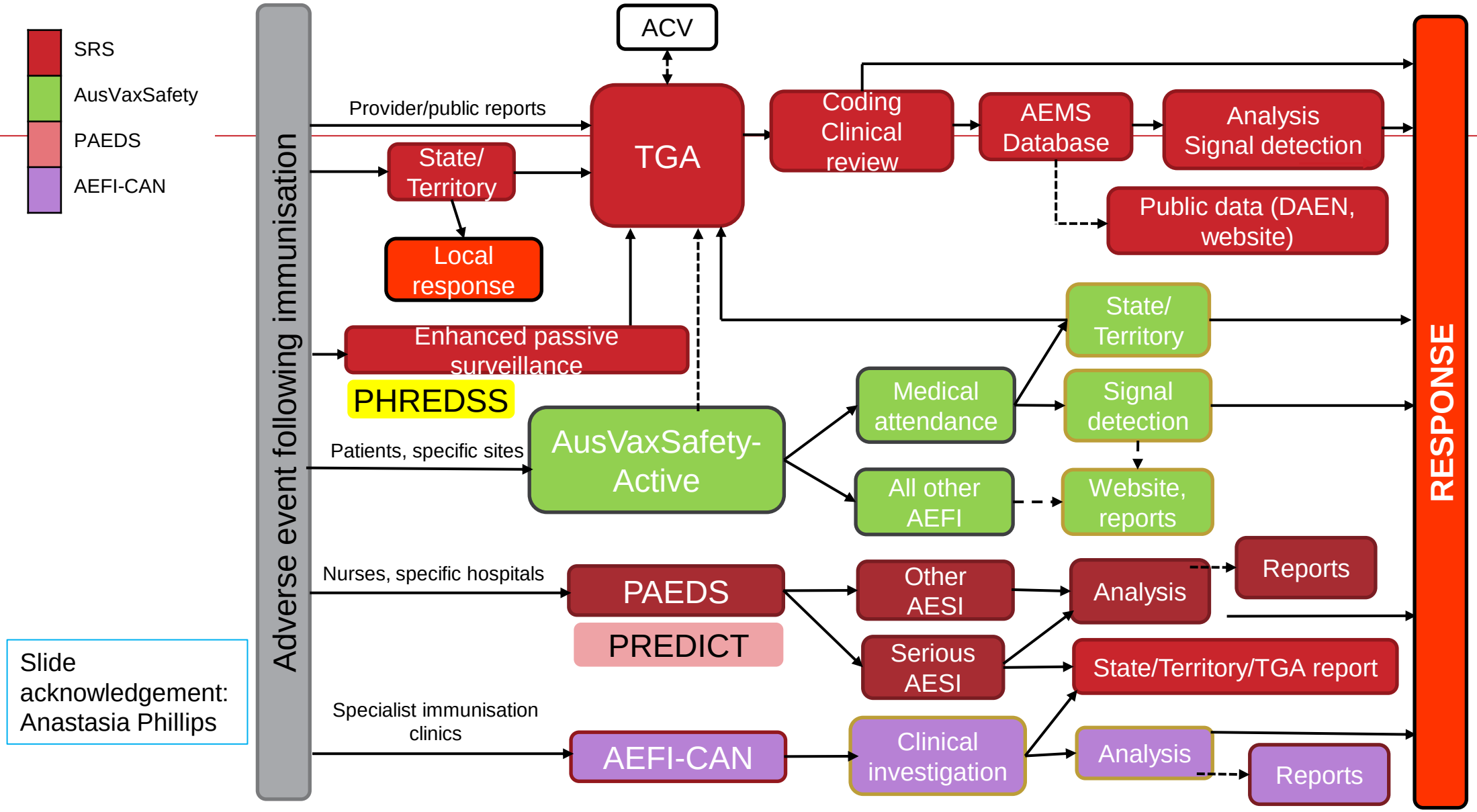


**Figure 1: PHU Management of AEFI**






**Specialist clinics**

- VicSIS
- NSWISS
- QASIS
- Stan Perron (WA)
- SASIC
- Royal Hobart
- Centenary (ACT)

Slide acknowledgement: Anastasia Phillips

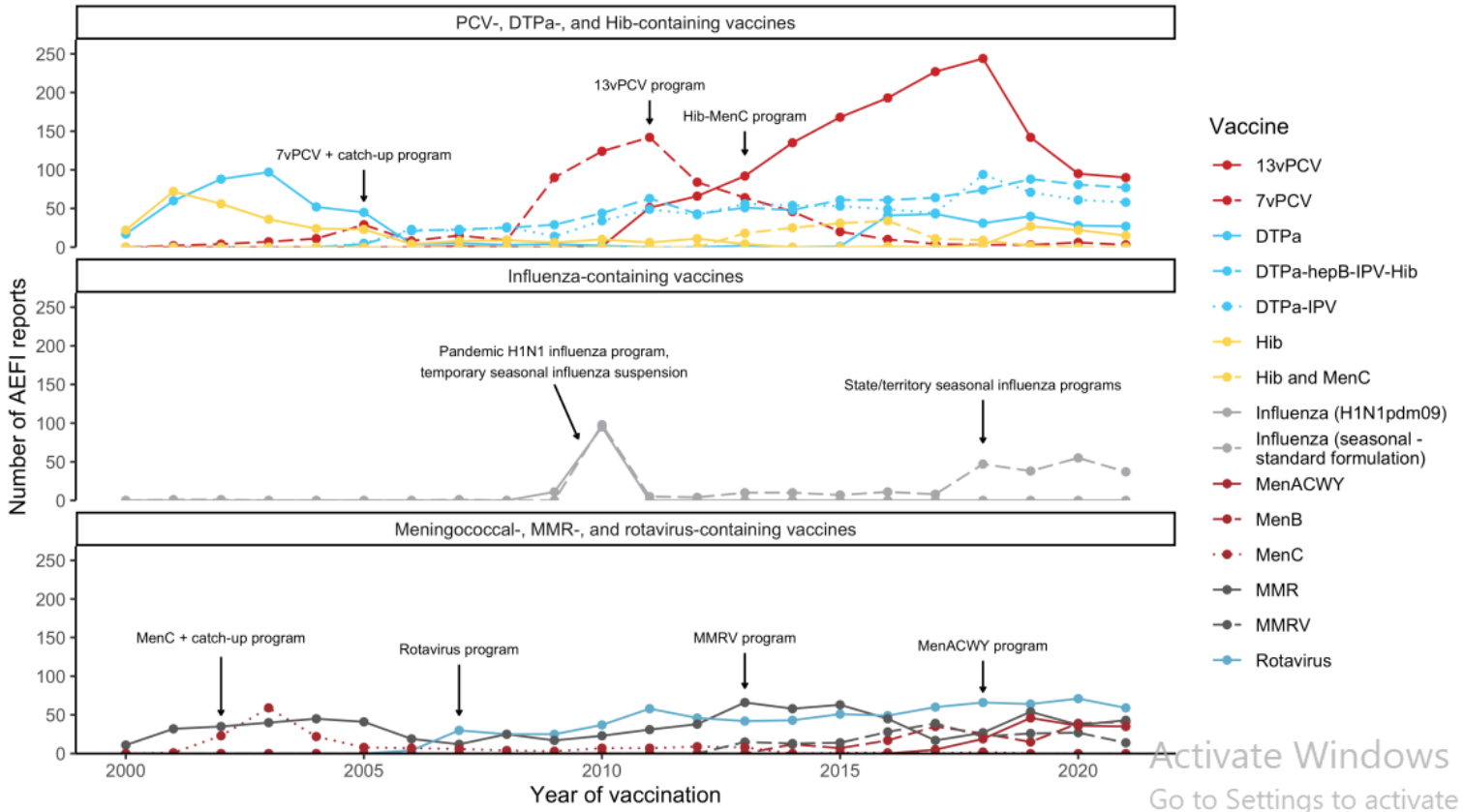
ACV – Advisory Committee on Vaccines; AEFI-CAN - Adverse Events Following Immunisation – Clinical Assessment Network; AEMS - Adverse Events Management System; PAEDS – Paediatric Active Enhanced Disease Surveillance; TGA – Therapeutic Goods Administration. Solid lines represent AEFI reporting, analysis & response; dashed lines represent communication around AEFI reports and pharmacovigilance.

https://www.ncirs.org.au/health-professionals/specialist-immunisation-services

# Surveillance over time - monitor for change

Australian Government
Department of Health and Aged Care

**Figure 2**. Adverse event following immunisation reports in NSW for children aged <7 years in the Adverse Event Management System database from 2000 to 2021 (excluding COVID-19 vaccines), by year and vaccine



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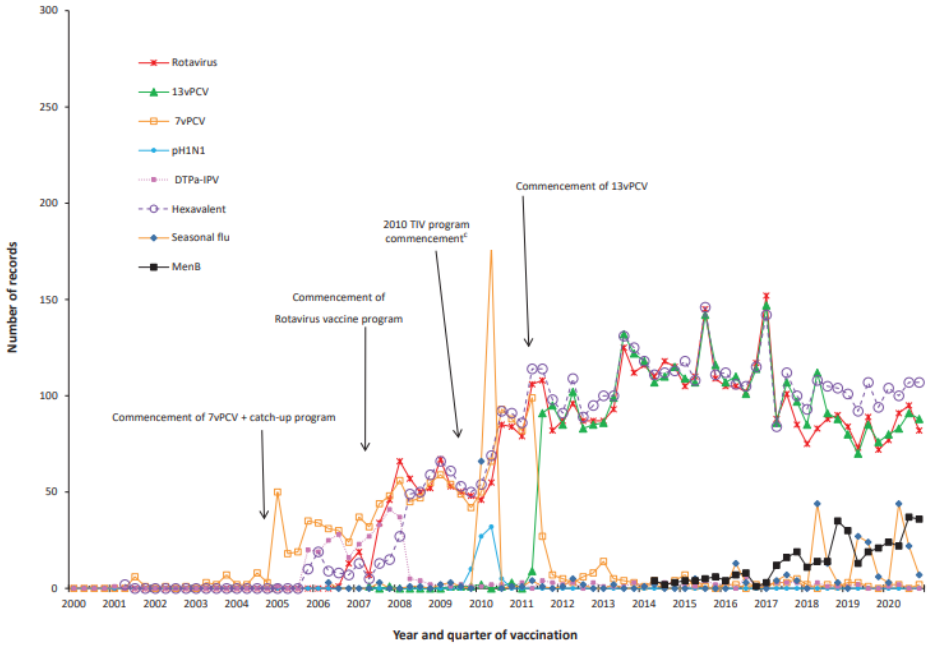
## Communicable Diseases Intelligence

### Surveillance of adverse events following immunisation in Australia annual report, 2020

Aditi Dey, Han Wang, Helen Quinn, Alexis Pillsbury, Megan Hickie, Lucy Deng, Nicholas Wood, Frank Beard, Kristine Macartney

**Figure 2: Adverse events following immunisation for children aged < 1 year, AEMS database, 2000 to 2020, by year and quarter of vaccination[a,b]**



# Flu vaccine safety surveillance in 2010


- Safety signal detected
- All influenza vaccine suspended
- Fluvax/Fluvax Jnr (CSL) 4 febrile seizure per 1000 doses!
- Specific brand taken off market for children

You have an important role in identifying and reporting adverse events of special interest

# What is an adverse event of special interest?

- Seen with “natural infection”
  - Eg COVID-19 infection can cause myocarditis
- Proven or theoretical association with immunisation in general
  - Eg anaphylaxis
- Proven or theoretical association with a vaccine platform/s
  - Eg facial nerve palsy and intranasal vaccine

| AESI Rationale to include as AESI (1, 2, 3, 4 and/or 5) | Brighton Case Definition Status |
|---|---|
| **AESI included because they are seen with COVID-19 Disease [3,4]** | |
| Acute respiratory distress syndrome | Submitted (Vaccine) |
| Multisystem inflammatory syndrome (children & adults) | Submitted (Vaccine) |
| Acute cardiovascular injury *(includes: myocarditis/pericarditis, microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease arrhythmia)* | Myocarditis/pericarditis near completion. Others not yet started |
| Coagulation disorder *(includes: thrombotic disorders, bleeding disorders)* | Thrombosis near completion; Bleeding disorder WG to be formed |
| Anosmia, ageusia | WG to be formed |
| Chilblain – like lesions | WG to be formed |
| Erythema multiforme | Not yet started |
| Single Organ Cutaneous Vasculitis | Published |
| Acute kidney injury | Published lab-based criteria (see *) |
| Acute liver injury | Published lab-based criteria (see #) |
| Acute pancreatitis NEW (Dec 2020) | Not yet started |
| Rhabdomyolysis NEW (Dec 2020) | Not yet started |
| Subacute thyroiditis NEW (Dec 2020) | Not yet started |
| **AESI included because they have a proven or theoretical association with immunization in general** | |
| Anaphylaxis [1,2] | Published |
| Thrombocytopenia [1,2,3,4] | Published |
| Generalized convulsion [1,2] | Published |
| Acute disseminated encephalomyelitis [4] | Published |
| Guillain Barré Syndrome [3,4] | Published |
| **AESI included because they have a proven or theoretical association with specific vaccine platform(s)** | |
| Acute aseptic arthritis r-VSV | Published |
| Aseptic meningitis Live vaccines | Published |
| Encephalitis / Encephalomyelitis Live vaccines | Published |
| Idiopathic Peripheral Facial Nerve Palsy Intranasal EColi Heat Labile Toxin Adjuvanted Vaccine | Published |
| Vaccine associated enhanced disease 1(Formalin inactivated measles/RSV; HIV), 2(Chimeric YF Dengue), 5 (SARS / MERS-CoVs) | In press (Vaccine) |

- AESI in COVID vaccines
- COVID-19-updated-AESI-list.pdf
- Brightoncollaboration.us

# Why look at adverse events of special interest?

- Understand risk and severity
  - Specific populations
- Causality assessment
  - Need detailed clinical information
- Longer term Outcomes

- Does AESI recur with re-vaccination?

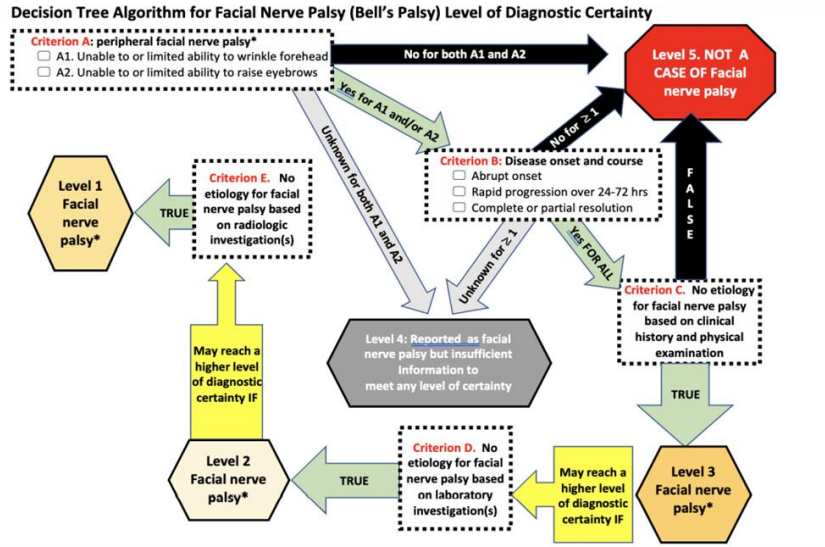
- Knowledge needed by public health, healthcare providers and most importantly the community

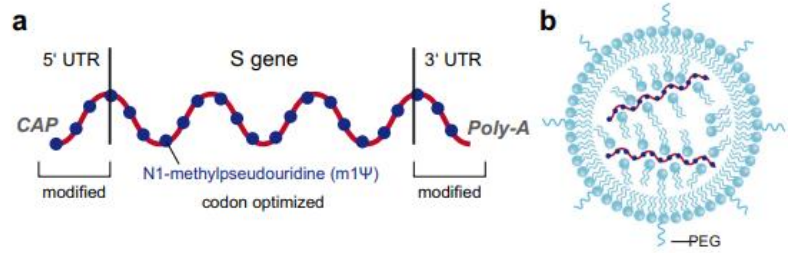
# AESI need a case definition

- Brighton, CDC, MHRA, TGA

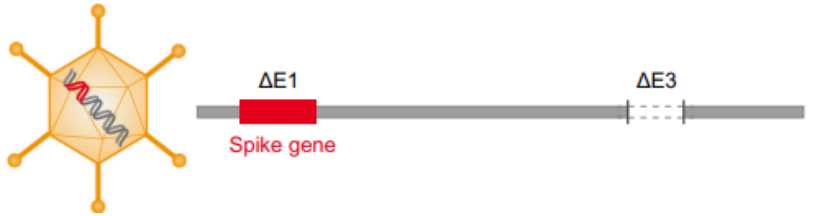
| 1. COURSE OF ILLNESS: must be able to check both 1.1 AND 1.2 to meet any level of certainty for anaphylaxis | | |
|---|---|---|
| ☐ 1.1 SUDDEN ONSET of signs & symptoms<br>*Working group defines this as "an event that occurred unexpectedly and without warning leading to a marked change in a subject's previously stable condition"* | | ☐ 1.2 RAPID PROGRESSION of signs & symptoms<br>*Working group did not define this and further noted that "Using an arbitrarily restrictive setpoint might bias future data collection unnecessarily." Accordingly, it is open to judgement.* |
| **2. ≥ 2 body systems involved: check all symptoms/signs present by checking appropriate boxes in rows below. Ideally these should be documented in writing (E.G. AEFI report, clinical record in immunization clinic, Emergency room, or other clinical setting. Alternatively, a verbal report from a professional (R.N., M.D, Pharmacist) who witnessed the event.** | | |
| **Body System** | **B. MAJOR CRITERIA** | **C. MINOR CRITERIA** |
| SKIN<br>**excluding hereditary angioedema* | ☐ Generalized urticaria (hives)<br>☐ Generalized erythema<br>☐ Angioedema* (general or localized including lip)<br>☐ Generalized pruritus WITH skin rash | ☐ Localized injection site urticaria<br>☐ Red AND itchy eyes<br>☐ Generalized prickle sensation<br>☐ Generalized pruritus WITHOUT skin rash |
| RESPIRATORY (RESP) | ☐ Bilateral wheeze (bronchospasm; by stethoscope)<br>☐ Stridor<br>☐ Upper airway swelling (tongue, throat, uvula, larynx)<br>☐ ≥ 2 indicators of respiratory distress:<br>○ Tachypnea<br>○ Cyanosis<br>○ Grunting<br>○ Chest wall retractions<br>○ Increased use of accessory respiratory muscles | ☐ Persistent dry cough<br>☐ Hoarse voice<br>☐ Sensation of throat closure<br>☐ Sneezing OR rhinorrhea<br>☐ Difficulty breathing WITHOUT wheeze or stridor |
| CARDIO-VASCULAR (CV) | ☐ Measured hypotension<br>☐ ≥ 3 signs of uncompensated shock:<br>○ Tachycardia<br>○ Capillary refill >3 seconds<br>○ Reduced central pulse volume<br>○ Decreased level or loss of consciousness | ☐ ≥ 2 signs of reduced peripheral circulation<br>○ Tachycardia<br>○ Capillary refill >3 seconds<br>○ Decreased level of consciousness |
| GASTRO-INTESTINAL (GI) | NONE | ☐ Nausea ☐ Vomiting<br>☐ Abdominal pain ☐ Diarrhea |
| LABORATORY | NONE | ☐ Elevated mast cell tryptase (> upper normal limit for laboratory doing test) |

- Anaphylaxis
- Bells palsy
- GBS
- Myocarditis
- Thrombosis and Thrombocytopenia syndrome

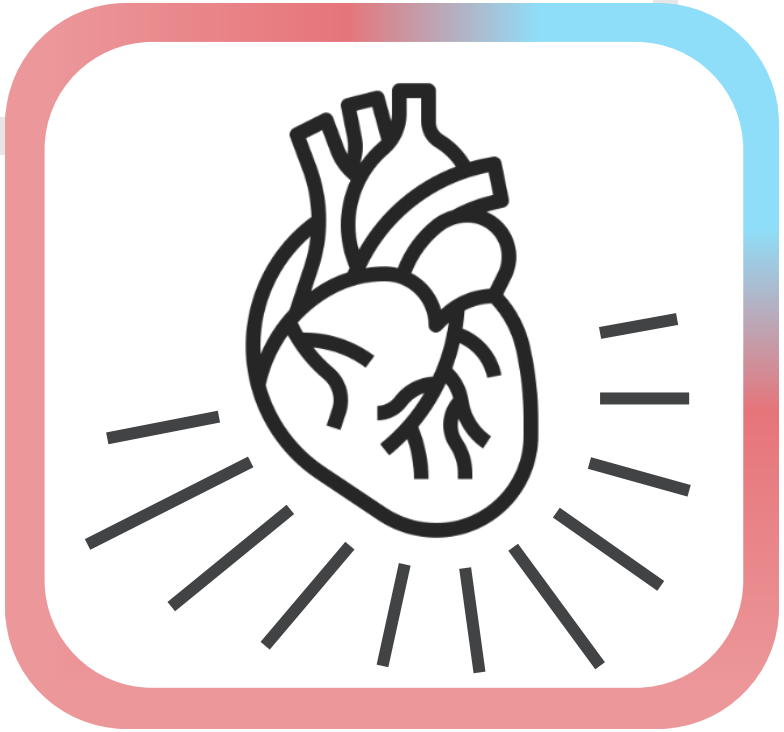




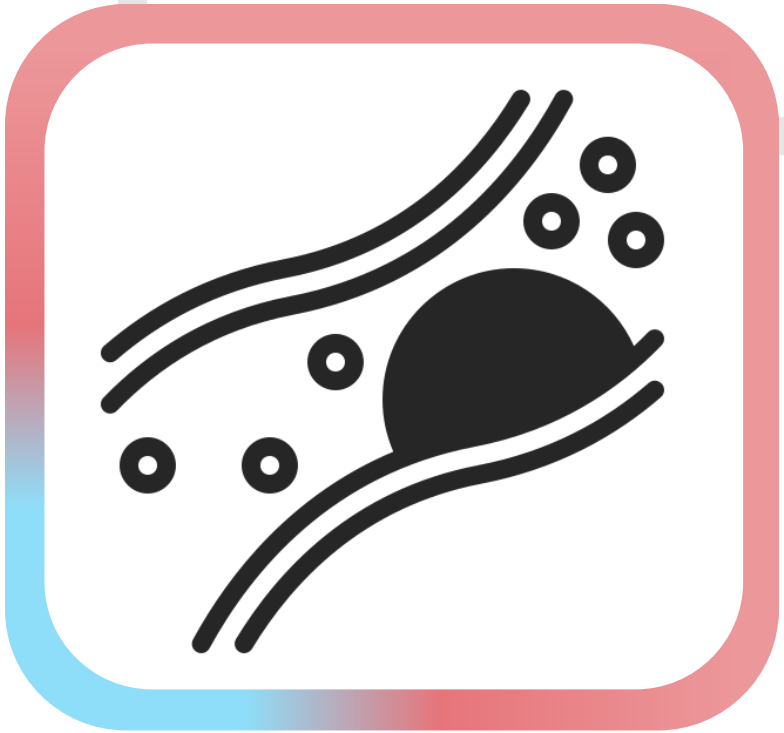

## mRNA vaccines




## Adenoviral vector vaccines



## Myocarditis

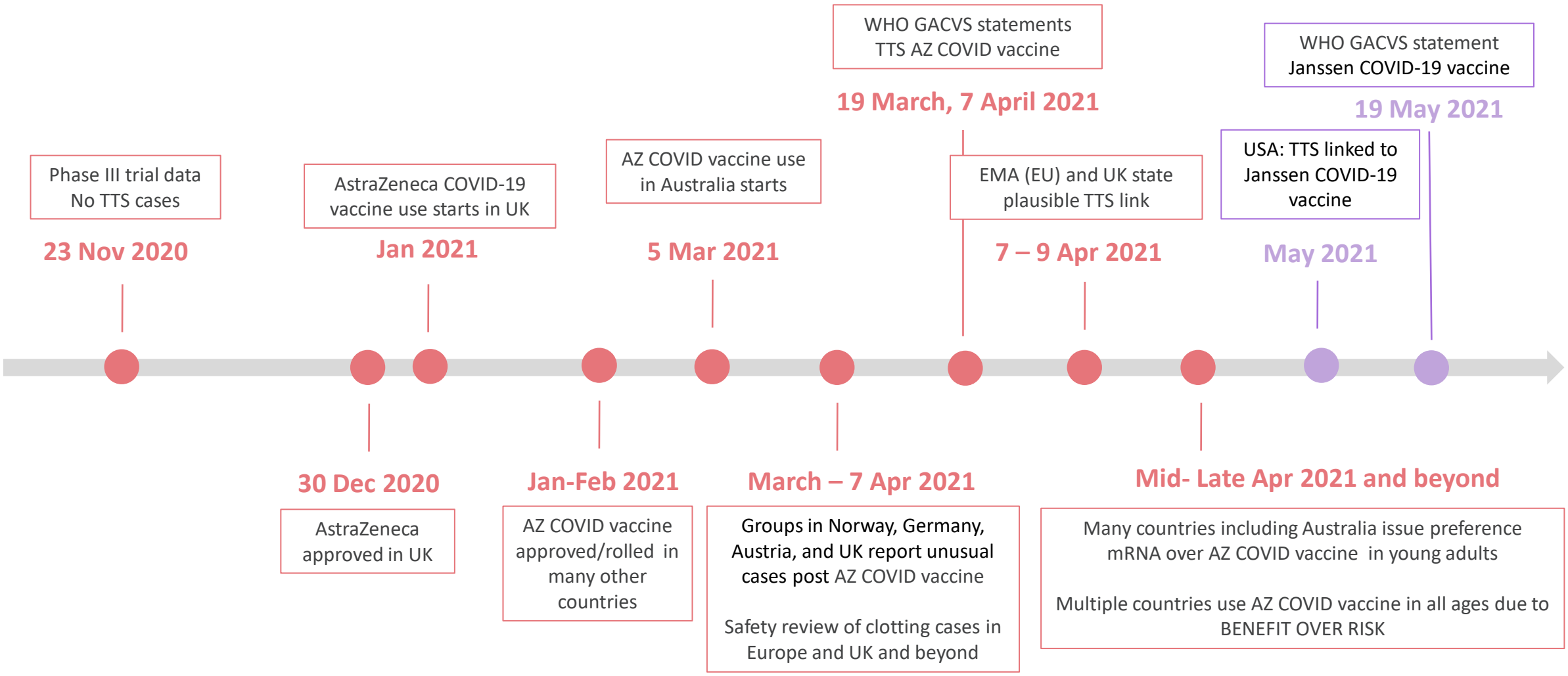


## Thrombosis with Thrombocytopenia Syndrome TTS

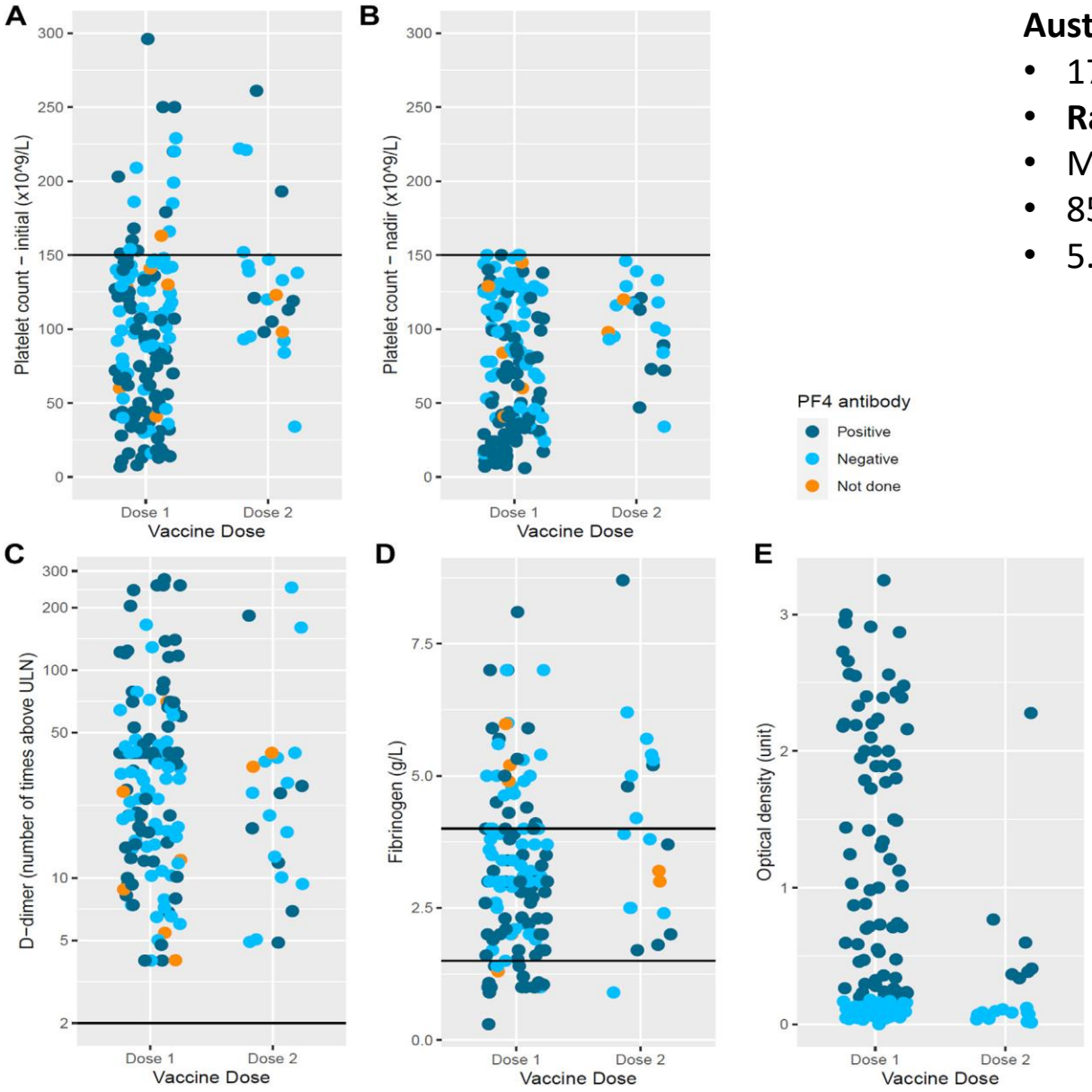


npj Vaccines (2021) 6:104 ; https://doi.org/10.1038/s41541-021-00369-6

# Early timeline: emergence and recognition of TTS/VITT

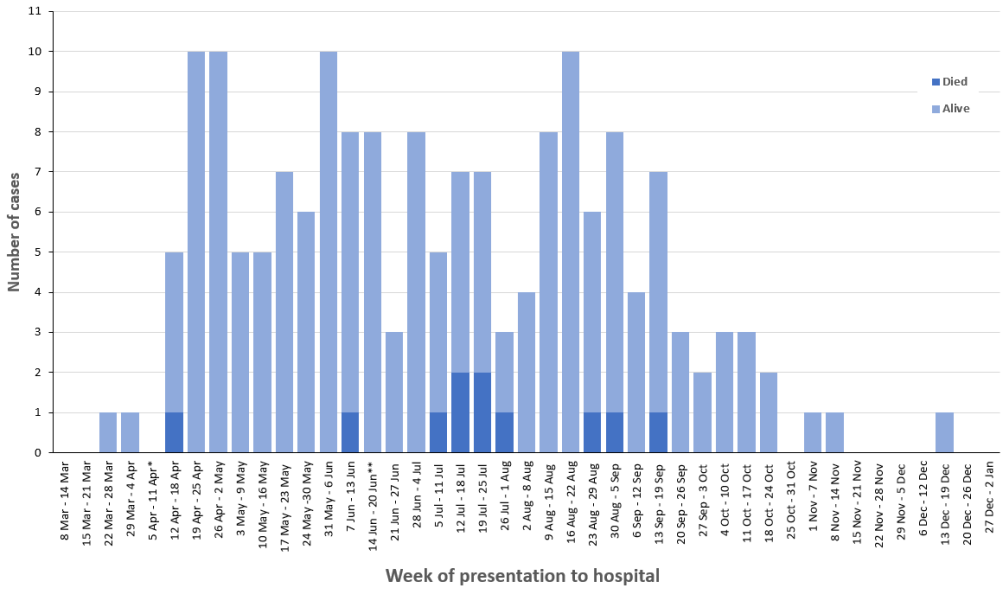


# Active TTS case finding in Australia




**Australia -** ChAdOx1-S

- 170 TTS cases - 87% after the first dose
- **Rates: 2.1 per 100,000 dose 1 and 0.34 post dose 2**
- Median age 66 years (IQR 55–74) [90% of 60+ had AZ vaccine in Aus]
- 85% discharged home (median LOS 6 days), 9.4% rehabilitation
- 5.3% died (8/9 from TTS)



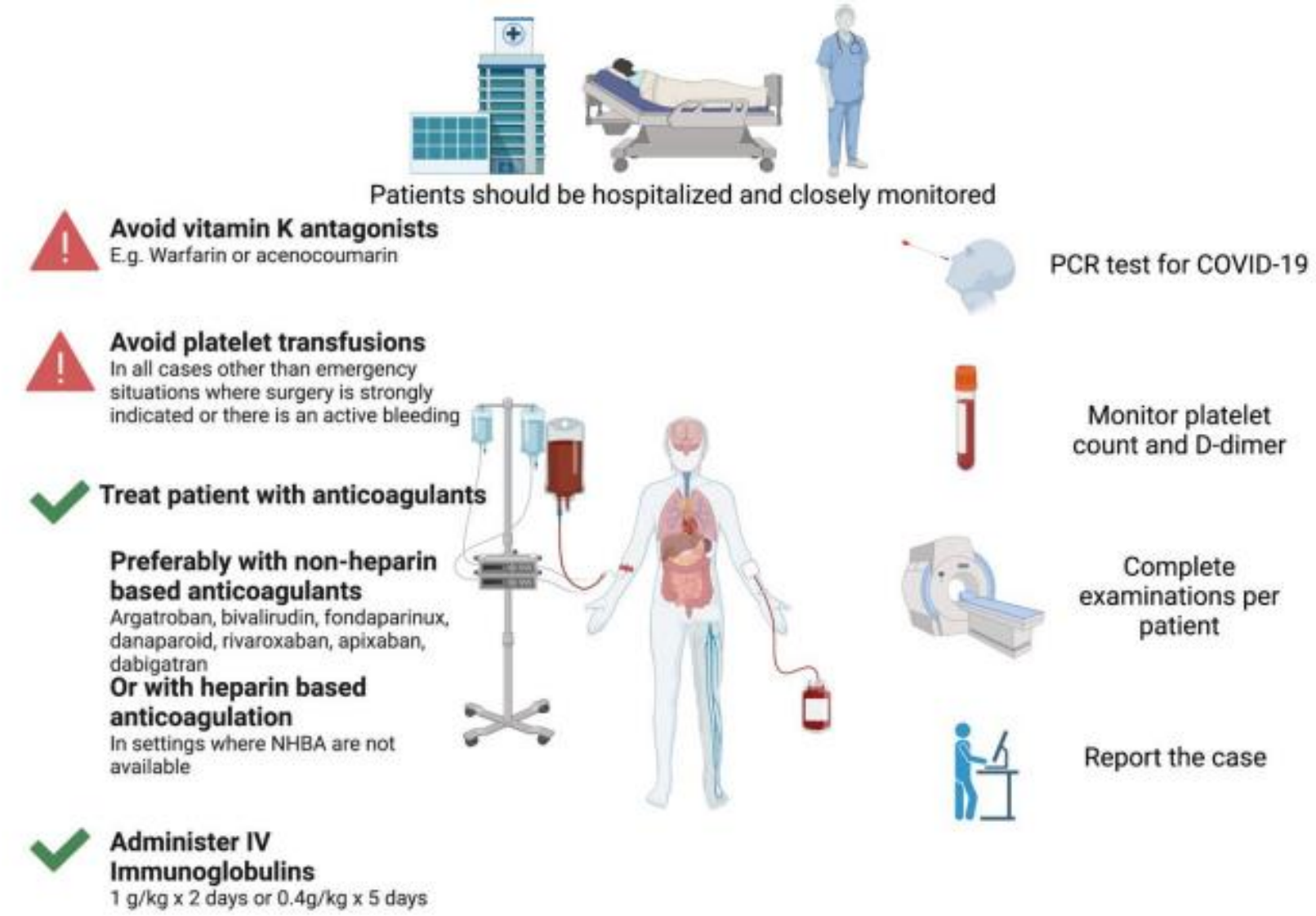

Tran et al, Lancet WP 2023 https://doi.org/10.1016/j.lanwpc.2023.100894;

# Select policy responses: TTS / VITT and viral vector vaccines

| Country (Organisation) | Initial policy / program response | | Subsequent preferential recommendation to mitigate TTS* | |
|---|---|---|---|---|
| | Age group | Details | Age group | Details |
| Australia (ATAGI) | <50 years | Comirnaty preferred over Vaxzevria | <60 years | Comirnaty preferred over Vaxzevria |
| Canada (NACI) | <55 years | **Suspension** of Vaxzevria | ≥30 years | Vaxzevria and Janssen can be used "if the individual prefers an earlier vaccine rather than wait for an mRNA vaccine" |
| Denmark (SST) | All | **Discontinuation** of Vaxzevria program | | |
| Germany (PEI & STIKO) | All | **Suspension** of Vaxzevria for 15 days (15 March – 30 March 2021) | <60 years | Vaxzevria "not to be primarily used" in this age group – at physician discretion only |
| Norway (NIPH) | All | **Discontinuation** of Vaxzevria program | | |
| Spain (Ministerio de Sanidad) | All | **Suspension** of Vaxzevria for 8 days (16 March – 24 March 2021; Janssen program commenced in April) | 60-69 years | Vaxzevria restricted to this age group |
| | | | ≥40 years | Janssen recommended for this age group only (rollout later 2021) |
| Sweden (Fohm) | <65 years | **Suspension** of Vaxzevria program (And cancellation of Janssen program rollout for all ages) | | |
| UK (JCVI) | <30 years | Alternative vaccine to Vaxzevria preferred in those without risk factors for severe disease | <40 years | Alternative vaccine to Vaxzevria preferred in those without risk factors for severe disease |
| US (ACIP & FDA) | All | **Suspension** of Janssen for 10 days (13 April – 23 April 2021) | ≥18 years | mRNA vaccines preferred over Janssen |

*There may be preferential recommendations for other purposes - this is not included in this table.

# How best to manage TTS cases
# Description of cases = informs treatment guidelines



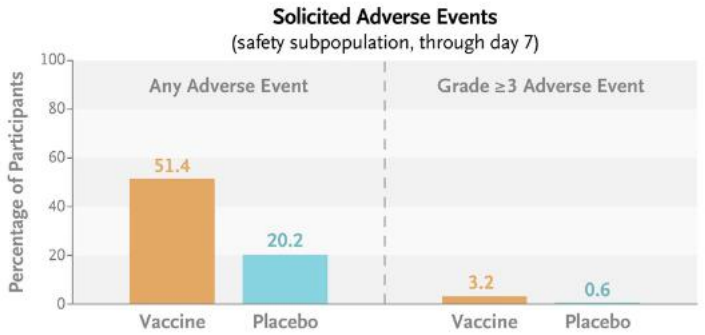

WHO Guide on TTS

# Future directions and Questions?
# TTS and Adenoviral vector vaccines

To answer these questions we need the cases?

- Risk with same vaccine doses repeated?
  - Risk in previously infected v infection naiive?
- Relationship with other causally linked events from same platform/s
  - eg other haematologic, GBS?, myopericarditis?
- Biologic mechanism
- Future adenovirus vectored vaccine pipeline?
  - eg RSV Adv26 vaccine effective but development ceased

**Ad26.RSV.preF–RSV preF protein vaccine in older adults**




Falsey A, et al N Engl J Med 2023;388:609-20

# Myocarditis and pericarditis

# Myocarditis reports to TGA

**Table 1. Reports of suspected myocarditis and pericarditis received by the TGA to 7 August 2022¥**

| | | Comirnaty (Pfizer) (43.4 million doses given) | | Spikevax (Moderna) (5.2 million doses given) | |
|---|---|---|---|---|---|
| | | All cases | Cases in adolescents (12-17 years) | All cases | Cases in adolescents (12-17 years) |
| **Suspected myocarditis cases*** | | **1,380** | **223** | **192** | **32** |
| Likely myocarditis†‡ | Level 1 | 49 | 8 | 2 | 0 |
| | Level 2 | 479 | 143 | 86 | 22 |
| | Level 3 | 137 | 11 | 16 | 3 |

# VAERS reporting rates of myocarditis (per 1 million doses administered) after mRNA COVID-19 vaccination, days 0–7 and 8–21 post-vaccination*,†

| | | 0–7 days | | | 8–21 days | | | 0–7 days | | | 8–21 days | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Males | | | Males | | | Females | | | Females | | |
| | Age (yrs) | Dose 1 | Dose 2 | Booster | Dose 1 | Dose 2 | Booster | Dose 1 | Dose 2 | Booster | Dose 1 | Dose 2 | Booster |
| Pfizer-BioNTech | 5–11 | 0.2 | 2.6 | 0.0 | 0.6 | 0.0 | 0.0 | 0.2 | 0.7 | 0.0 | 0.2 | 0.0 | 0.0 |
| | 12–15 | 5.3 | 46.4 | 15.3 | 1.2 | 1.2 | 0.9 | 0.7 | 4.1 | 0.0 | 0.4 | 0.2 | 0.9 |
| | 16–17 | 7.2 | 75.9 | 24.1 | 1.7 | 3.2 | 1.3 | 0.0 | 7.5 | 0.0 | 0.7 | 0.4 | 0.0 |
| Pfizer-BioNTech and Moderna | **18–24** | **4.2** | **38.9** | **9.9** | **1.1** | **2.2** | **0.4** | **0.6** | **4.0** | **0.6** | **0.2** | **0.7** | **0.0** |
| | **25–29** | **1.8** | **15.2** | **4.8** | **0.4** | **1.1** | **0.5** | **0.4** | **3.5** | **2.0** | **0.2** | **0.0** | **0.8** |
| | **30–39** | **1.9** | **7.5** | **1.8** | **0.4** | **0.8** | **0.2** | **0.6** | **0.9** | **0.6** | **0.3** | **0.2** | **0.0** |
| | **40–49** | **0.5** | **3.3** | **0.4** | **0.2** | **0.5** | **0.0** | **0.4** | **1.6** | **0.6** | **0.2** | **0.2** | **0.0** |
| | **50–64** | **0.5** | **0.7** | **0.4** | **0.2** | **0.3** | **0.1** | **0.6** | **0.5** | **0.1** | **0.2** | **0.5** | **0.1** |
| | **65+** | **0.2** | **0.3** | **0.6** | **0.3** | **0.2** | **0.1** | **0.1** | **0.5** | **0.1** | **0.1** | **0.2** | **0.1** |

* As of May 26, 2022; reports verified to meet case definition by

† An estimated 1–10 cases of myocarditis per 100,000 person ye
and 8–21 risk intervals, this estimated background is **0.2 to 2.2 p**

**Highest rate in young males after 2nd dose of mRNA vaccine – 1 in 10000 2nd doses**
**Rate not increased with booster doses (so far)**

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-07-19/03-COVID-Shimabukuro

AusVaxSafety
An NCIRS led collaboration

*Australia's active vaccine safety system*

www.ausvaxsafety.org.au

## AusVaxSafety adverse event of special interest (AESI) follow-up program

AusVaxSafety is conducting long-term follow-up surveillance of individuals who experienced an adverse event of special interest following COVID-19 vaccination.

- Thrombosis with Thrombocytopenia Syndrome
- Myocarditis

## How it works

### Potential participants identified

Individuals that meet the program selection criteria are identified and invited to participate in AusVaxSafety follow-up program.

### Participant enrolls in follow-up program

Following consultation, individual agrees to participate and is enrolled in the relevant AESI study arm.

### Follow-up of participant begins

Participants are contacted and/or sent surveys at different time points over a period which ask questions around general health, relevant follow up investigations and psychological health.

### De-identified data are collected and analysed

Data collected from participants are de-identified and analysed by clinical specialists and epidemiologists.

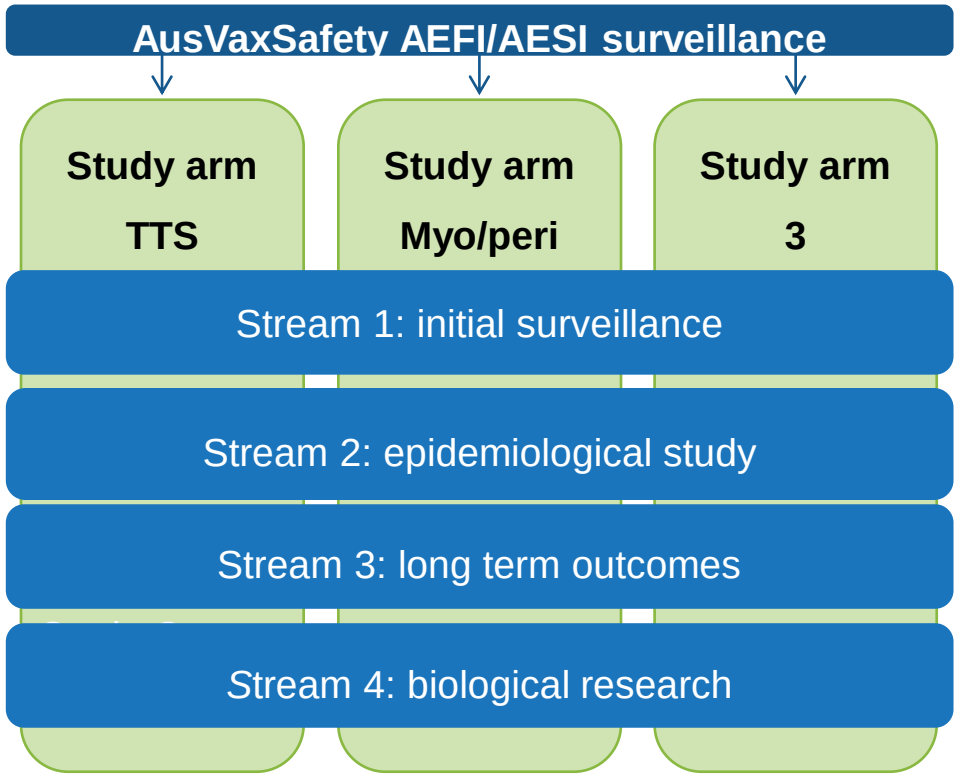
### Findings published

Results published highlighting key findings and recommendations for the future.

# Long term follow up of TTS and myocarditis cases

AusVaxSafety
An NCIRS led collaboration

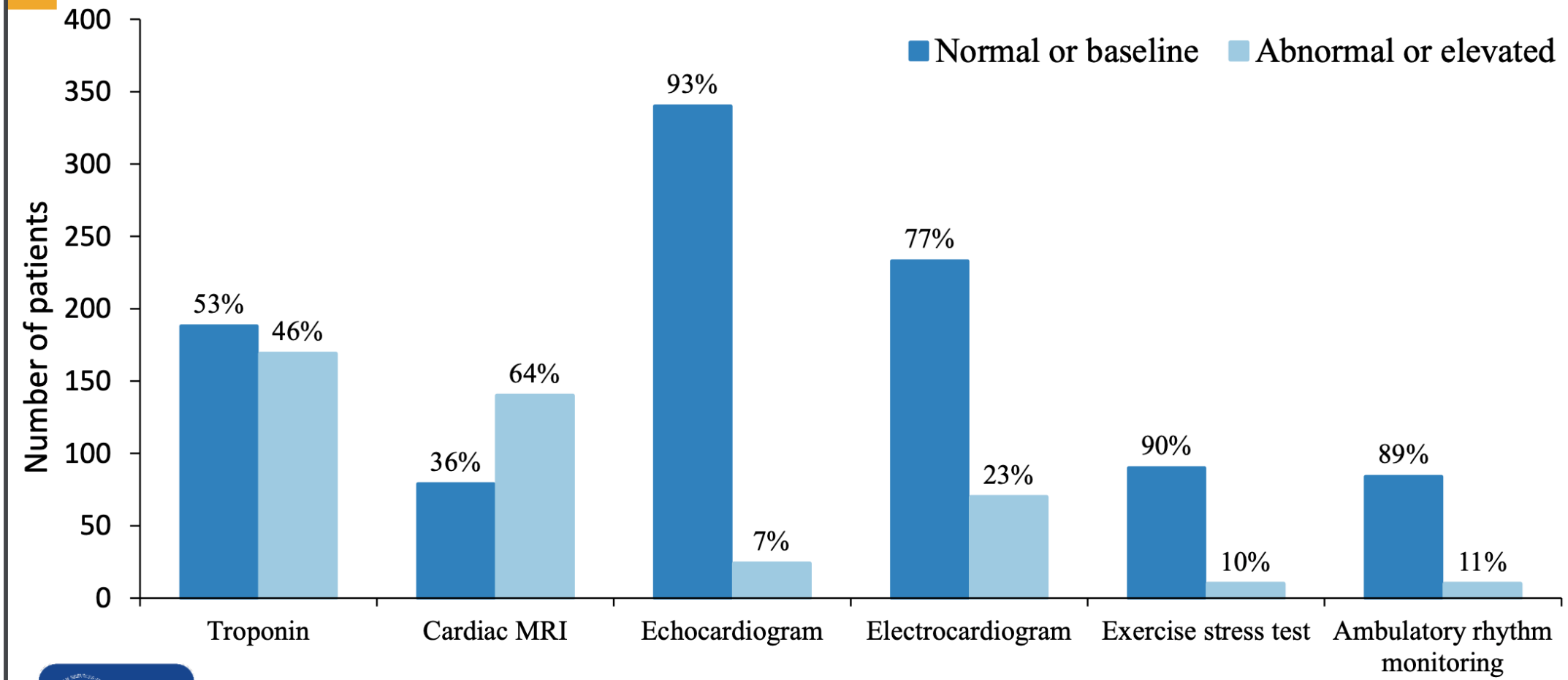
- A collaboration with
  - State/territory health departments
  - TGA
  - THANZ
  - CSANZ
- National ethics umbrella
- Long term clinical and health outcomes
- Biological samples




**NSW**
TTS n= 79 cases
Myocarditis n=144 cases

Both conditions under follow up

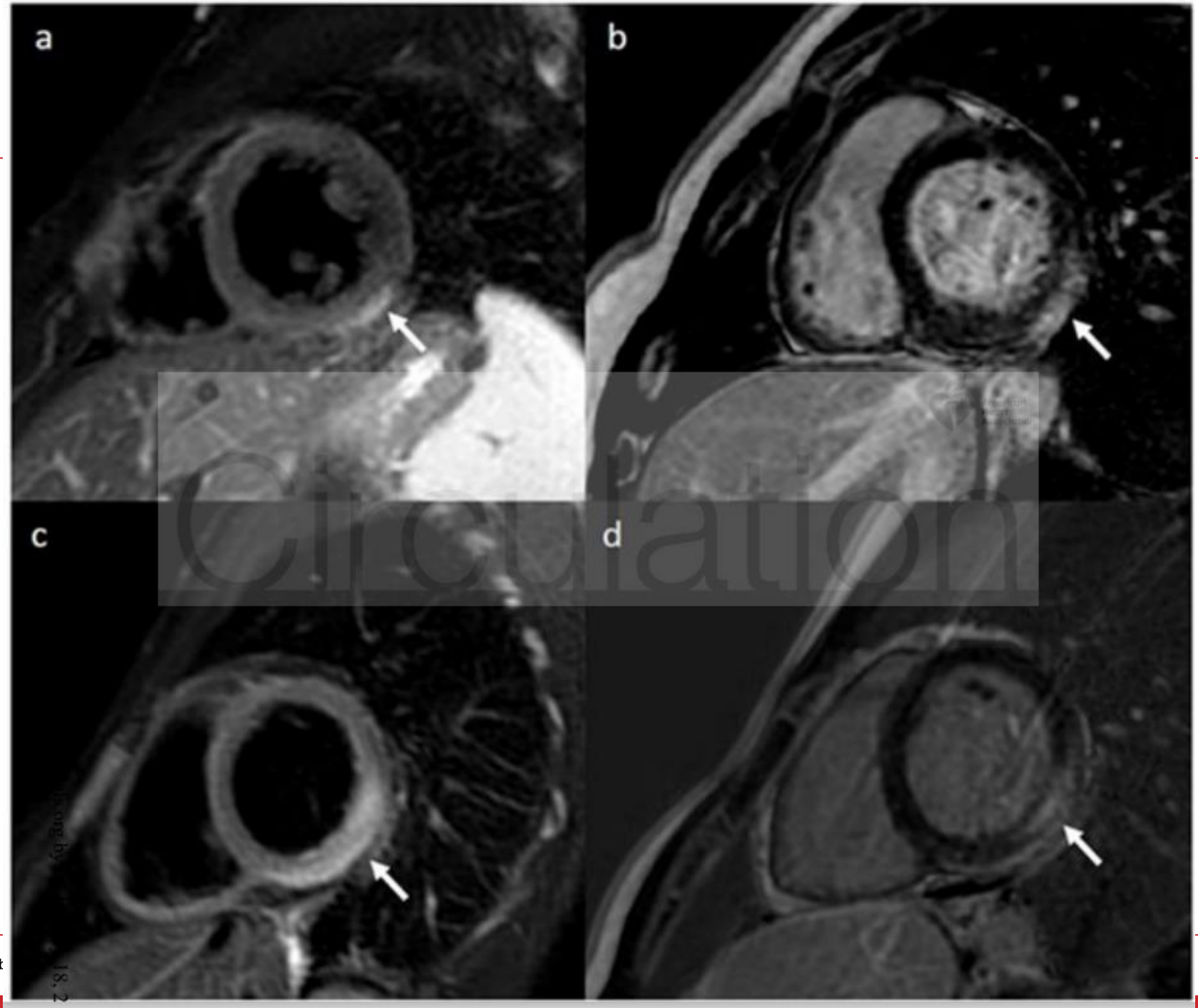
# Results of the most recent cardiac function test (n=380)








Kracalik - https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf



# Adrenaline: to give or not to give?!

## A tale of COVID-19 vaccination anaphylaxis cases in NSW

Collaboration with NCIRS and NSW MoH staff

Kathryn Tapper
Lucy Deng

NCIRS National Centre for Immunisation Research and Surveillance

THE UNIVERSITY OF SYDNEY

# Brighton levels by vaccine brand and dose number

| Characteristic | Overall, N = 222[1] | AZ Dose 1, N = 59[1] | AZ Dose 2, N = 9[1] | Moderna Dose 1, N = 2[1] | Pfizer Dose 1, N = 100[1] | Pfizer Dose 2, N = 52[1] |
|---|---|---|---|---|---|---|
| **BCCD** | | | | | | |
| Level 1 | 32 (14%) | 8 (14%) | 2 (22%) | 0 (0%) | 12 (12%) | 10 (19%) |
| Level 2 | 59 (27%) | 12 (20%) | 1 (11%) | 1 (50%) | 33 (33%) | 12 (23%) |
| Level 3 | 2 (0.9%) | 0 (0%) | 0 (0%) | 0 (0%) | 1 (1.0%) | 1 (1.9%) |
| Level 4 | 97 (44%) | 26 (44%) | 6 (67%) | 0 (0%) | 42 (42%) | 23 (44%) |
| Level 5 | 32 (14%) | 13 (22%) | 0 (0%) | 1 (50%) | 12 (12%) | 6 (12%) |

[1] n (%)

**42% were level 1, 2 or 3**

**Many cases = anxiety related response**

**58% = unlikely anaphylaxis**

# Revaccination outcomes by initial vaccine brand

| Characteristic | Overall, N = 222[1] | AstraZeneca, N = 68[1] | Moderna, N = 2[1] | Pfizer, N = 152[1] |
|---|---|---|---|---|
| **Further vaccination** | 176 (79%) | 61 (90%) | 2 (100%) | 113 (74%) |
| **Revaccination vaccine brand** | | | | |
| Astrazeneca | 61 (35%) | 21 (34%) | 0 (0%) | 40 (35%) |
| Moderna | 12 (6.8%) | 3 (4.9%) | 2 (100%) | 7 (6.2%) |
| Pfizer | 103 (59%) | 37 (61%) | 0 (0%) | 66 (58%) |
| **Revaccination AEFI** | 14 (8.2%) | 3 (4.9%) | 0 (0%) | 11 (10%) |

- **<u>Recurrence of anaphylaxis = rare</u>**
  - Only 4 cases had a recurrence of anaphylaxis (BCCD Level 2)
- The remaining 10 cases were classified as either BCCD Level 4 or 5

# Bell's palsy following COVID-19 immunisation in NSW: Clinical profile and revaccination outcomes

Acknowledgements
Dr Emma Goeman
Staff Specialist in Immunisation
NSW Immunisation Specialist Service

Investigators:
NCIRS – Emma Goeman, Deepali Thosar, Kathryn Tapper, Lucy Deng, Nicholas Wood
NSW Ministry of Health: Sarah Khanlari, Isis Maitland-Scott, Louise Baker

NCIRS National Centre for Immunisation Research and Surveillance

THE UNIVERSITY OF SYDNEY

# Results

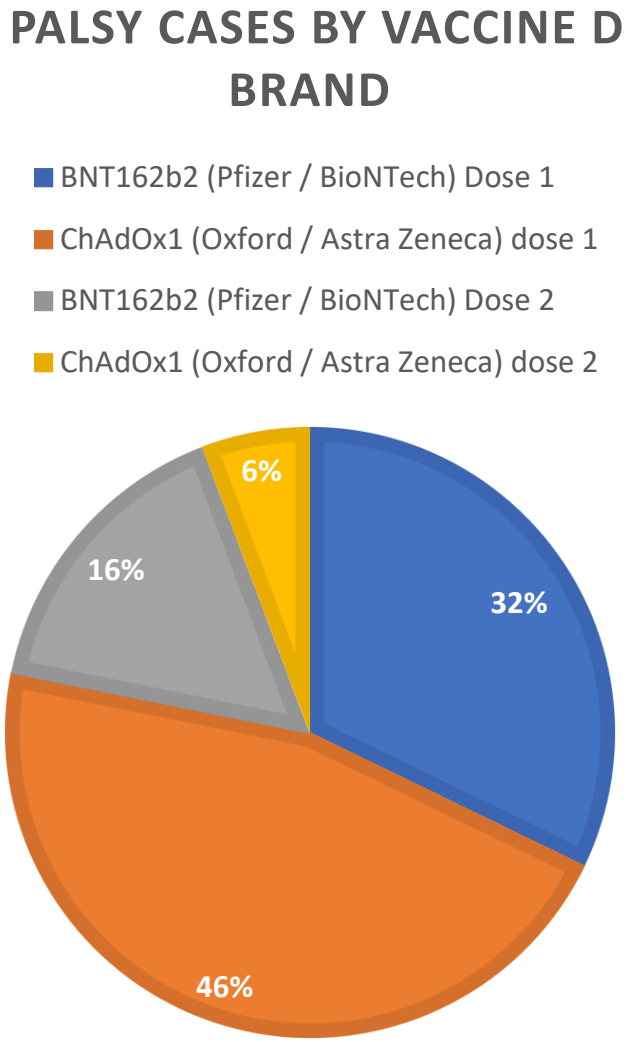
87 reported cases
02/2021 – 01/2022

68 cases (78.2%) after dose 1

19 cases (21.8) after dose 2

Age:13 to 79 years
(median 48; IQR 37 – 64 years)

Females 46%; males 54%




**Clinical information, Brighton classifications and results of telephone follow up to be provided in live talk at CDIC.**

# Results - Revaccination

## Bell's palsy after dose 1

**60/68 (88%) had a subsequent dose of a COVID-19 vaccine**

**37/60 (61.7%) had same vaccine**
**23/60 (38.3%) switched platforms**

## Bell's palsy after dose 2

**11/19 (57.9%) had a subsequent dose of a COVID-19 vaccine**

**6/11 (54%) switched platforms (NB booster)**

**Overall revaccination rate = 81.6% (71/87)**

AIR and NCIMS follow up period at least until dose 3, or minimum 6 months post onset of Bell's palsy.

**Only 1 of 71 (1.4%) revaccinated patients had a subsequent AEFI report in NCIMS**



**Clinical information, Brighton classifications and results of telephone follow up to be provided in live talk at CDIC.**

# Rare genetic abnormality and MMR adverse event

Australian Government
Department of Health

ATAGI
Australian Technical Advisory Group on Immunisation

## IFNAR1 Deficiency and Serious Adverse Events Following Immunisation

22 April 2022
Version 1

### Summary

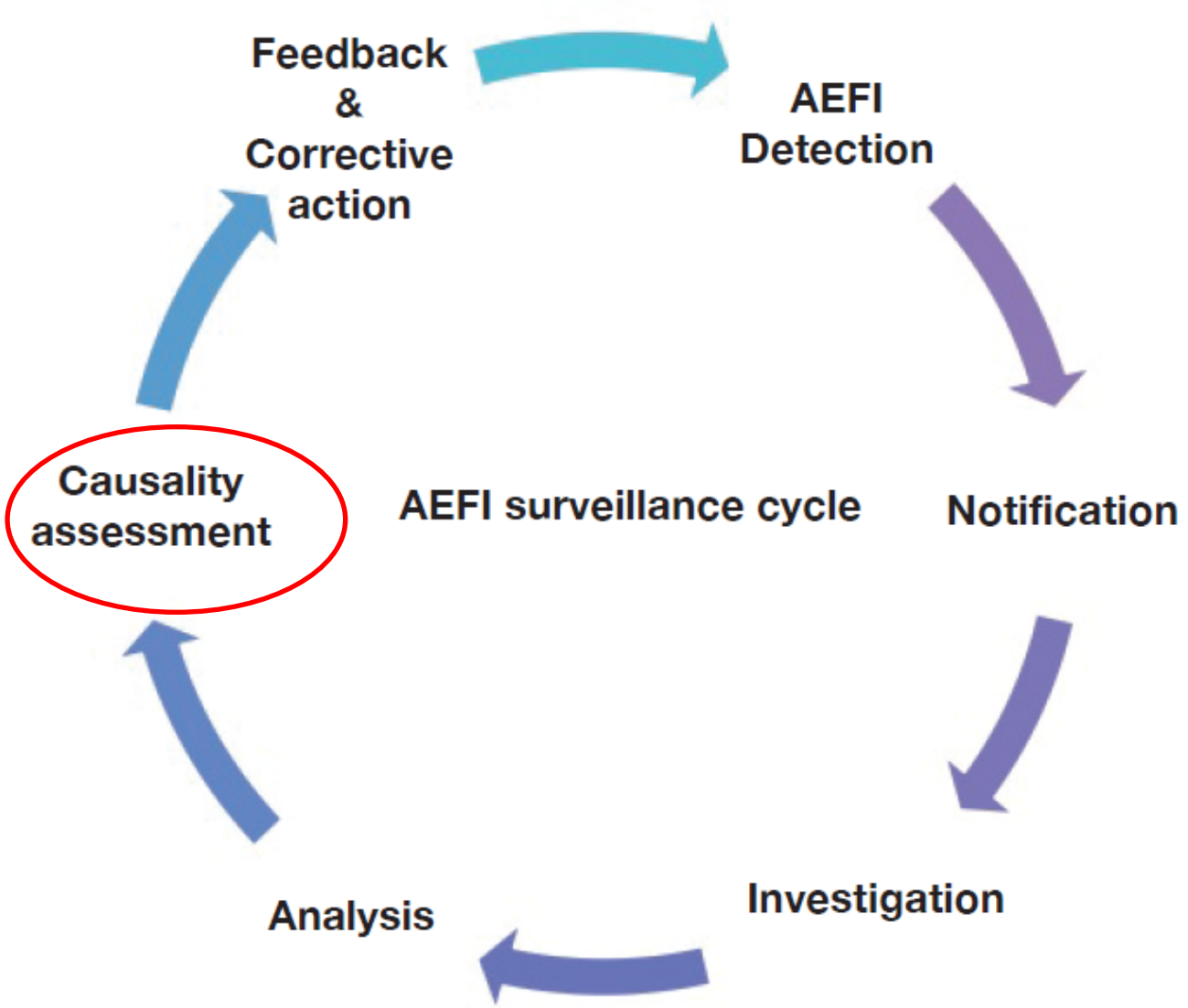

- Measles is an important vaccine preventable disease and, due to high vaccine coverage, is currently only seen in Australia in the setting of outbreaks and sporadic imported cases. The disease can be more severe in individuals that are immunocompromised.
- IFNAR1 deficiency is a rare inherited condition affecting some people in Australia of Western Polynesian heritage including Tongan, Samoan, and Niuean.[1]
- It is associated with severe illness and death from certain viral infections and also potentially from live-attenuated virus vaccines, mainly the measles, mumps, and rubella (MMR) vaccine.
- Currently, the diagnosis of IFNAR1 deficiency prior to vaccination is challenging.
- ATAGI recommends that all people in Australia, including people of Tongan, Samoan, and Niuean heritage, continue to receive the MMR vaccine given that illness from measles and mumps infections is more severe in unvaccinated individuals, including those with undiagnosed IFNAR1 deficiency. Ongoing work to assist in the early identification of individuals affected by this rare disorder is needed.

# Challenges with AESI reporting

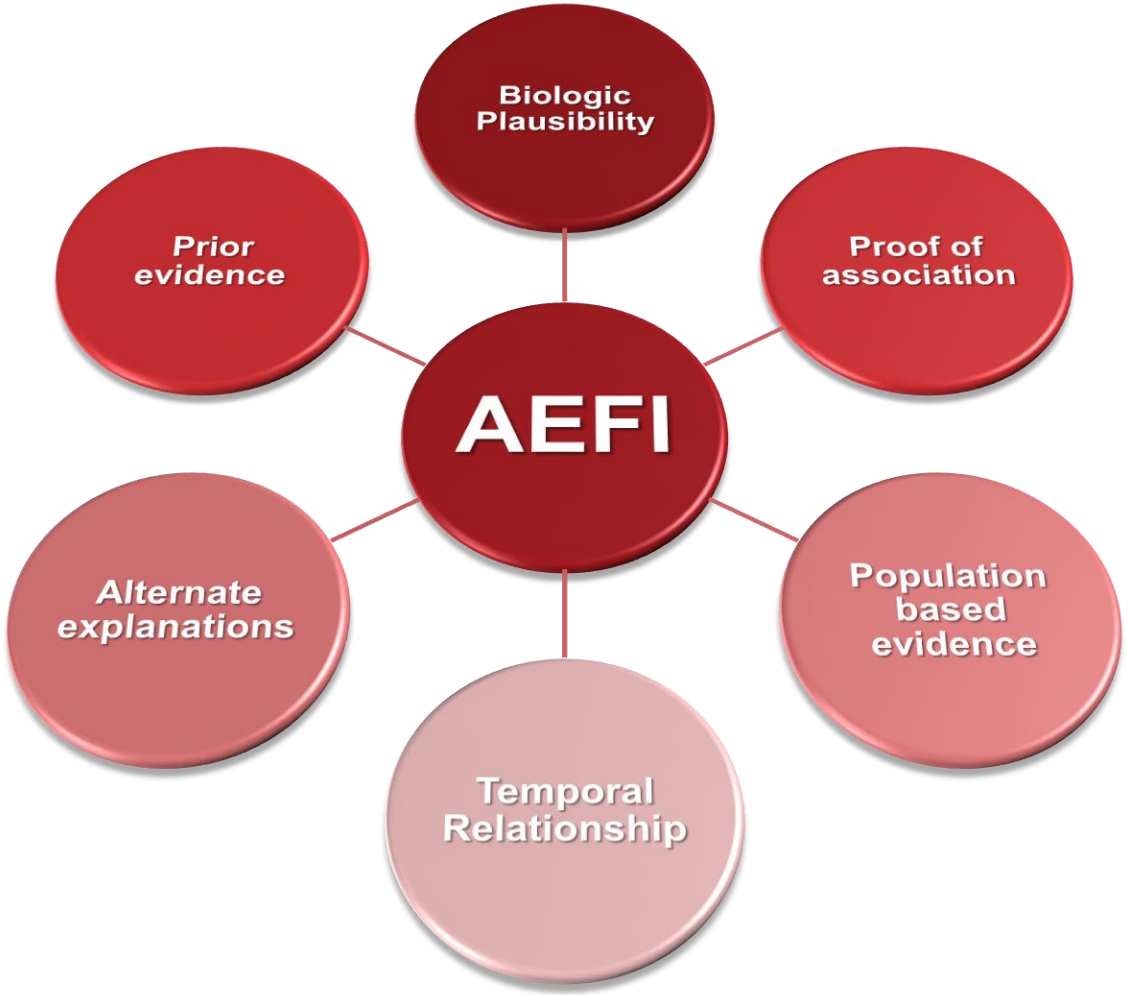
**Thrombosis with Thrombocytopenia Syndrome**

| | | |
|---|---|---|
| Complex new syndrome – no ICD codes or simple dx tests | Case ascertainment difficult - onset delayed | Different case definitions |
| Absent diagnostic testing, eg d-dimer, PF4 Ab tests, CT/MRI | Clinical data not reported | Different analytical methods |
| Different vaccines used at different ages/times | Available denominator data | Limited data from LMICs to understand and compare demography with HICs, eg on risk by ethnic group |

# WHO Vaccine safety surveillance cycle



# When considering causality for a single case



# Case selection for formal causality assessment

Serious AEFI

**Death, Hospitalisation, Significant disability, Life threatening**, or
Congenital anomaly/ Birth defect

Clusters & events above expected rate/ severity

If **immunisation error is suspected** (e.g. bacterial abscess, severe local reaction, high fever or sepsis, BCG lymphadenitis, toxic shock syndrome)

Evaluation of suspected Signals

Significant **events of unexplained cause** within 30 days of vaccination

Other AEFI*

Events causing **significant parental or community concern** e.g. hypotonic , hyporesponsive episode (HHE); febrile seizures

*if the reviewing team / committee decides as a **special case or to conduct special studies**

# Vaccine Safety Investigation Group – Work Instruction

## Pharmacovigilance and Special Access Branch
## Signal Investigation Unit

### Criteria to Convene the VSIG

The 'WHO Global manual on surveillance of adverse events following immunization' recommends that investigations that require the services of national-level experts need to be prioritised.[1] Consequently, the VSIG will be convened when the following criteria are met:

1) When an **AEFI of concern** or a **safety signal of concern** is identified by the TGA or OHP; AND
2) The TGA and OHP agree that the AEFI or signal:
    a. Has the potential to change the favourable benefit-risk balance of the vaccine in a National or State Immunisation program OR
    b. Could threaten public confidence in vaccine safety; AND
3) The case(s) is/are considered **eligible** for assessment and/or investigation.

# WHO causality assessment worksheet

## Step 1 (Eligibility)

| Name of the Patient | Name of one or more vaccines administered before this event | What is the Valid Diagnosis? | Does the diagnosis meet a case definition? |
|---|---|---|---|
| | | | |

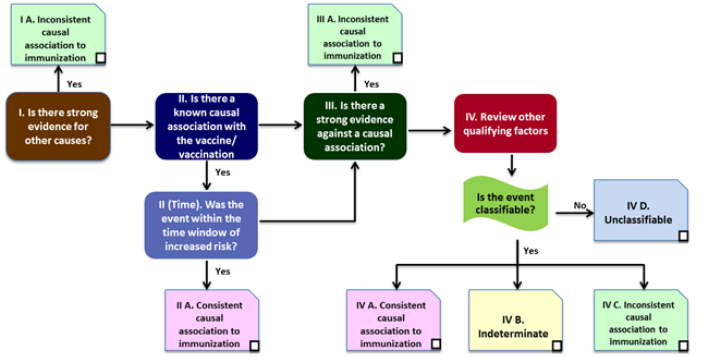
Create your question on causality here
Has the _____ vaccine / vaccination caused _____? (The event for review in step 2)

## Step 2 (Event Checklist) ✓ (check) all boxes that apply

| I. Is there strong evidence for other causes? | Y N UK NA | Remarks |
|---|---|---|
| Does a clinical examination, or laboratory tests on the patient, confirm another cause? | □□□□ | |
| **II. Is there a known causal association with the vaccine or vaccination?** | | |
| *Vaccine product(s)* | | |
| Is there evidence in the literature that this vaccine(s) may cause the reported event even if administered correctly? | □□□□ | |
| Did a specific test demonstrate the causal role of the vaccine or any of the ingredients? | □□□□ | |
| *Immunization error* | | |
| Was there an error in prescribing or non-adherence to recommendations for use of the vaccine (e.g. use beyond the expiry date, wrong recipient etc.)? | □□□□ | |
| Was the vaccine (or any of its ingredients) administered unsterile? | □□□□ | |
| Was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal at the time of administration? | □□□□ | |
| Was there an error in vaccine constitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)? | □□□□ | |
| Was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunization session etc.)? | □□□□ | |
| Was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)? | □□□□ | |
| *Immunization anxiety* | | |
| Could the event have been caused by anxiety about the immunization (e.g. vasovagal, hyperventilation or stress-related disorder)? | □□□□ | |
| **II (time). If "yes" to any question in II, was the event within the time window of increased risk?** | | |
| Did the event occur within an appropriate time window after vaccine administration? | □□□□ | |
| **III. Is there strong evidence against a causal association?** | | |
| Is there strong evidence against a causal association? | □□□□ | |
| **IV. Other qualifying factors for classification** | | |
| Could the event occur independently of vaccination (background rate)? | □□□□ | |
| Could the event be a manifestation of another health condition? | □□□□ | |
| Did a comparable event occur after a previous dose of a similar vaccine? | □□□□ | |
| Was there exposure to a potential risk factor or toxin prior to the event? | □□□□ | |
| Was there acute illness prior to the event? | □□□□ | |
| Did the event occur in the past independently of vaccination? | □□□□ | |
| Was the patient taking any medication prior to vaccination? | □□□□ | |
| Is there a biological plausibility that the vaccine could cause the event? | □□□□ | |

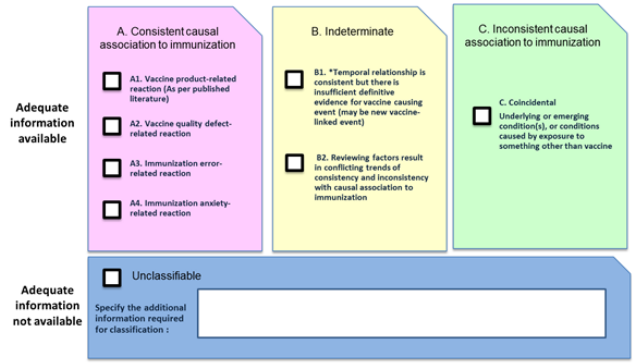
Y: Yes N: No UK: Unknown NA: Not applicable

## Step 3 (Algorithm) review all steps and ✓ all the appropriate boxes




**Notes for Step 3:**

## Step 4 (Classification) ✓ all boxes that apply




*B1: This is a potential signal and maybe considered for investigation

**Summarize the classification logic:**
*With available evidence, we could conclude that the classification is _____ because:*

Page 1

Page 2

# AEFI surveillance issues

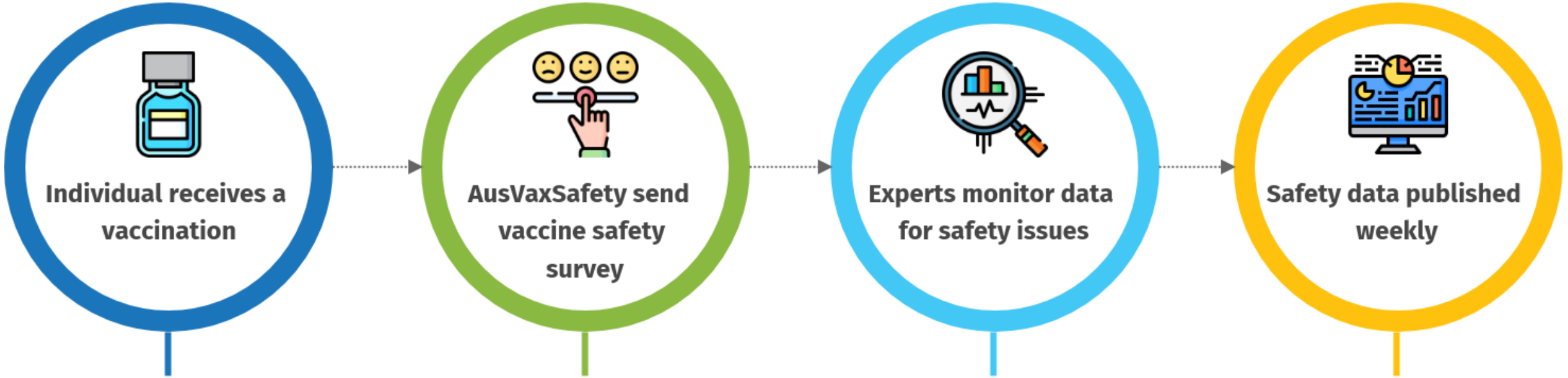
- Passive
  - Under reporting (NSW rate = ½ of Victoria)
  - Feedback to reporter not systematic
  - Incomplete case details
  - Centralised management of serious AESI’s
  - No routine longer term follow up
  - Death data not reported comprehensively
- Active
  - Link to passive system
- AEFI management
  - No dedicated adult clinics in NSW

AusVaxSafety
An NCIRS led collaboration

# Australia's active vaccine safety surveillance system

*Monkeypox surveillance*

# How AusVaxSafety active vaccine surveillance works




Individual receives a vaccination at a participating AusVaxSafety clinic.

AusVaxSafety sends a vaccine safety survey following vaccination giving participants the opportunity to report any adverse events they may have experienced and if they had to seek medical attention as a result.

Vaxtracker
Smartvax

Epidemiologist and vaccine experts monitor and analyse de-identified survey responses to check for safety issues.

If the person reported going to the doctor or emergency department, this is flagged with the clinic. The clinic follows up with the vaccinated person and notifies the Therapeutic Goods Administration if required.

AusVaxSafety reports to the Department of Health and publishes safety data at:

**www.ausvaxsafety.org.au**

# Mpox vaccine safety when given intradermal

## Vaccine safety surveys completed

**5,689**
JYNNEOS 0.1 mL intradermal dose 1

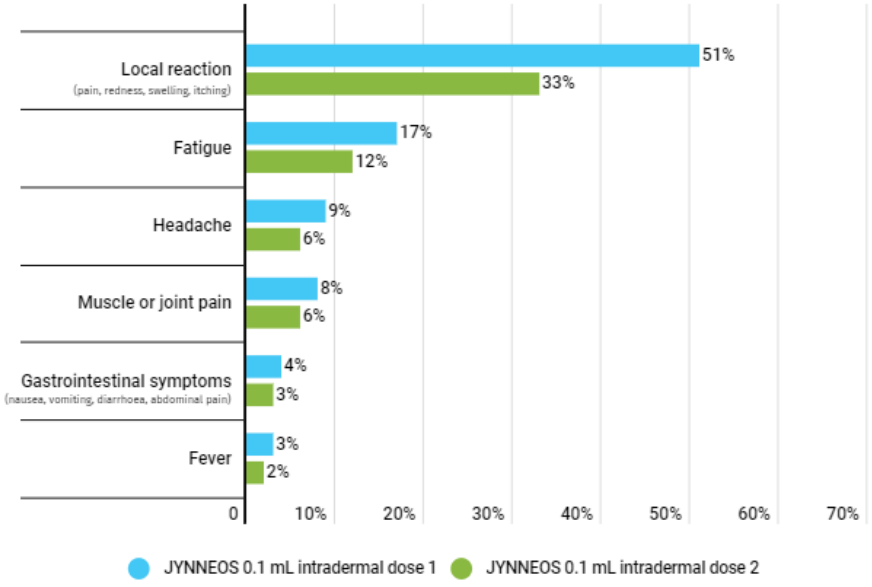
**3,635**
JYNNEOS 0.1 mL intradermal dose 2

## Reported at least one adverse event





## Commonly reported adverse events



# New vaccines

RSV

Shingrix

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Japanese encephalitis

NCIRS
National Centre for Immunisation Research and Surveillance

# Shingrix

NCIRS
National Centre
for Immunisation
Research and
Surveillance

## NIP-funded shingles vaccination schedule from 1 November 2023

## 2-dose schedule with Shingrix® 0.5ml vial (GSK) given intramuscularly.

| Eligible groups | Dosing schedule / Dose intervals |
|---|---|
| Adults aged 65 years and over (non-Indigenous) | Give 2-6 months apart in immunocompetent people |
| Aboriginal and Torres Strait Islander adults aged 50 years and over | Give 2-6 months apart in immunocompetent people |
| Immunocompromised adults aged 18 years and over with the following medical conditions:<br>• haemopoietic stem cell transplant<br>• solid organ transplant<br>• haematological malignancy<br>• advanced or untreated HIV. | Give 1-2 months apart in people who are immunocompromised |
| REPORT all vaccinations to the Australian Immunisation Register (AIR) – both NIP and private vaccines. | |

Eligible people who have received one dose of Shingrix® vaccine privately can receive their second dose free under the NIP. There is currently no recommendation for booster doses of Shingrix® vaccine.

# Zoe 70

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 15, 2016 VOL. 375 NO. 11

## Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older

A.L. Cunningham, H. Lal, M. Kovac, R. Chlibek, S.-J. Hwang, J. Díez-Domingo, O. Godeaux, M.J. Levin, J.E. McElhaney, J. Puig-Barberà, C. Vanden Abeele, T. Vesikari, D. Watanabe, T. Zahaf, A. Ahonen, E. Athan, J.F. Barba-Gomez, L. Campora, F. de Looze, H.J. Downey, W. Ghesquiere, I. Gorfinkel, T. Korhonen, E. Leung, S.A. McNeil, L. Oostvogels, L. Rombo, J. Smetana, L. Weckx, W. Yeo, and T.C. Heineman, for the ZOE-70 Study Group*

**Table 2.** Vaccine Reactogenicity and Safety Overall.

| Time Period and Event | HZ/su Group | | Placebo Group | |
|---|---|---|---|---|
| | *no. of participants/ total no.* | *% (95% CI)* | *no. of participants/ total no.* | *% (95% CI)* |
| **Within 7 days after vaccination in the reactogenicity subgroup*** | | | | |
| Any reaction | 399/505 | 79.0 (75.2–82.5) | 149/505 | 29.5 (25.6–33.7) |
| Grade 3 reaction† | 60/505 | 11.9 (9.2–15.0) | 10/505 | 2.0 (1.0–3.6) |
| Injection-site reaction | 374/505 | 74.1 (70.0–77.8) | 50/505 | 9.9 (7.4–12.8) |
| Pain | 347/505 | 68.7 (64.5–72.7) | 43/505 | 8.5 (6.2–11.3) |
| Redness | 198/505 | 39.2 (34.9–43.6) | 5/505 | 1.0 (0.3–2.3) |
| Swelling | 114/505 | 22.6 (19.0–26.5) | 2/505 | 0.4 (0.0–1.4) |
| Grade 3 injection-site reaction† | 43/505 | 8.5 (6.2–11.3) | 1/505 | 0.2 (0.0–1.1) |
| Systemic reaction | 267/504 | 53.0 (48.5–57.4) | 127/505 | 25.1 (21.4–29.2) |
| Fatigue | 166/504 | 32.9 (28.8–37.2) | 77/505 | 15.2 (12.2–18.7) |
| Myalgia | 157/504 | 31.2 (27.1–35.4) | 41/505 | 8.1 (5.9–10.9) |
| Headache | 124/504 | 24.6 (20.9–28.6) | 55/505 | 10.9 (8.3–13.9) |
| Shivering | 75/504 | 14.9 (11.9–18.3) | 22/505 | 4.4 (2.7–6.5) |
| Fever | 62/504 | 12.3 (9.6–15.5) | 13/505 | 2.6 (1.4–4.4) |
| Gastrointestinal symptoms | 55/504 | 10.9 (8.3–14.0) | 40/505 | 7.9 (5.7–10.6) |
| Grade 3 systemic reaction† | 30/504 | 6.0 (4.1–8.4) | 10/505 | 2.0 (1.0–3.6) |

# Dose 1 similar to Dose 2

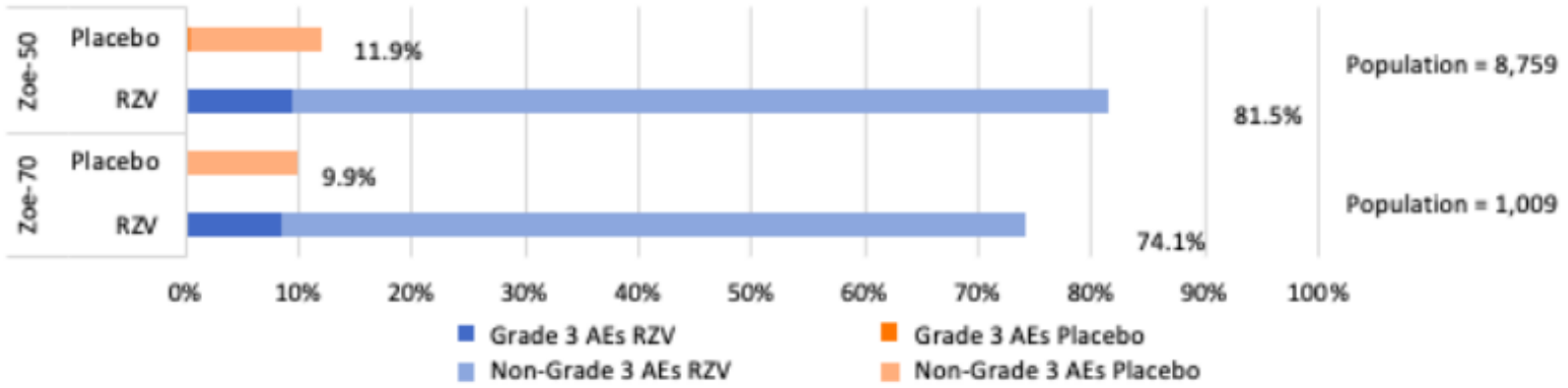
**Table S4.** Incidence of solicited reactions reported during the 7-day post-vaccination period by dose and by age group (ZOE-70 reactogenicity subgroup)

| | | Any reaction | | | Systemic reactions | | | Injection-site reactions | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Age group | Group | N | n | % (95% CI) | N | n | % (95% CI) | N | n | % (95% CI) |
| **Dose 1** | | | | | | | | | | |
| 70–79 yr | HZ/su | 283 | 209 | 73.9 (68.3–78.9) | 282 | 118 | 41.8 (36.0–47.8) | 283 | 188 | 66.4 (60.6–71.9) |
| | Placebo | 284 | 60 | 21.1 (16.5–26.3) | 283 | 53 | 18.7 (14.4–23.8) | 284 | 19 | 6.7 (4.1–10.3) |
| ≥80 yr | HZ/su | 219 | 152 | 69.4 (62.8–75.4) | 219 | 78 | 35.6 (29.3–42.3) | 219 | 140 | 63.9 (57.2–70.3) |
| | Placebo | 220 | 51 | 23.2 (17.8–29.3) | 220 | 43 | 19.5 (14.5–25.4) | 220 | 12 | 5.5 (2.8–9.3) |
| **Dose 2** | | | | | | | | | | |
| 70–79 yr | HZ/su | 280 | 196 | 70.0 (64.3–75.3) | 280 | 121 | 43.2 (37.3–49.2) | 280 | 186 | 66.4 (60.6–71.9) |
| | Placebo | 282 | 42 | 14.9 (10.9–19.6) | 281 | 34 | 12.1 (8.5–16.5) | 282 | 12 | 4.3 (2.2–7.3) |
| ≥80 yr | HZ/su | 213 | 133 | 62.4 (55.6–69.0) | 212 | 75 | 35.4 (29.0–42.2) | 212 | 121 | 57.1 (50.1–63.8) |
| | Placebo | 209 | 38 | 18.2 (13.2–24.1) | 208 | 31 | 14.9 (10.4–20.5) | 209 | 14 | 6.7 (3.7–11.0) |
| **Overall by subject** | | | | | | | | | | |
| 70–79 yr | HZ/su | 283 | 233 | 82.3 (77.4–86.6) | 283 | 160 | 56.5 (50.5–62.4) | 283 | 218 | 77.0 (71.7–81.8) |
| | Placebo | 284 | 79 | 27.8 (22.7–33.4) | 284 | 68 | 23.9 (19.1–29.3) | 284 | 28 | 9.9 (6.7–13.9) |
| ≥80 yr | HZ/su | 222 | 166 | 74.8 (68.5–80.3) | 221 | 107 | 48.4 (41.7–55.2) | 222 | 156 | 70.3 (63.8–76.2) |
| | Placebo | 221 | 70 | 31.7 (25.6–38.2) | 221 | 59 | 26.7 (21.0–33.0) | 221 | 22 | 10.0 (6.3–14.7) |

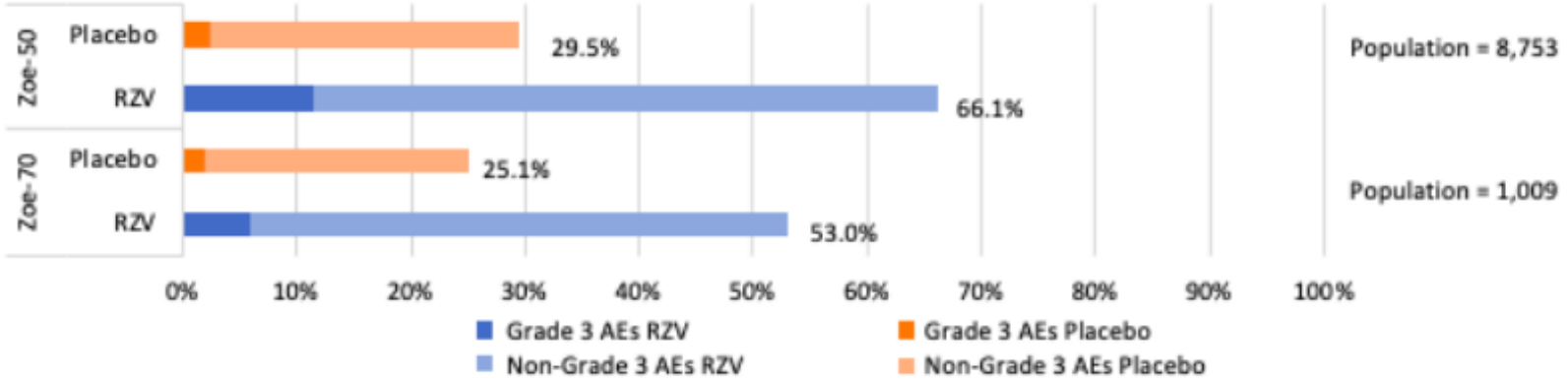
HZ/su, herpes zoster subunit vaccine; N, number of subjects with at least one documented dose; n, number of subjects presenting at least one type of symptom.

# Shingrix reactogenicity

**Solicited local adverse events (AEs)**
Recorded using diary cards post vaccination (Local solicited AEs include pain, redness, swelling)
follow up: 7 days
No. participants: 9769
(2 RCTs)




**Solicited general/systemic AEs**
Recorded using diary cards post vaccination. General solicited AEs include: fever, fatigue, gastrointestinal (GI) symptoms, headache, shivering, myalgia
follow up: 7 days
No. participants: 9762
(2 RCTs)



# AusVaxSafety data

| | | Medical attendance | Fever |
|---|---|---|---|
| **All respondents** | **Any Shingrix dose alone or concomitant (n=8770)** | 0.5% | 11.2% |
| | **Shingrix alone (subset of above, n=7949)** | 0.5% | 11.3% |
| **Respondents 50-69 years** | **Any Shingrix dose (n=4997)** | 0.5% | 13.2% |
| **Respondents 70+ years** | **Any Shingrix dose (n=3660)** | 0.4% | 8.2% |

# RSV - the road ahead

Acknowledgements
Lauren Dalton
Jean Li Kim Moy
Rama Kandasamy
Philip Britton

# RSV vaccine for elderly - >60 years

U.S. FOOD & DRUG ADMINISTRATION

Home / News & Events / FDA Newsroom / Press Announcements / FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine

FDA NEWS RELEASE

## FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine

*Arexvy Approved for Individuals 60 Years of Age and Older*

**Arexvy – GSK**

Pfizer

Pfizer Press release | Vaccines | Vaccines

## U.S. FDA Approves ABRYSVO™, Pfizer's Vaccine for the Prevention of Respiratory Syncytial Virus (RSV) in Older Adults

Wednesday, May 31, 2023 - 05:49pm

# Safety of GSK RSV vaccine

TABLE 2. Safety* of 1 dose of GSK respiratory syncytial virus RSVPreF3 vaccine in adults aged ≥60 years — multiple countries, 2021–2023

| Safety event | Risk for event | | |
|---|---|---|---|
| | RSVPreF3 recipients no./No. (%)† | Placebo recipients no./No. (%)§ | Relative risk (95% CI)¶ |
| Serious AE** | 549/12,570 (4.4) | 540/12,604 (4.3) | 1.02 (0.91–1.15) |
| Severe reactogenicity events†† | 37/979 (3.8) | 9/976 (0.9) | 4.10 (1.99–8.45) |
| Inflammatory neurologic events§§ | 3 events in trials without placebo recipients¶¶ | —¶¶ | —¶¶ |

AESI

- Atrial fibrillation within 30 days
  - GSK =10 events
  - Controls = 4
- Inflammatory neurologic events in GSK vaccine
  - GBS = 1 case
  - ADEM = 2 cases
    - Both had concomitant flu vaccine

# Safety of Pfizer RSV vaccine

TABLE 4. Safety* of 1 dose of Pfizer respiratory syncytial virus RSVpreF vaccine in adults aged ≥60 years — multiple countries, 2021–2023

| Safety event | Risk for event: RSVpreF recipients no./No. (%)† | Risk for event: Placebo recipients no./No. (%)§ | Relative risk (95% CI)¶ |
|---|---|---|---|
| Serious AE** | 792/18619 (4.3%) | 749/18334 (4.1%) | 1.04 (0.94–1.15) |
| Severe reactogenicity events†† | 36/3673 (1.0%) | 24/3491 (0.7%) | 1.43 (0.85–2.39) |
| Inflammatory neurologic events§§ | 3/18622 (—)¶¶ | 0/18335 (—) | —¶¶ |

AESI

- Atrial fibrillation within 30 days
  - GSK =10 events (6 pre-existing AF)
  - Controls = 4 (2 pre-existing AF)
- Inflammatory neurologic events in Pfizer vaccine = 3
  - GBS = 2 cases
  - Polyneuropathy = 1 case

# Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

## Recommendations for Use of RSV Vaccines in Older Adults

On June 21, 2023, ACIP recommended that adults aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision-making.[§§§§]

Shared decision making

### Clinical Guidance

**Shared Clinical Decision-Making for Adults Aged ≥60 years.** Unlike routine and risk-based vaccine recommendations, recommendations based on shared clinical decision-making do not target all persons in a particular age group or an identifiable risk group. For RSV vaccination, the decision to vaccinate a patient should be based on a discussion between the health care provider and the patient, which might be guided by the patient's risk for disease and their characteristics, values, and preferences; the provider's clinical discretion; and the characteristics of the vaccine.

# Early infant RSV prevention

# US FDA approves Nirsevimab for use in infants

U.S. FOOD & DRUG ADMINISTRATION

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Home / News & Events / FDA Newsroom / Press Announcements / FDA Approves New Drug to Prevent RSV in Babies and Toddlers

FDA NEWS RELEASE

## FDA Approves New Drug to Prevent RSV in Babies and Toddlers

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More Press Announcements

**For Immediate Release:** July 17, 2023

Español

Today, the U.S. Food and Drug Administration approved Beyfortus (nirsevimab-alip) for

**Content current as of:**
07/18/2023

**Regulated Product(s)**
Drugs

# FDA briefing document - safety

**Table 2 Overview of Safety in Healthy Term and Preterm Infants Through at Least Day 150 Post Dose: Proposed-Dose Safety Pool**

| | Subjects with ≥ 1 event, n (%) | |
|---|---|---|
| | Placebo (N = 1284) | Nirsevimab (N = 2570) |
| Any AE | 1060 (82.6) | 2158 (84.0) |
| Any AE related to IP | 18 (1.4) | 33 (1.3) |
| AE ≥ Grade 3 | 81 (6.3) | 102 (4.0) |
| AE ≥ Grade 3 related to IP | 1 (< 0.1) | 1 (< 0.1) |
| Serious AE | 135 (10.5) | 195 (7.6) |
| Serious AE related to IP | 1 (< 0.1) | 0 |
| Death (none considered IP related) | 3 (0.2) | 6 (0.2) |
| AEs of special interest [a] (Investigator assessment) | 0 | 6 (0.2) [b] |
| New Onset of Chronic Disease (none considered IP related) | 4 (0.3) [c] | 3 (0.1) [d] |

**Rash**
Nirsevimab=0.9%

Placebo = 0.6%

**ISR**
Nirsevimab = 0.3%

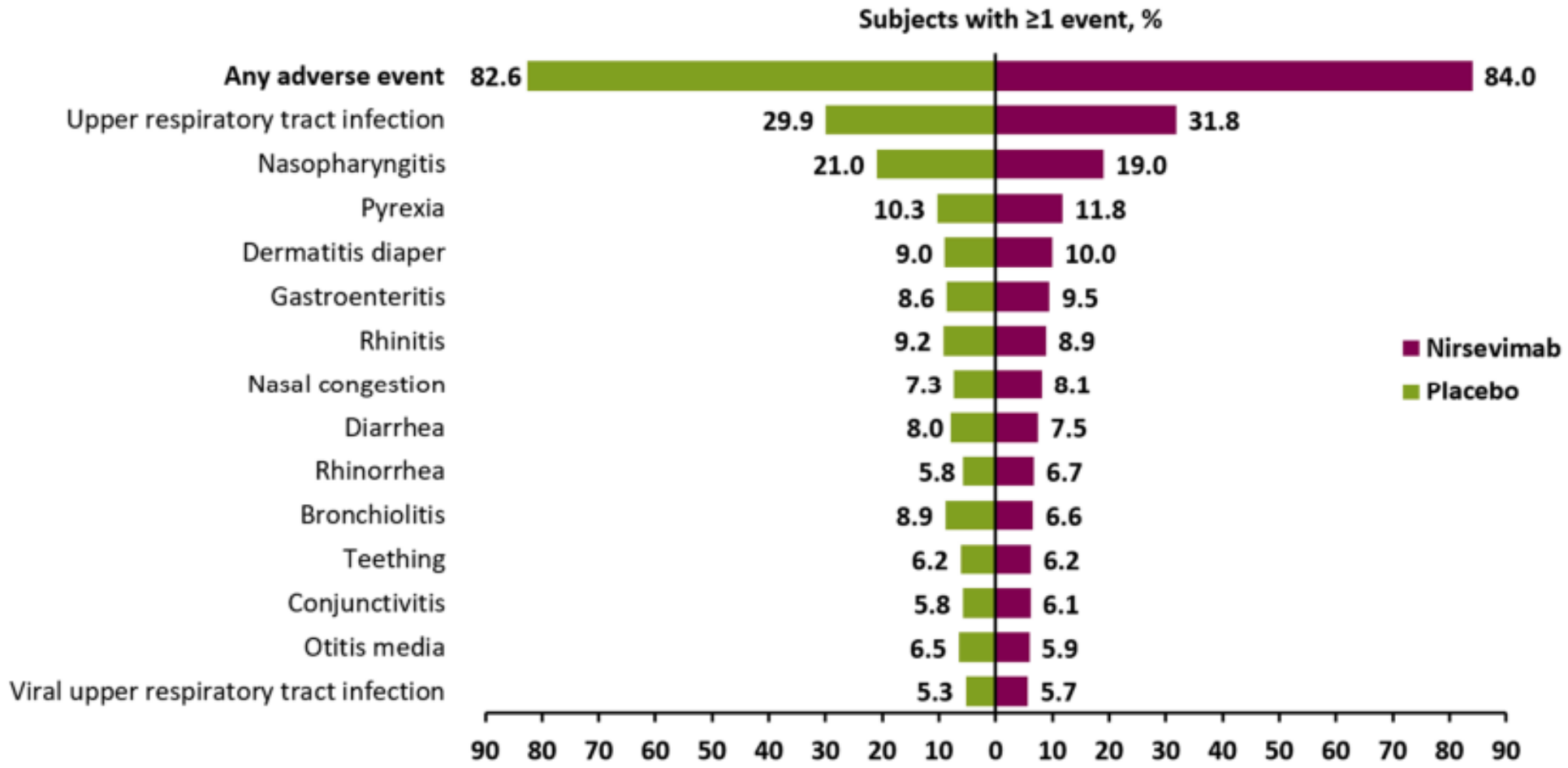
Placebo = 0%



https://www.fda.gov/media/169228/download

# FDA briefing document

**Figure 2** **Most Frequent Treatment-Emergent Adverse Events (≥ 5% of Subjects) Through at Least Day 150 Post Dose (Proposed-Dose Safety Pool)**




https://www.fda.gov/media/169228/download

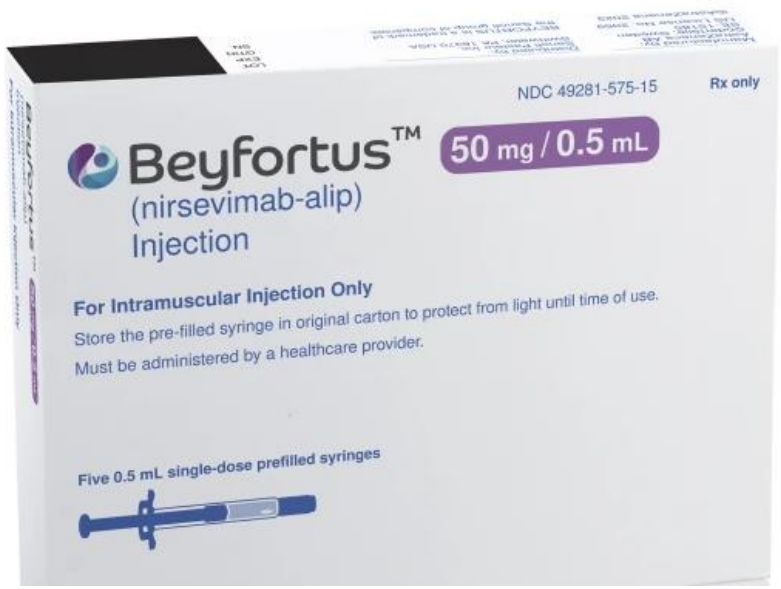
AP

U.S. WORLD POLITICS VIDEO SPOTLIGHT ENTERTAINMENT SPORTS BUSINESS SCIENCE FACT CHECK CLIMATE HEALTH PH

Israel-Hamas war Jim Jordan Jets trade Mecole Hardman California earthquake Natalee Holloway case

AP FACT CHECK

# Posts mislead on clinical trial deaths to suggest new RSV drug for babies isn't safe



# Next steps in Australia

- TGA submission = prescription medicines under evaluation
  - Nirsevimab
  - GSK Arexvy
  - Pfizer Abrysvo
- ATAGI
- PBAC
- Consumers and providers

# Emergence of Japanese encephalitis in Australia and implications for a national vaccination strategy

**Professor Nick Wood**

Acknowledgements
Dr Archana Koirala
Prof Colleen Lau
Alexandra Hendry
Narayan Gyawali
Dr Luis Furuya Kanamori
Prof. Greg Devine

NCIRS
National Centre
for Immunisation
Research and
Surveillance

# Imojev®

**LICENSED**

- Live attenuated
- 9mo +
- Single dose 0.5mL (=1 vial)
- Subcutaneous injection
- Adults: 85% protective levels of neutralising antibodies against all 4 wild-type strains

**WHAT IF?**

- Intradermal injection
- Single dose 0.1mL
- Up to 4-5 doses per vial

ID vaccine is Dose sparing

<u>Gaps</u>

- Immunogenicity
- safety

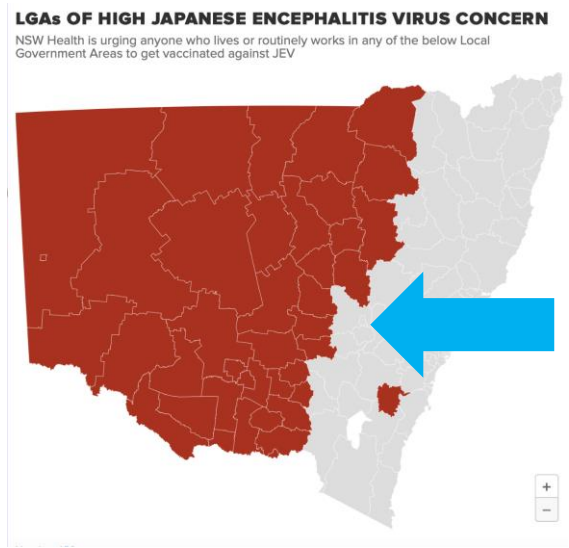
# Study design: SC v ID

Commenced 30th January 2023

## Randomised ID vs SC trial

- pts already eligible for SC immunisation excluded

- Pregnant women and immunosuppressed excluded




**N= 900**

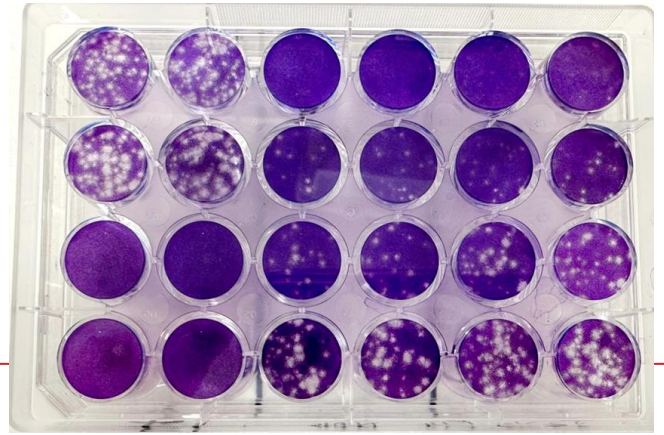
- Age cohorts

| | Cohort 1 | Cohort 2 | Cohort 3 | Cohort 4 |
|---|---|---|---|---|
| Age | **5 yrs to <10 yrs** | **10 yrs to <18yrs** | **18yrs to <50 yrs** | **50+ yrs** |
| Subcutaneous administration | N=100 | N=100 | N=100 | N=150 |
| Intradermal administration | N=100 | N=100 | N=100 | N=150 |

# Visits 2, 3, 4 and 5

| Visit 2 (Day 7-10) | Visit 3 (Day 28-35) | Visit 4 (Day 180-210) | Visit 5 (Month 12-13) |
|---|---|---|---|
| Review worksheet parameters, AE | Review worksheet parameters, AE | Review worksheet parameters, AE | Review worksheet parameters, AE |
| Serology* – Abs<br>- *No serology for <10y*<br>- *10y+ opt-in* | Serology* – Abs | Serology* – Abs | Serology* – Abs |
| Review diary card | Serious adverse events | Serious adverse events | Serious adverse events |

Serology (PRNT) performed at QIMR – Greg Devine

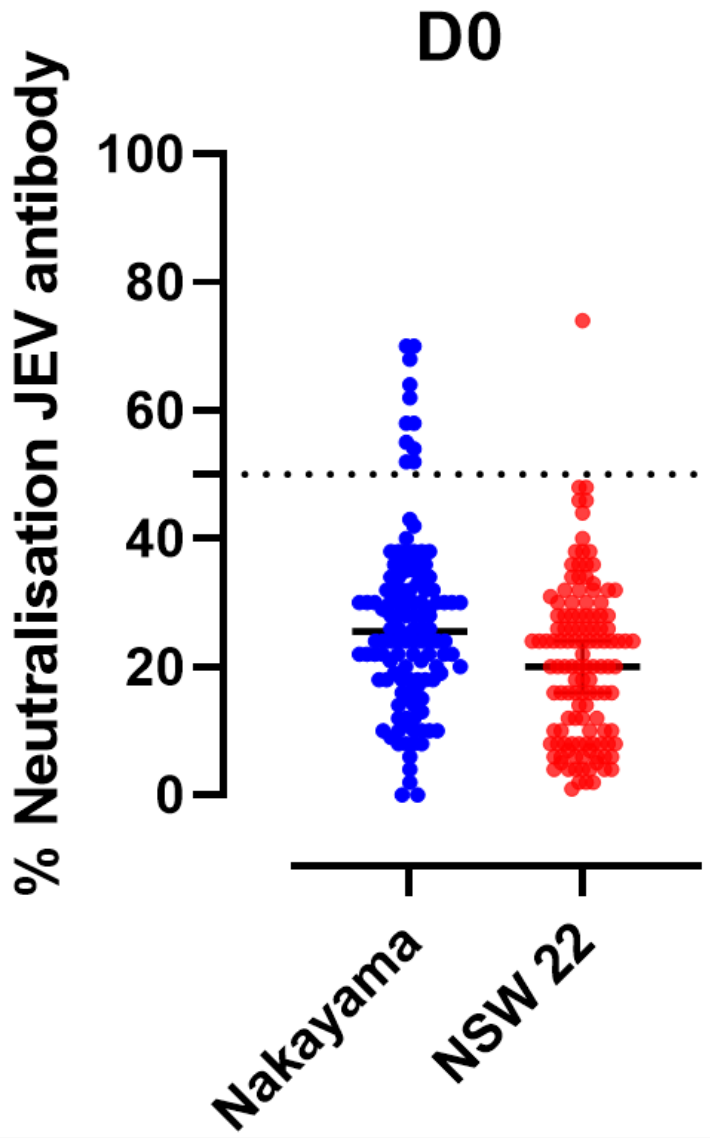


# Total recruitment – as at 14th June 2023

| | |
|---|---|
| Enrolled | Total = 228 |
| Eligible for vaccination | Total = 211 |

| Vaccinated | | 5 years to < 10 years | 10 years to < 18 years | 18 years to < 50 years | 50+ years |
|---|---|---|---|---|---|
| | **Subcutaneous** | 2 | 6 | 16 | 82 |
| | *(Change from previous report)* | *(+0)* | *(+0)* | *(+0)* | *(+0)* |
| | **Intradermal** | 0 | 6 | 17 | 82 |
| | *(Change from previous report)* | *(+0)* | *(+0)* | *(+0)* | *(+0)* |

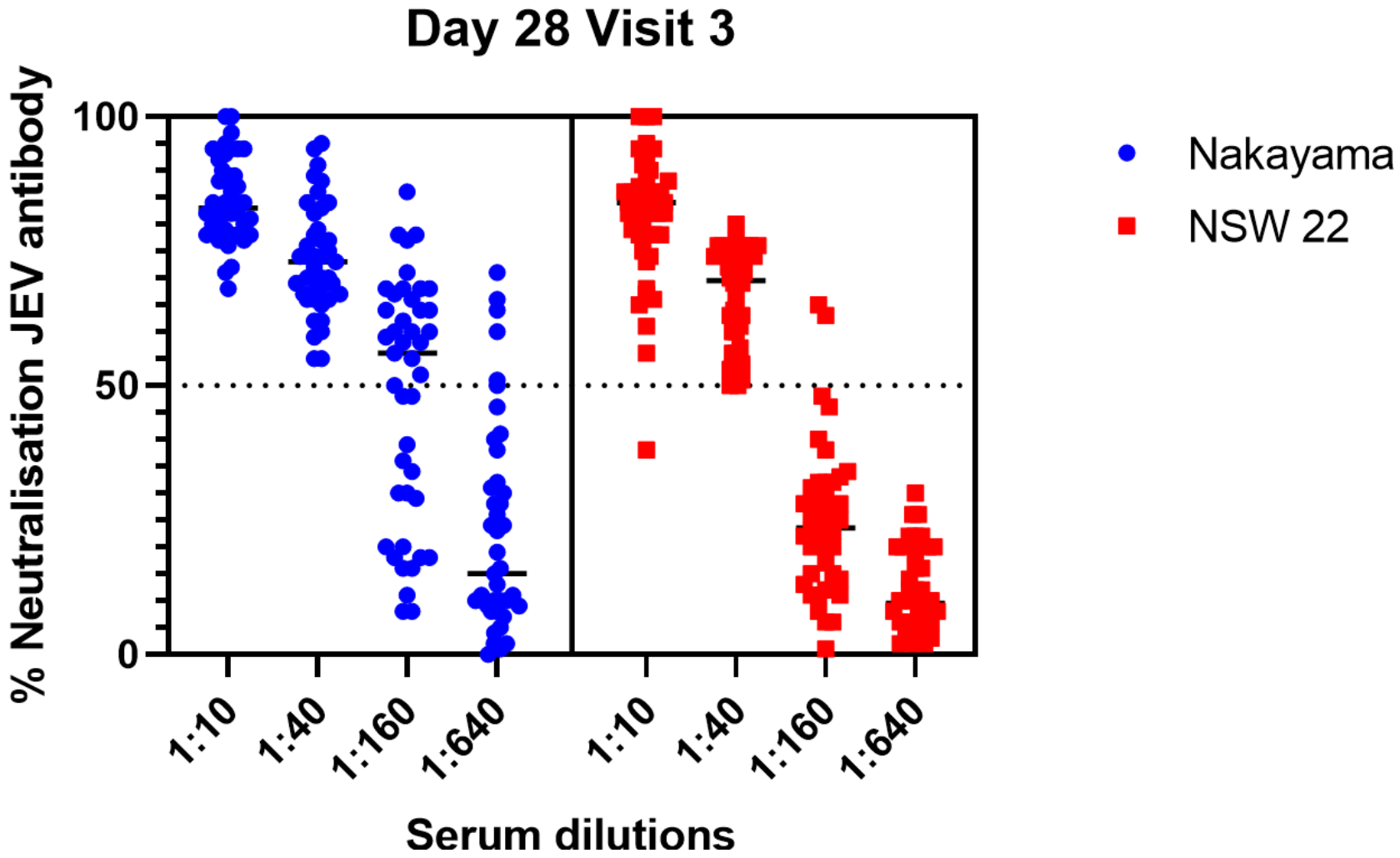
# Early serology results



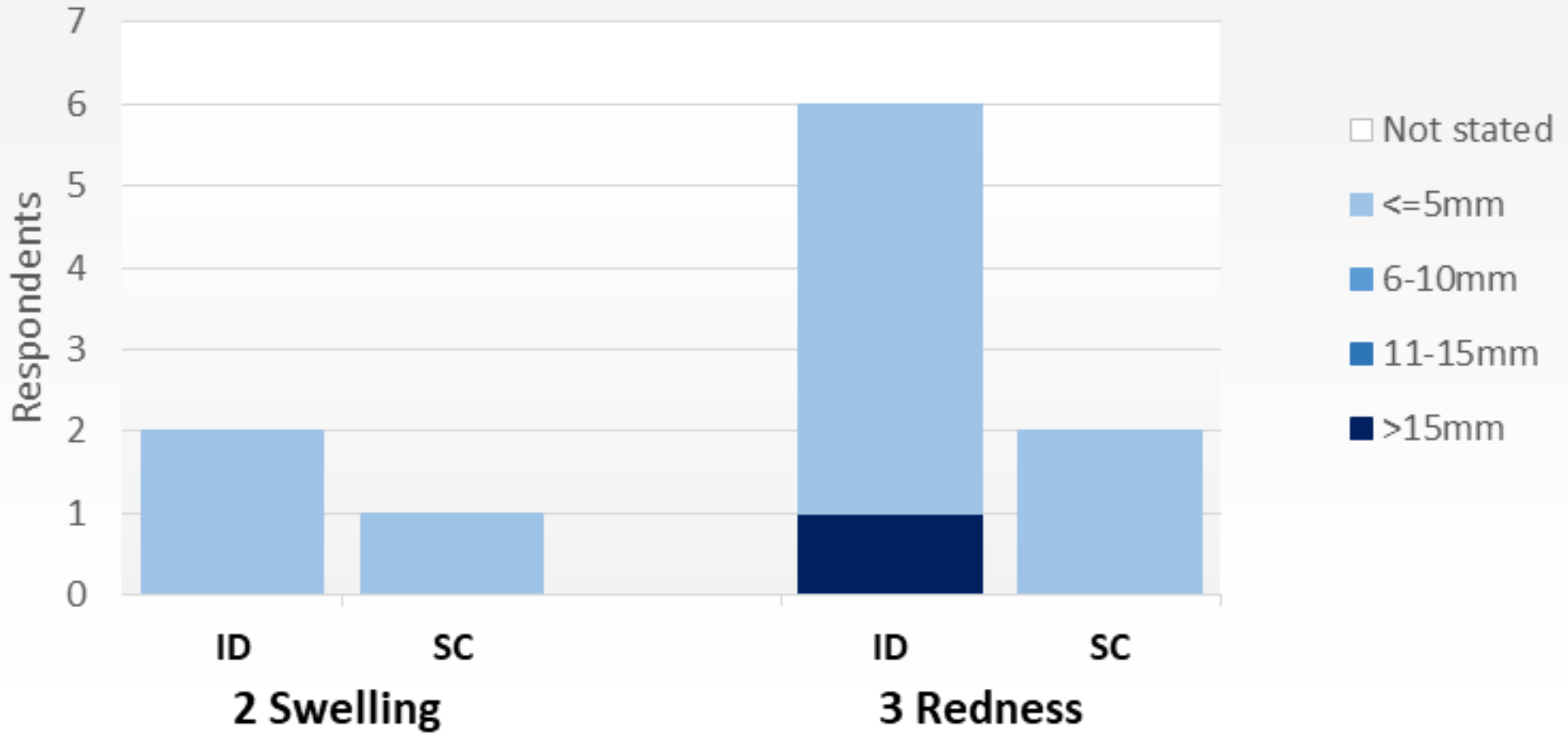

Out of 126 samples analysed for both Nakayama and NSW 22;

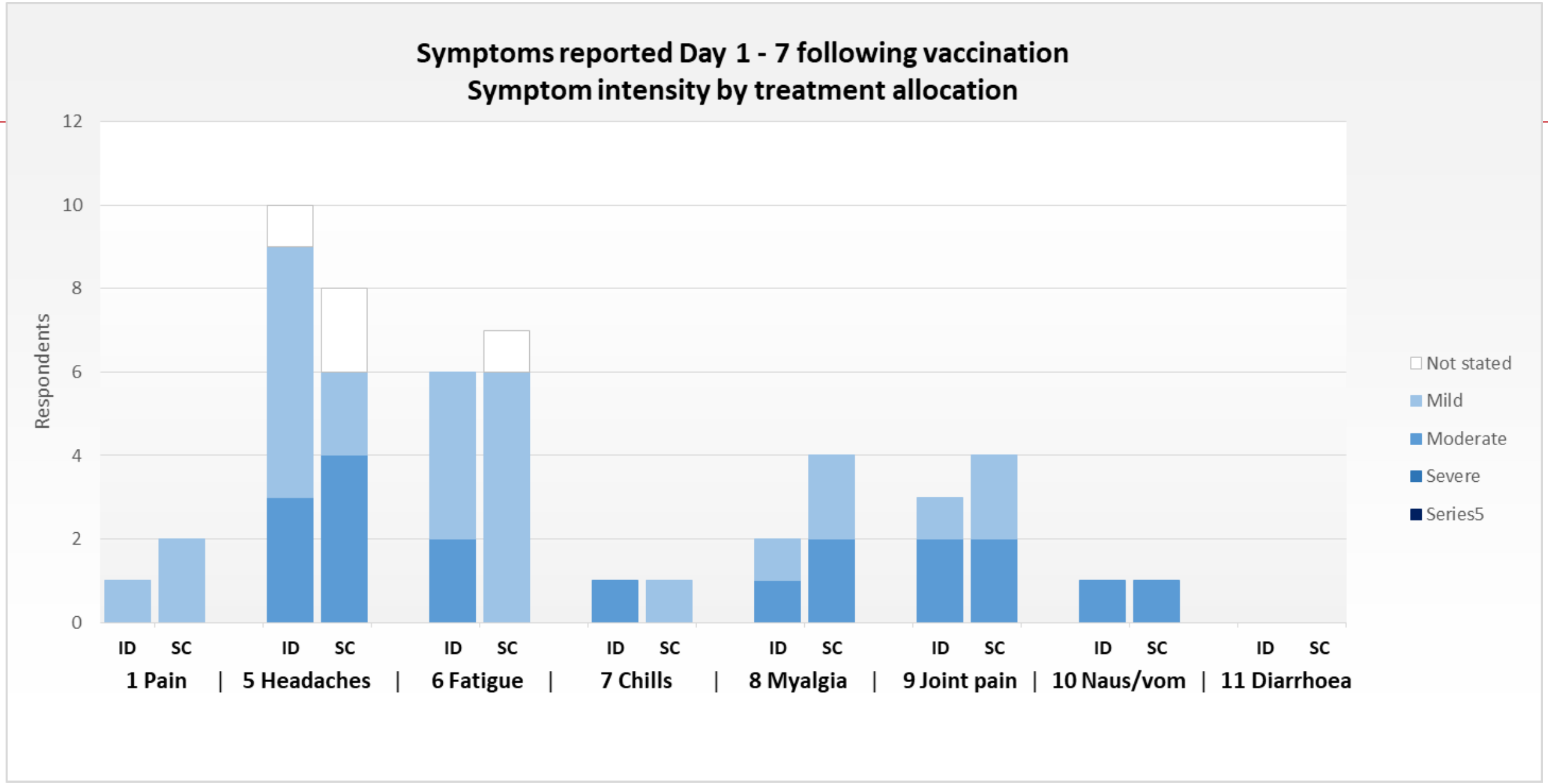
**Reactive samples**

Nakayama = 11
NSW = 1


Day 28 Visit 3
% Neutralisation JEV antibody
100
50
0
1:10
1:40
1:160
1:640
1:10
1:40
1:160
1:640
Serum dilutions
Nakayama
NSW 22

# Swelling and redness reported Day 1 - 7 following vaccination
## Diameter by treatment allocation




Symptoms reported Day 1 - 7 following vaccination
Symptom intensity by treatment allocation
Respondents
12
10
8
6
4
2
0
ID SC ID SC ID SC ID SC ID SC ID SC ID SC ID SC
1 Pain | 5 Headaches | 6 Fatigue | 7 Chills | 8 Myalgia | 9 Joint pain | 10 Naus/vom | 11 Diarrhoea
Not stated
Mild
Moderate
Severe
Series5

# Anticipated future

## Can JEV be eradicated from Australia?

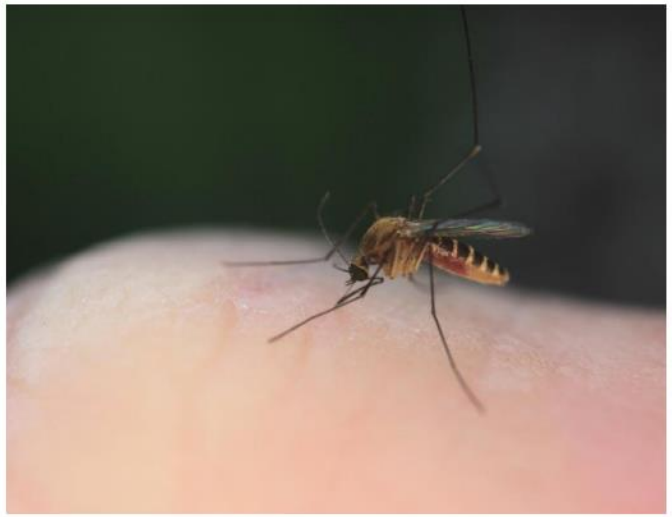
There are still many knowledge gaps that need to be addressed to determine future transmission patterns for JEV in Australia. These include:

- The origin and pathway of the virus in Australia.
- The competence of other vector species apart from *Cx. annulirostris*.
- Environment, changing climatic conditions and different vector/host transmission dynamics that influence JEV spread in different locations across Australia.
- The role of other potential vertebrate hosts.

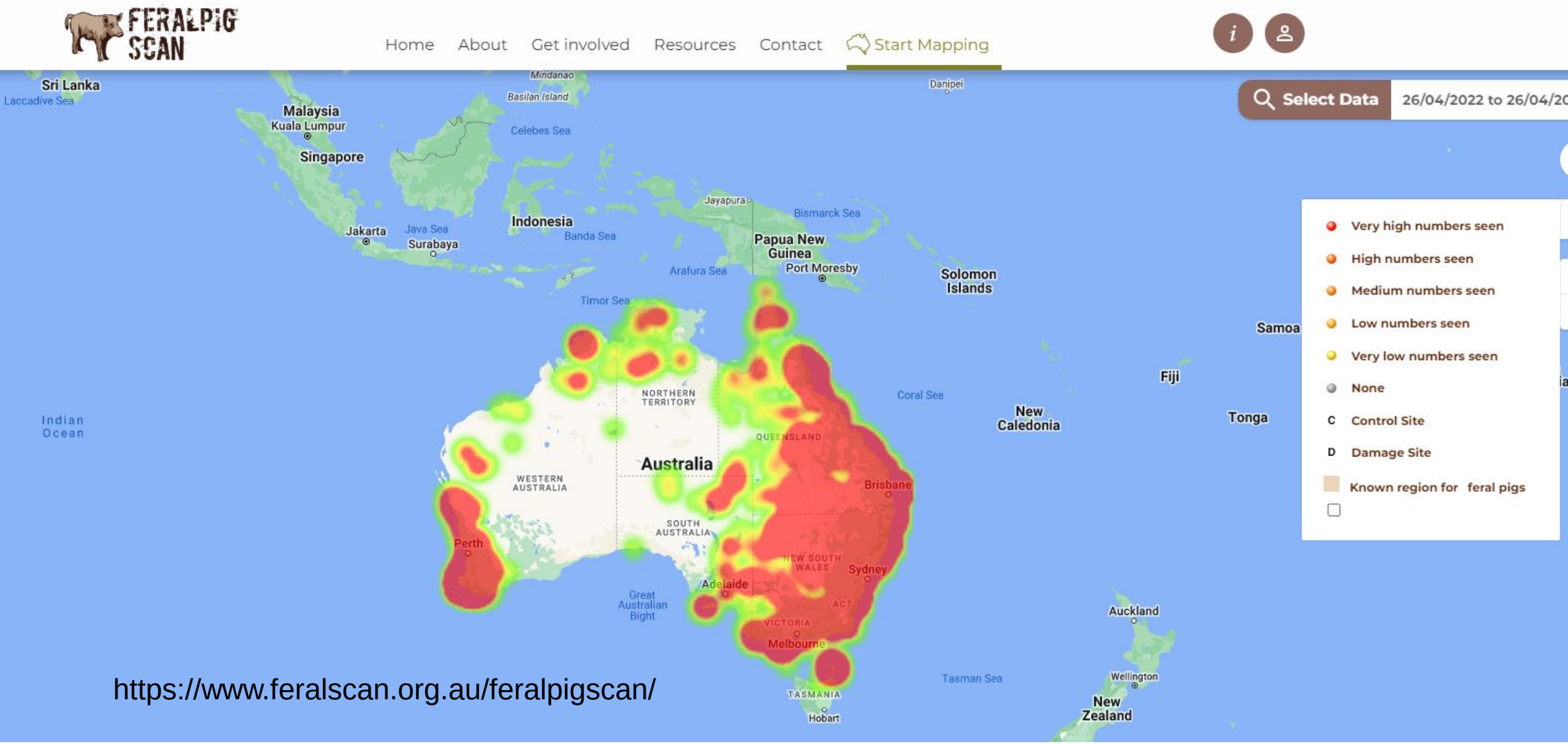
The evidence currently available suggests that the virus is widespread (present in multiple states), and present in feral pigs and vectors which may provide an environmental reservoir for the virus, meaning eradication is therefore unlikely.

https://www.health.gov.au/sites/default/files/2023-06/joint-national-japanese-encephalitis-virus-outbreak-response-plan.pdf

# Environment



# Australia and feral pigs




https://www.feralscan.org.au/feralpigscan/

# Summary

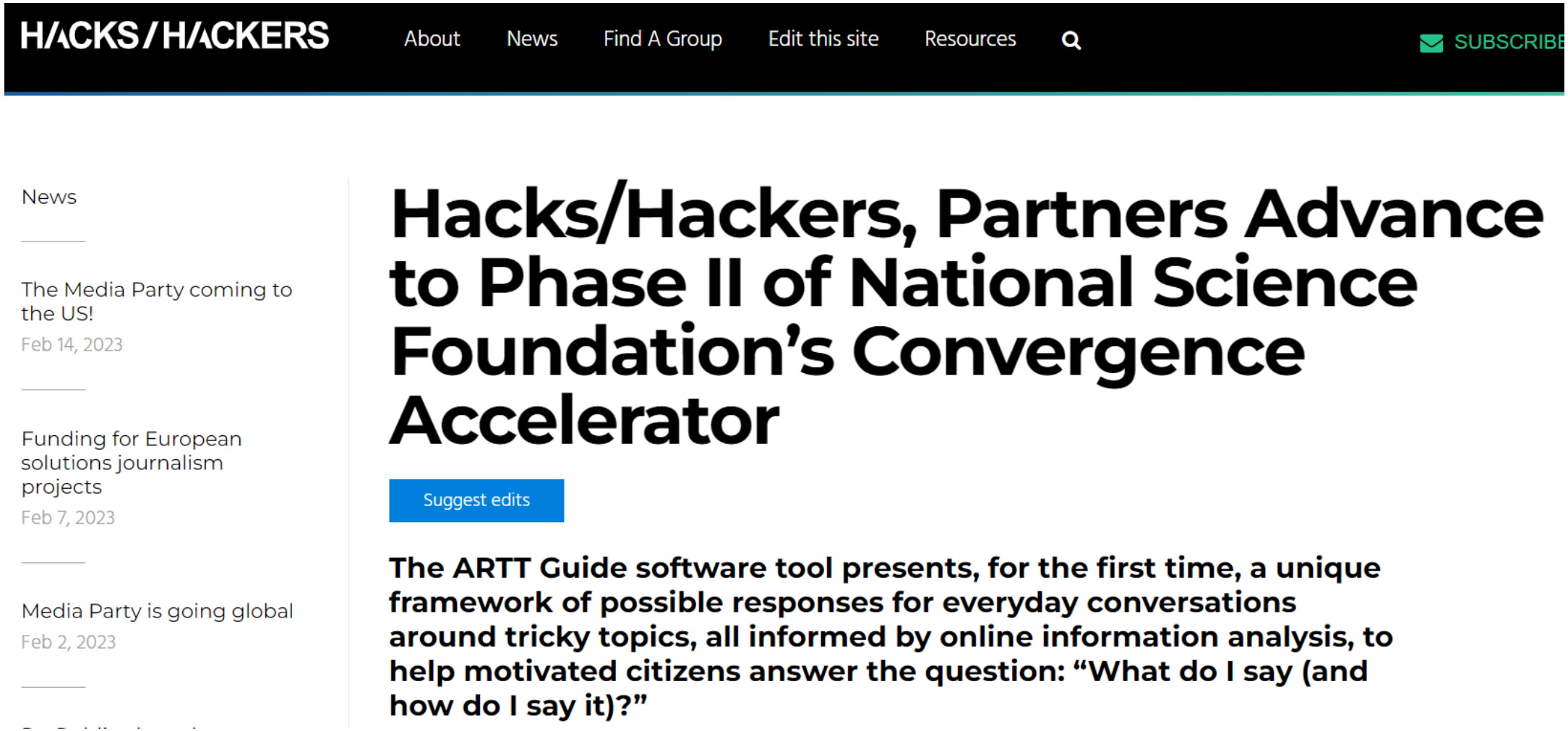
- Outbreak from March to December 2022 with 45 cases
- Strong rollout of vaccines with over 130 000 doses
- Intradermal route – potential dose sparing option under investigation
- Serosurveillance - >90% seronegative and potentially vulnerable to infection
- National Outbreak response plan has been developed
- Future – not certain and includes a range of scenarios
- States deciding on vaccine recommendations

# Where to next with vaccine safety?

# Or

# After dinner ramblings!

# Tool to fact check vaccine comments on social media



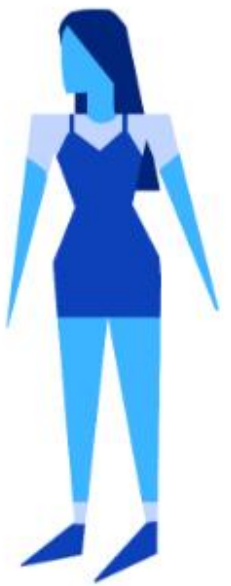
Institute for Vaccine Safety
Johns Hopkins Bloomberg School of Public Health

Choose language

English

# Let's Talk Shots

## I want to learn about vaccines for:



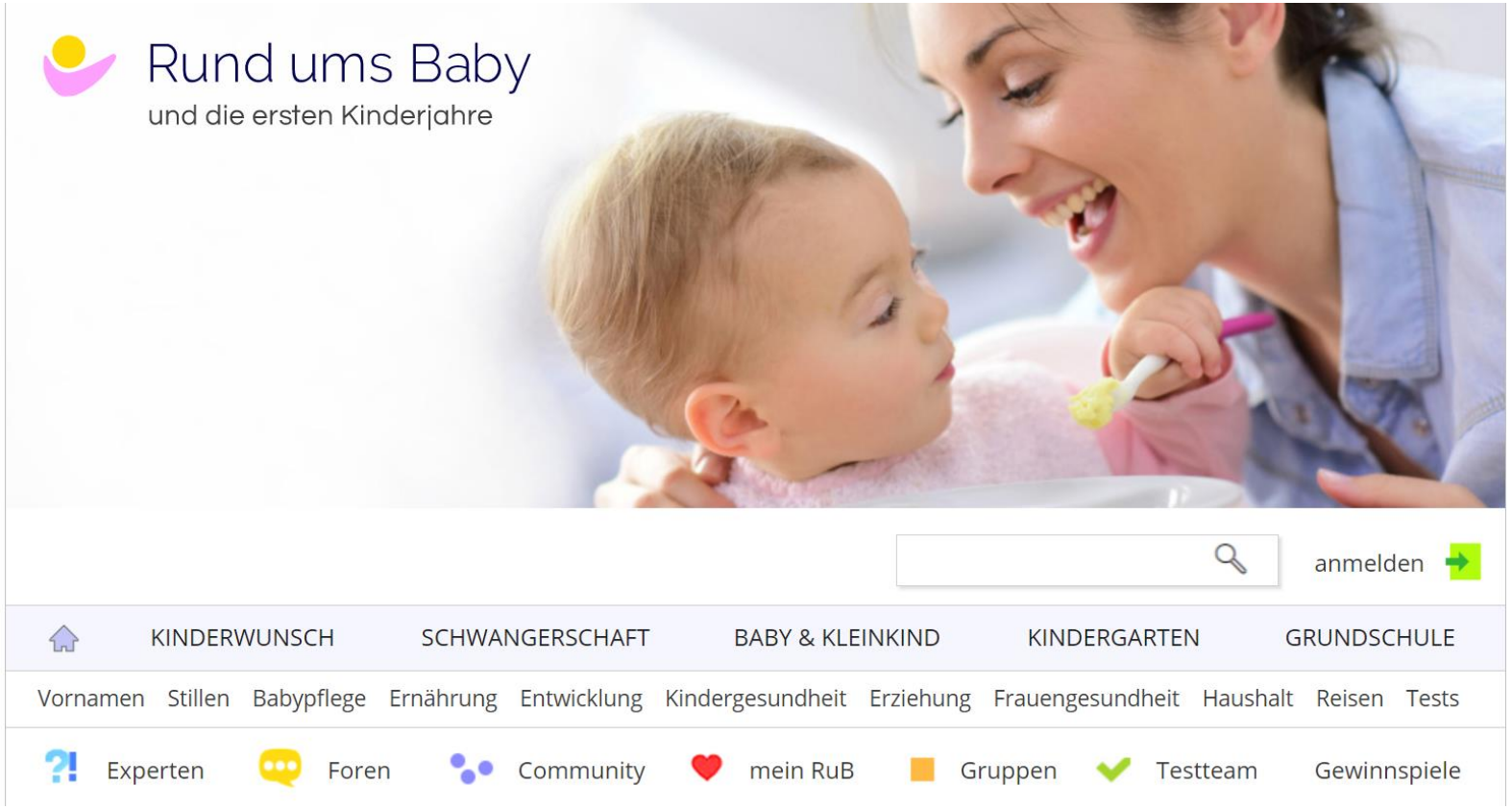
https://www.letstalkshots.com/main/

My baby (0-2 years)

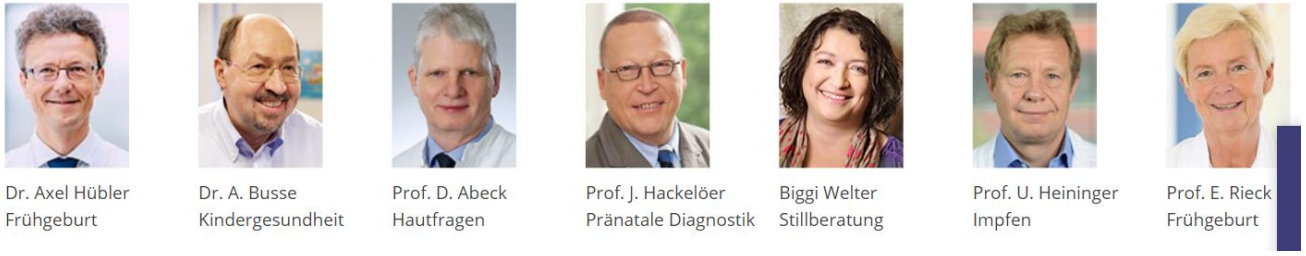
My child (3-10 years)

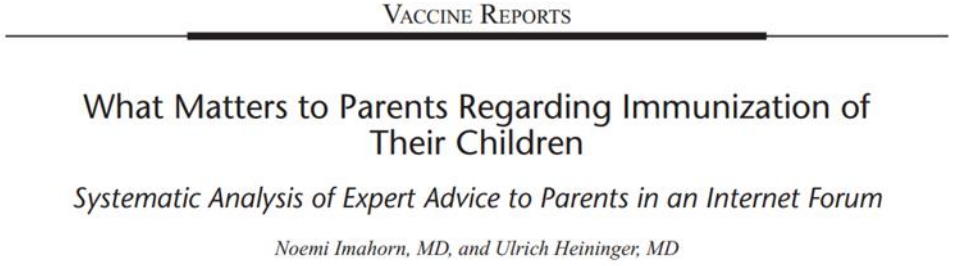
My pre-teen or teen (11-18 years)

# Answering questions from public

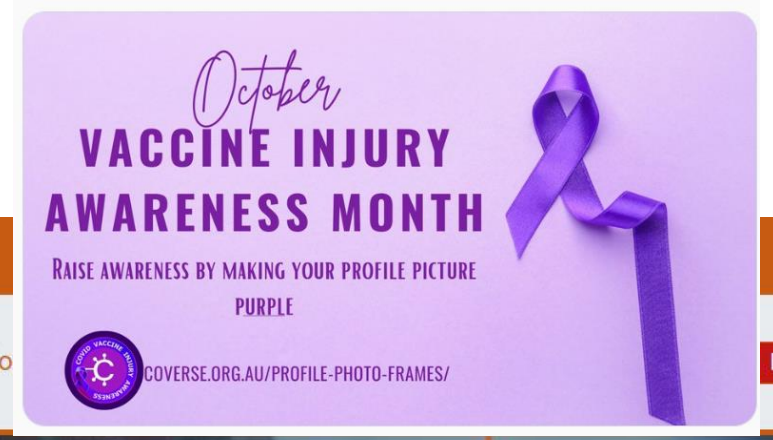



Wir sind für dich da: Unsere 50 Experten antworten auf deine Fragen - persönlich und kostenlos



# Engagement with communities




CoVerse

Home | About Us | For Patients | For Family | For Do | Donate

**COVERSE is the only non-profit organisation in Australia run by and for people who have suffered a significant adverse reaction following their COVID-19 vaccination.**

**Science-led, patient oriented, and invested in the integrity of our health system, we are the peak body representing COVID-19 vaccine-injured Australians.**

This website is the central hub for our advocacy. It also provides patients and health professionals with information about COVID-19 vaccine injuries, and leading edge insights on how to treat them.

**Register with us...**

... to become part of our community and to help establish independent data that supports our efforts.

## Latest News

Long-term adverse effects
10th October 2023

New Matilda does vaccine injuries
18th September 2023

UK Covid-19 Inquiry begins
14th September 2023

Australians speak out about vaccine harms
28th July 2023

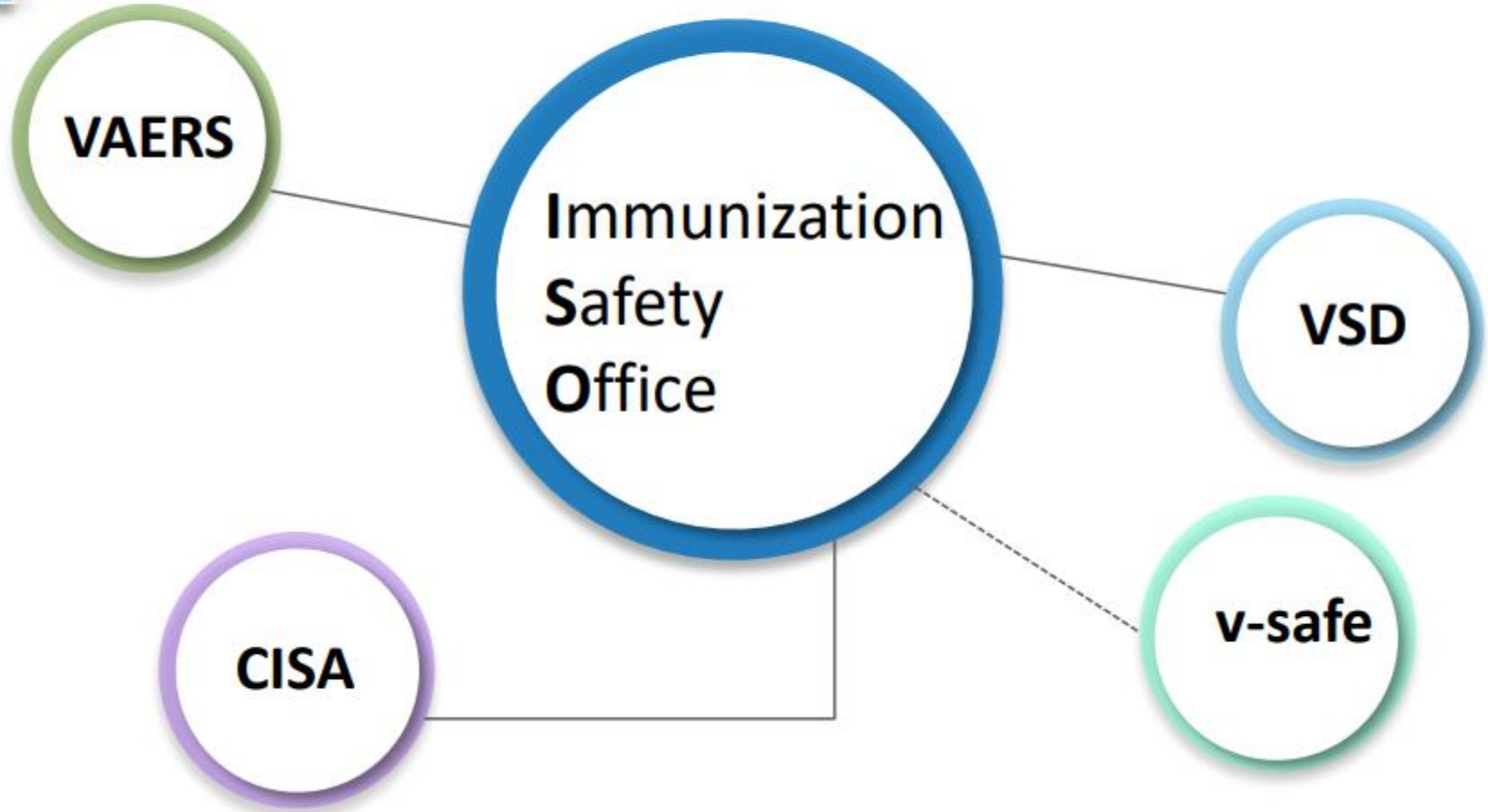
Growing recognition of Post Vaccine Syndrome
4th July 2023

more news...

**download our government submission**

# Public recruitment for vaccine safety research

# CDC vaccine safety monitoring*



# US CDC and Immunization safety = centrally coordinated

## CDC's Immunization Safety Office conducts four primary vaccine safety activities:

### Vaccine Adverse Event Reporting System (VAERS)
An early warning system that helps CDC and FDA monitor problems following vaccination. Anyone can report suspected vaccine reactions and issues to VAERS.

### Vaccine Safety Datalink (VSD)
A collaboration between CDC and several health care organizations that allows ongoing monitoring and proactive searches of vaccine-related data.

### Clinical Immunization Safety Assessment (CISA) Project
A partnership between CDC and several medical centers that conduct clinical research on vaccine-associated health risks in certain groups of people.

### Emergency Preparedness for Vaccine Safety
In the event of a disease outbreak in which a mass vaccination campaign is needed, CDC activates emergency preparedness activities to ensure that vaccines remain safe.

➡ V-safe (active surveillance)

Vaccine safety coordinators

# Vaccine safety surveillance in USand Australia

| | US ISO | Australia |
|---|---|---|
| Passive surveillance | VAERS | TGA based national but state collected |
| Active surveillance | V-safe | AusVaxSafety |
| Active hospital based | Variety of networks | PAEDS |
| Vaccine safety data linkage | VSD | State based only<br>National – in development |
| Specialist immunization clinics | CISA | AEFI CAN |
| No fault injury compensation | VICP | COVID vaccine only |

National immunisation safety office within Australia's CDC

# COVID's impact to childhood vaccination

unicef | for every child

ACT

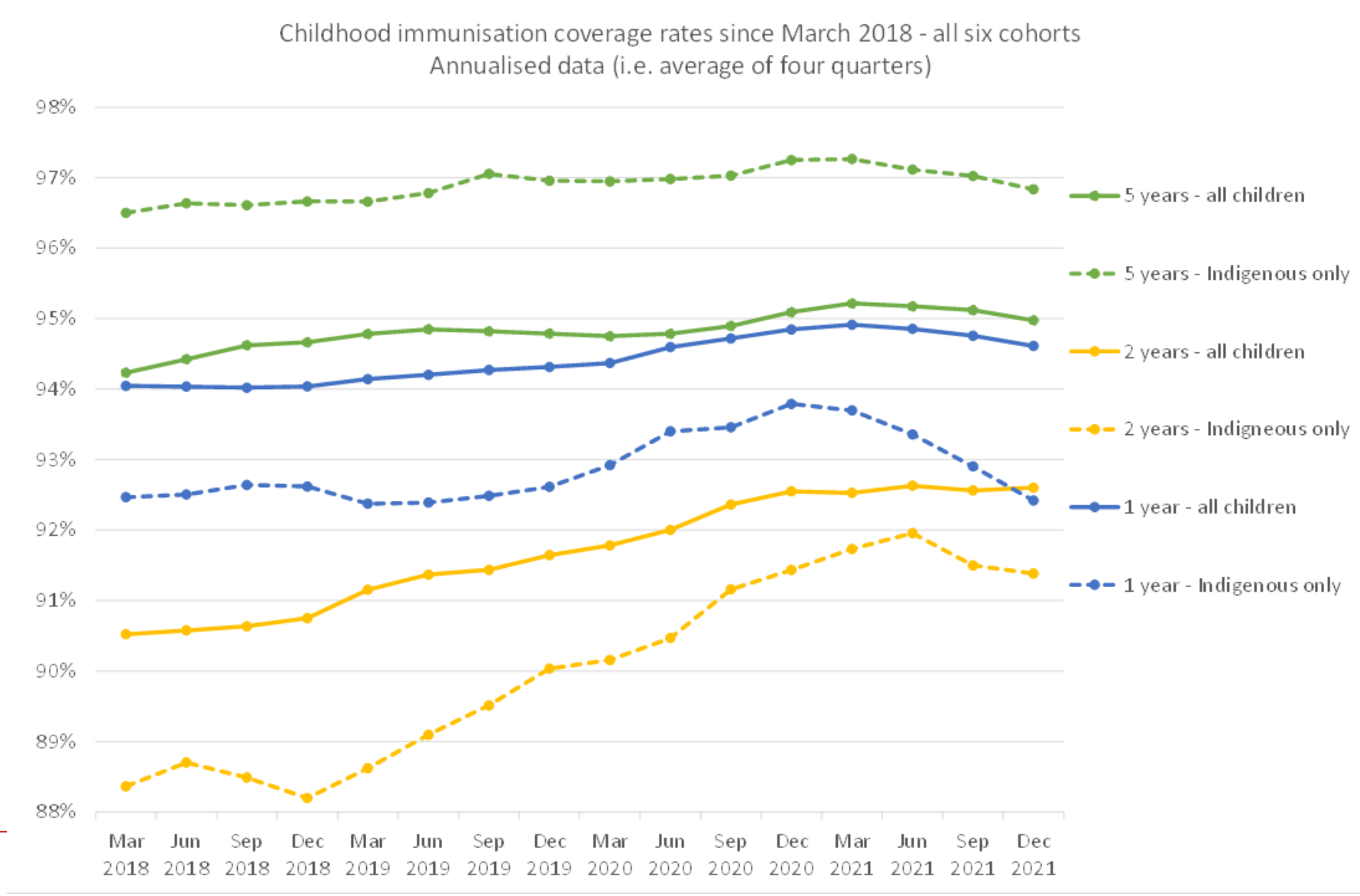
Press release

## COVID-19 pandemic leads to major backsliding on childhood vaccinations, new WHO, UNICEF data shows

*23 million children missed out on basic childhood vaccines through routine health services in 2020, the highest number since 2009 and 3.7 million more than in 2019*

15 July 2021

# National immunisation coverage rates



# Take home messages

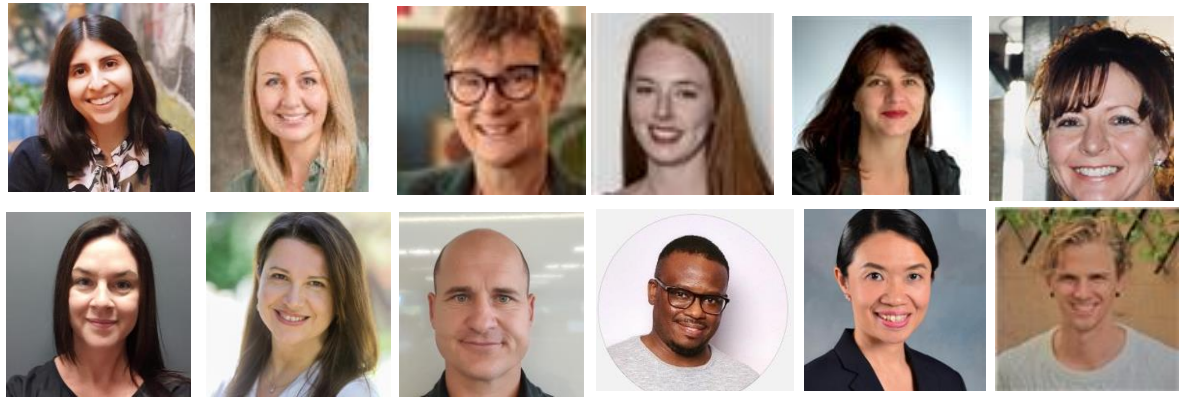
- Vaccine safety surveillance and reporting = essential role of primary health care

- Your input has national and international significance
  - Supports confidence and coverage
  - Understanding the risk
  - Define treatment and outcomes
  - Research

- Especially important when new vaccines introduced or used more widely
  - Shingrix
  - RSV
  - Japanese encephalitis
  - Vaxelis

# Acknowledgements and thanks!

- **NSW MoH staff**



Jo Sutherland, Sarah Khanlari, Isis Maitland Scott, Huei Ming Liu, Dunja Vecic, Patrick Anastassiadis, Angela Stuart, Danielle Kerrigan, Louise Baker, Sonya Ennis, Mareeka Hair, Eve Wu, Winifred Li, Jocelyn McRae, Jinxia Liu, Alyson Tulloch, Moniek, Borsovszky, Rohan Langstaff, Leonard Ncube, Melissa Hopkins, Katherine Cox, Thanjira Jiranantakan, Shawn Clackett

- **PHU staff**
- **AEFI expert panel co-chairs** - Victor Carey, David Durrheim

- **NSWISS team**
  - Lucy Deng, Rama Kandasamy, Emma Goeman, Archana Koirala, Ben Smith, Deidre Brogan, Ketaki Sharma, Sabira Shresthra, Deepali Thosar

- **Expert panels**
  - Vivien Chen, Lisa Clarke, Danny Hsu, Jenny Curnow, John Worthington, Andrew Bleasel, Richard Lindley, Hugo Morales, Darshi Ramanathan, Cardiologists – Clara Chow

# Thanks for listening

# Questions?