

ADULT IMMUNISATION FORUM

2023

This event will start at 8:30am AWST

22 JUNE 2023

8:30AM–5:00PM AWST



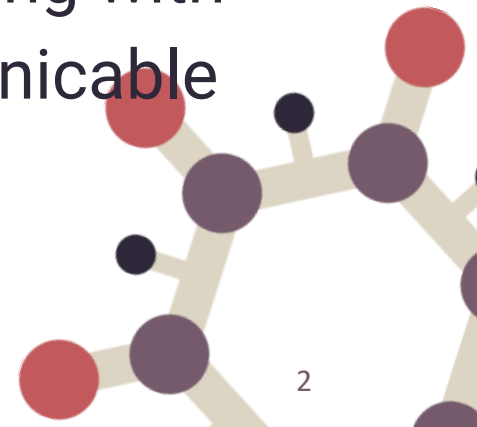
IMMUNISATION
COALITION

Vaccine Safety and VE

Lauren Bloomfield



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ACKNOWLEDGEMENT

May I first acknowledge the Wadjuk people of the Noongar nation, the traditional custodians of this land who are resilient in their custodianship

Let us celebrate their culture today and every day, and note how privileged we are to share this country

I pay my respects to elders: past, present and emerging

VACCINE SAFETY AND VE

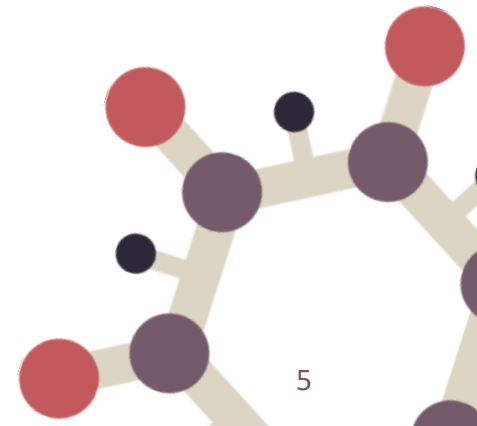
Today

- Understand the vaccine safety monitoring systems for adult vaccines in WA, including statutory reporting requirements
- Review the process for evaluating the effectiveness of vaccines

- How vaccine safety is monitored in WA
- Using data linkage to improve safety monitoring
- Assessing the effectiveness of vaccines



Vaccine safety



ADVERSE EVENTS FOLLOWING IMMUNISATION

An AEFI may be due to:

- A person's response to a vaccine
- conditions that may occur following the incorrect handling or administration of a vaccine
- coincidence, i.e. it would have occurred regardless of vaccination

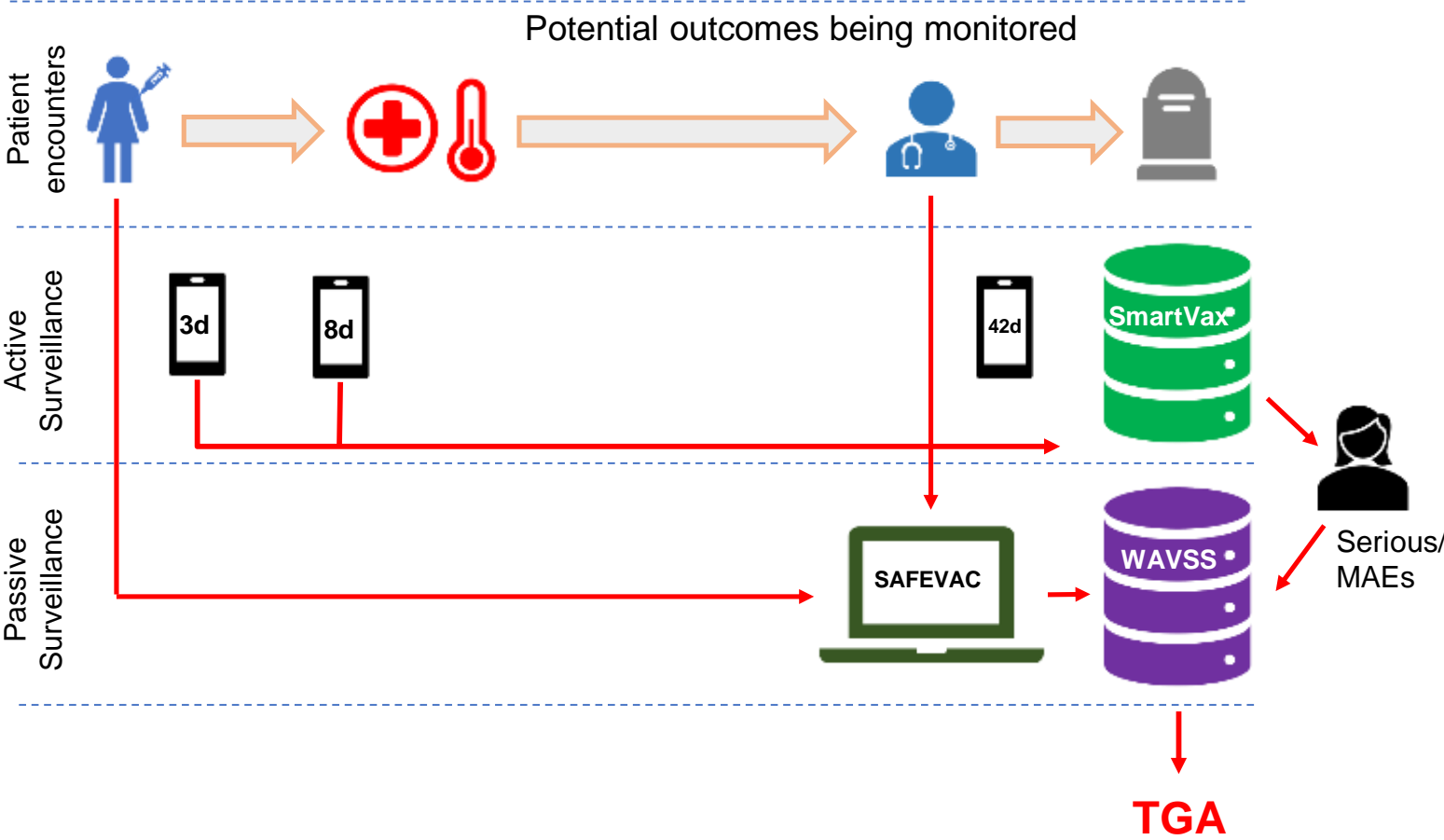
- Any event felt to be significant following immunisation should be reported, as well as a vaccination error
- You do not need to report common/minor/expected reactions, however any vaccine reaction which has affected the confidence of the vaccinee/family in future immunisation can and should be reported

- Any vaccinated individual, parents/guardians, immunisation providers or treating medical practitioner can report an AEFI to WAVSS

STATUTORY REQUIREMENTS

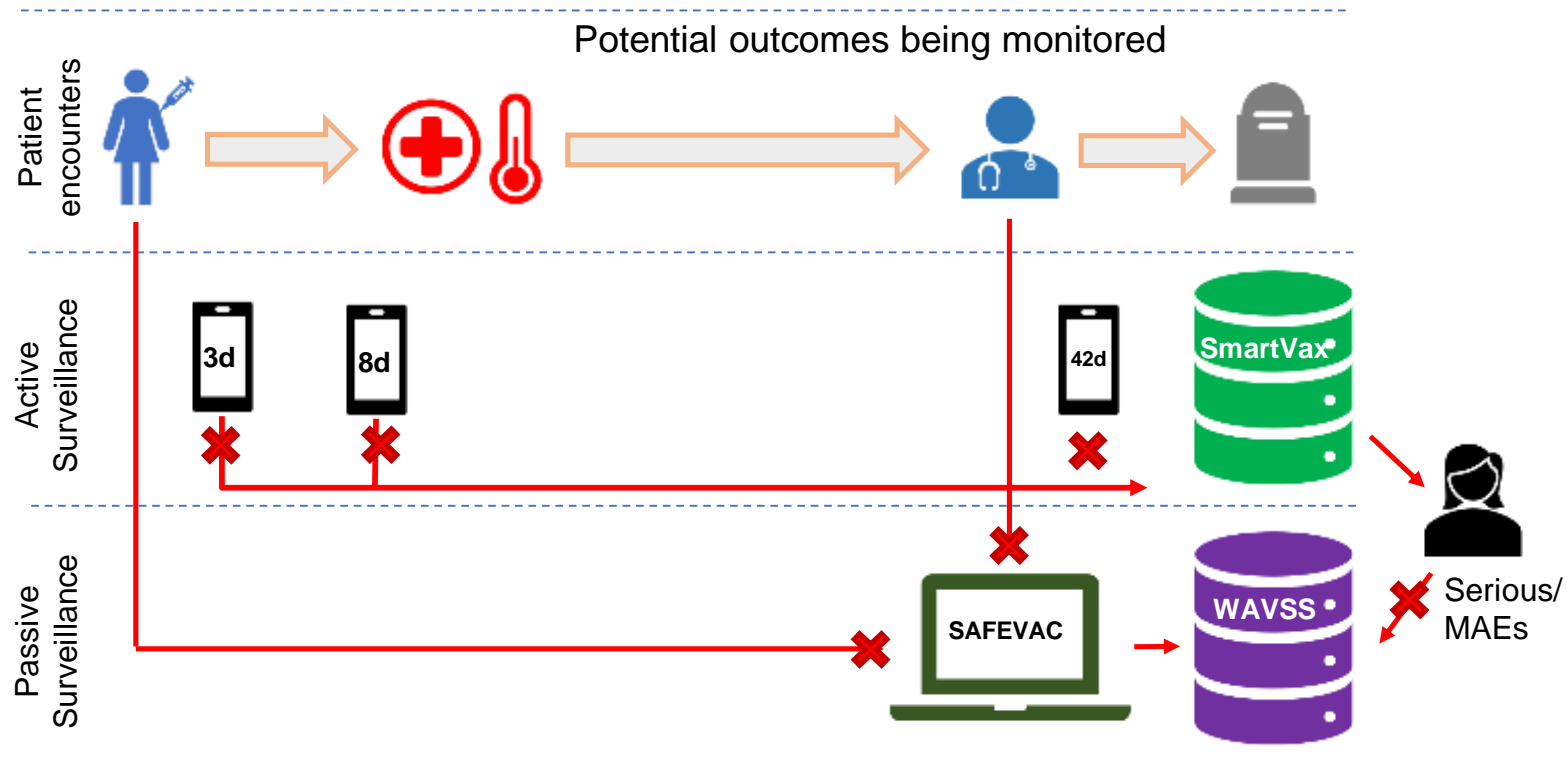
- Medical and nurse practitioners have a statutory responsibility to notify adverse events following immunisation (AEFI) to the Chief Health Officer, as per the requirements of the **Public Health Act 2016** and the **Public Health Regulations 2017**
- AEFIs may also be reported by
 - Other immunisation providers
 - Parents and guardians
 - Vaccinated individuals
- There is a central system that collects AEFI information in WA and reports to the TGA - Western Australian Vaccine Safety Surveillance (WAVSS) System

VACCINE SAFETY MONITORING WA



VACCINE SAFETY MONITORING WA

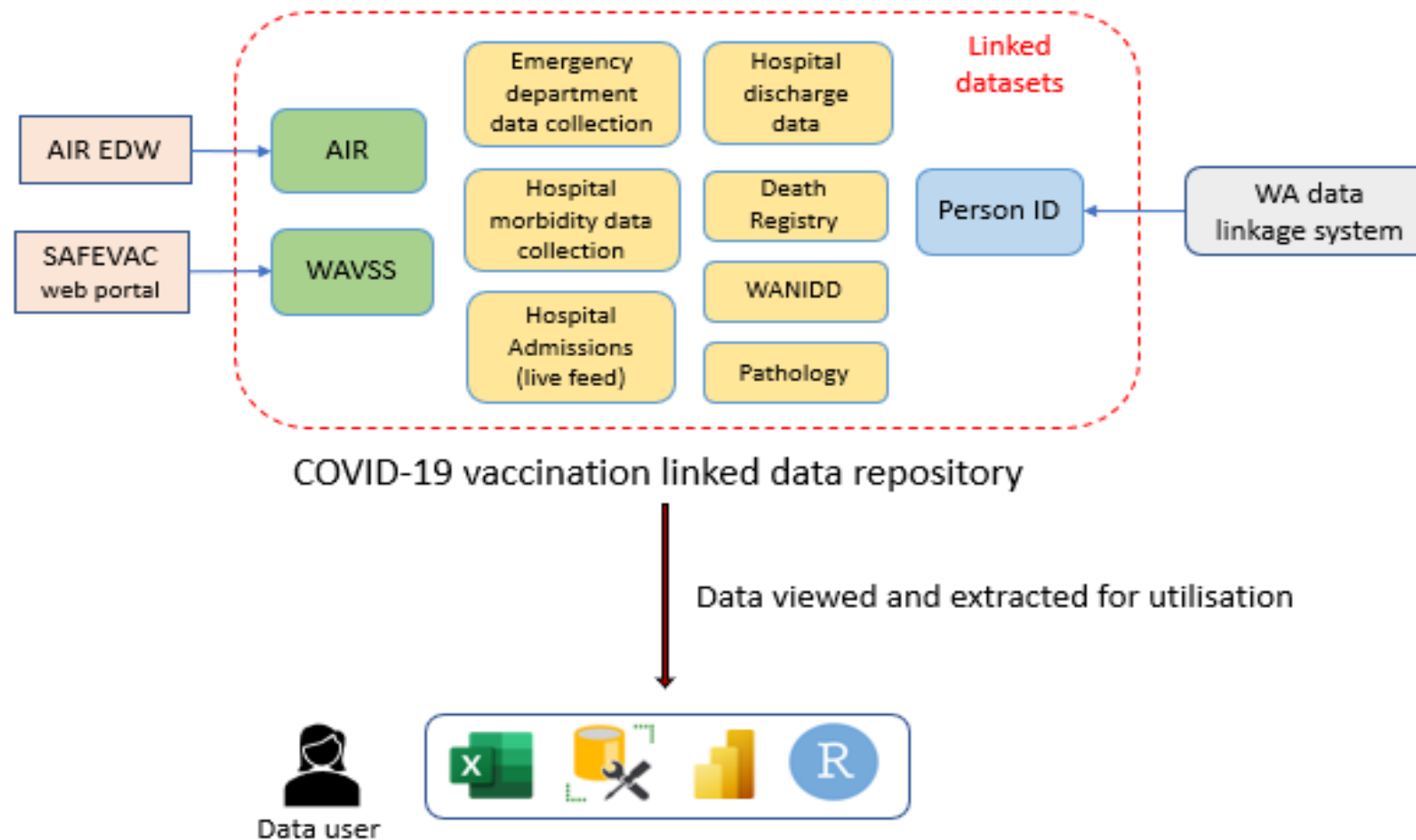
Potential gaps?



VACCINE SAFETY – DATA LINKAGE

- Data linkage is the process of connecting pieces of information that are thought to belong to the same person
- “Probabilistic” linkage means records are compared and “match scores” are assigned – records are linked when the scores pass a certain threshold of confidence.
- Most commonly used to analyse aggregate population/cohort data
- Using probabilistic linkage to analyse individual data carries the risk of error and requires appropriate validation
- WADLB have been doing linkage for the Department since 1995

VACCINE SAFETY – DATA LINKAGE



VACCINE SAFETY – DATA LINKAGE

- Not reliant on self or clinician report (all hospital contact post-vaccination)
 - Only covers the most serious events that **resulted in ED presentation or hospital admission**
 - Without initial clinician review, no preliminary determination of causation (proximal only) – ‘signal’
- Draws from existing data collections
- Covers almost the entire state
- Relatively timely (although some trade offs!)

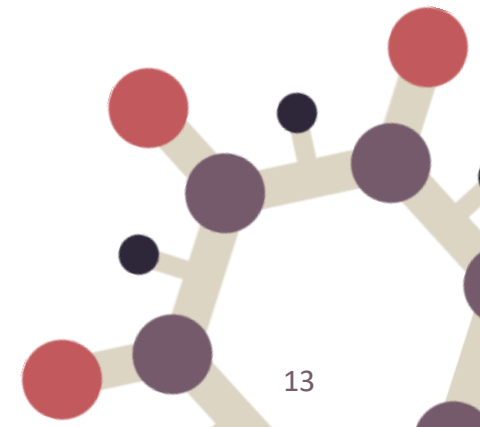
VACCINE SAFETY – DATA LINKAGE

Case finding

- Prospectively linking COVID vaccines for ICD-10-AM codes of interest
- Uses ED and admissions data (24 hrs - ~2 mo delays)
- Conditions of interest include TTS, myocarditis, pericarditis, GBS
 - Find cases with associated codes within X days of vaccination
 - Sent for clinician review
 - Entered into WAVSS if appropriate and managed via existing systems

	SAEFIs	AEFIs
TOTAL	562	12,751
<u>Active Surveillance</u>	114 (20%)	4,179 (33%)
Smartvax	37 (7%)	3,842 (30%)
- Smartvax cases also identified through Data Linkage	15 (3%)	380 (3%)
Additional cases by Data Linkage	77 (14%)	337 (3%)
<u>Passive Surveillance</u>	448 (80%)	8, 572 (67%)
- Cases also identified through Data Linkage	199 (35%)	483 (4%)

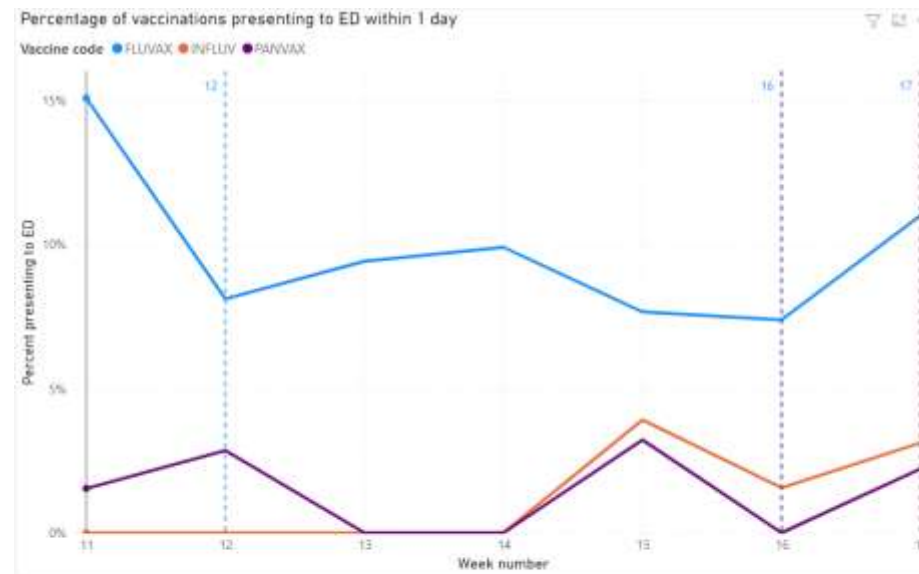
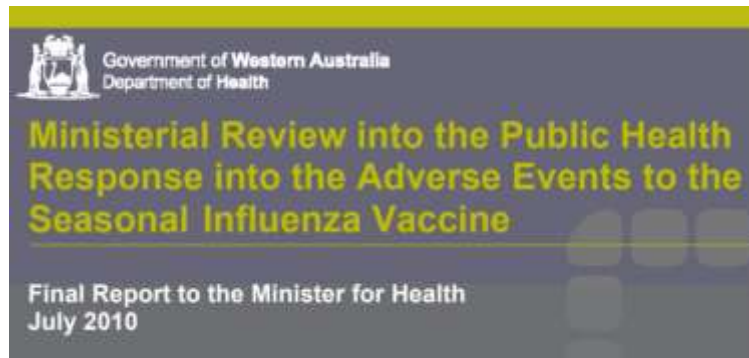
*Percentages are of the Total number of SAEFI or AEFI



VACCINE SAFETY – DATA LINKAGE

Proportional ED presentations

- Looking at the proportion of vaccinees who present to ED within ‘X’ days
- Validated using Fluvax 2010 data
- Currently being used for flu



Week 11 [08/03/2010] - Distribution of vaccines
Week 12 [19/03/2010] - Official launch of vaccine program
Week 16 [12/04/2010] - ED clinicians note increase in ED presentations for fever etc.
Week 17 [22/04/2010] - Temporary suspension of WA program
Week 17 [23/04/2010] - Suspension of 2010 Australia program

VACCINE SAFETY – DATA LINKAGE

Rapid cycle analysis (RCA)

- Used for newly introduced vaccines
- Detects a safety signal by comparing 'observed' vs 'expected' events
- Currently running for bivalent COVID vaccines (no signals detected)

VACCINE SAFETY – DATA LINKAGE

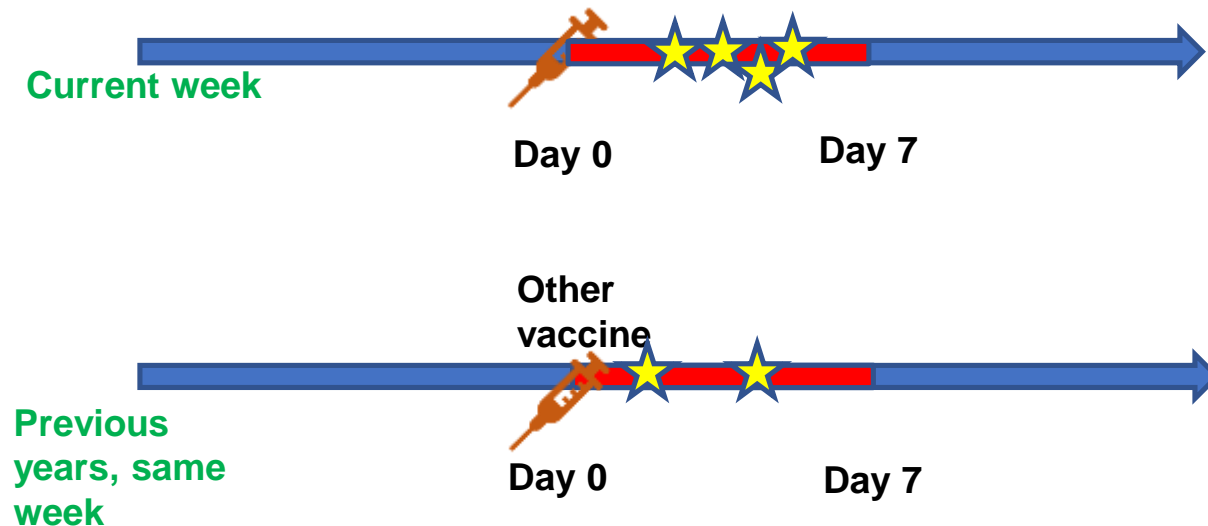
Rapid Cycle Analysis

Identify vaccine safety signals through linkage of AIR and ED data

Is there a higher rate of all-cause ED presentations within 0 to X days following vaccination compared to what we would expect?

Three main methods to identify 'expected' rate:

1. Historical rates



VACCINE SAFETY – DATA LINKAGE

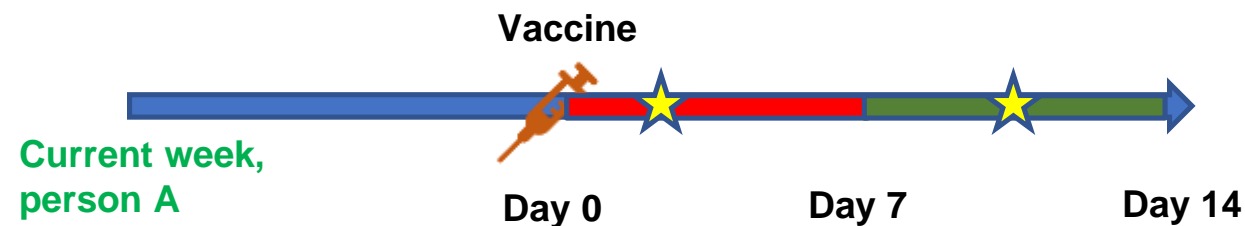
Rapid Cycle Analysis

Identify vaccine safety signals through linkage of AIR and ED data

Is there a higher rate of all-cause ED presentations within 0 to X days following vaccination compared to what we would expect?

Three main methods to identify ‘expected’ rate:

1. Historical rates
2. Self-control



VACCINE SAFETY – DATA LINKAGE

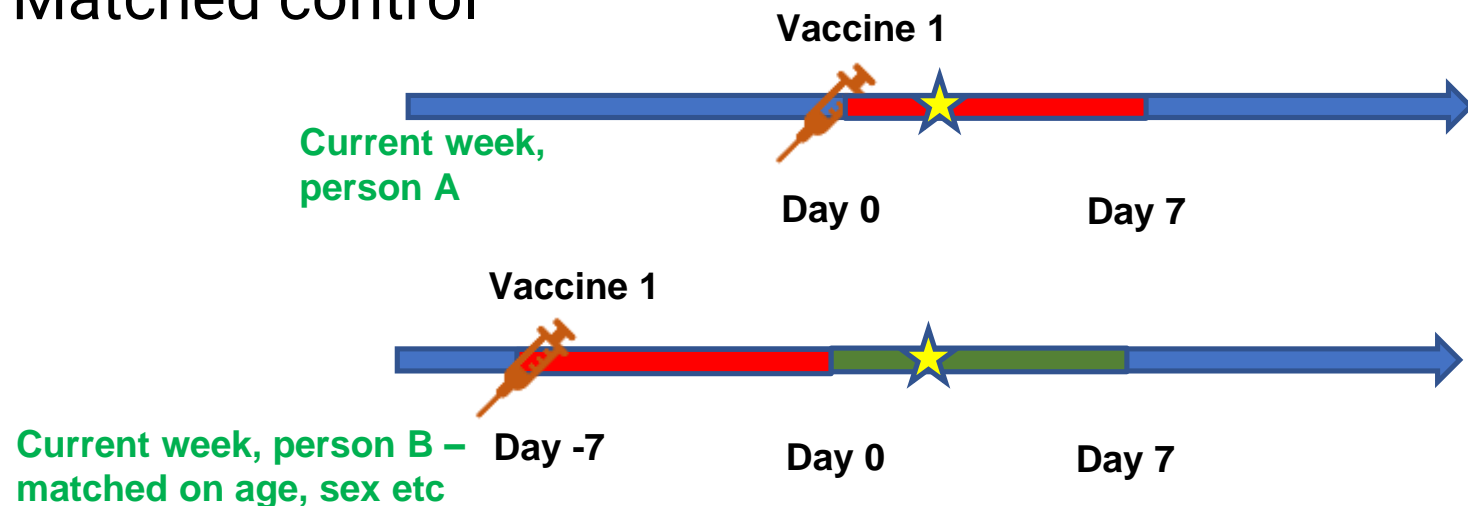
Rapid Cycle Analysis

Identify vaccine safety signals through linkage of AIR and ED data

Is there a higher rate of all-cause ED presentations within 0 to X days following vaccination compared to what we would expect?

Three main methods to identify ‘expected’ rate:

1. Historical rates
2. Self-control
3. Matched control

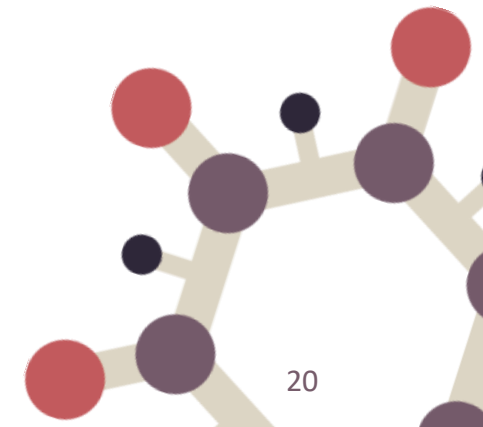


VACCINE SAFETY MONITORING

- Data linkage systems developed during COVID have increased local capacity to monitor signals
- A mix of passive and active surveillance currently being used to monitor for safety signals
- Active surveillance via data linkage does not cover events managed in primary care – **reporting via WAVSS still an integral part of surveillance!**
- Reports should be made to WAVSS via SAFEVAC
<https://www.safevac.org.au/>



Vaccine Effectiveness

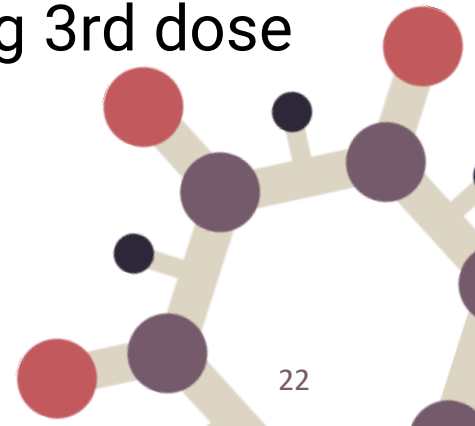


VACCINE EFFECTIVENESS

- Vaccine **efficacy** is the degree to which a vaccine prevents disease, and possibly also transmission, under ideal and controlled circumstances – comparing a vaccinated group with a placebo group
- Vaccine **effectiveness** (VE) refers to how well it performs ‘in the real world’
- VE requires large sample sizes of people with
 - Known exposure status (vaccination history)
 - Known outcome status
- We have been able to link all COVID-19 vaccination (by brand) to pathology results, hospitalisation data and mortality data to assess VE in WA – a COVID-naïve population

COVID VE IN WA

- As of 1 Feb 2022, very few cases of community transmission
- From over 2 million tests since 1 Jan 2020
 - ~1700 confirmed cases diagnosed locally
 - 34 of these designated as being acquired in WA
- Test-negative design; cases (PCR-positive) and controls (PCR-negative) were matched 1:1 on key demographics and week of test.
- $VE = (1 - aOR) * 100$ (adjusted w/ conditional regression c/o matching)
- 188,950 cases and 188,950 controls included in analysis
- Effectiveness against breakthrough infection wanes over time
- Effectiveness against severe disease (hosp. and death) following 3rd dose shown to be **>80%**



COVID VE IN WA

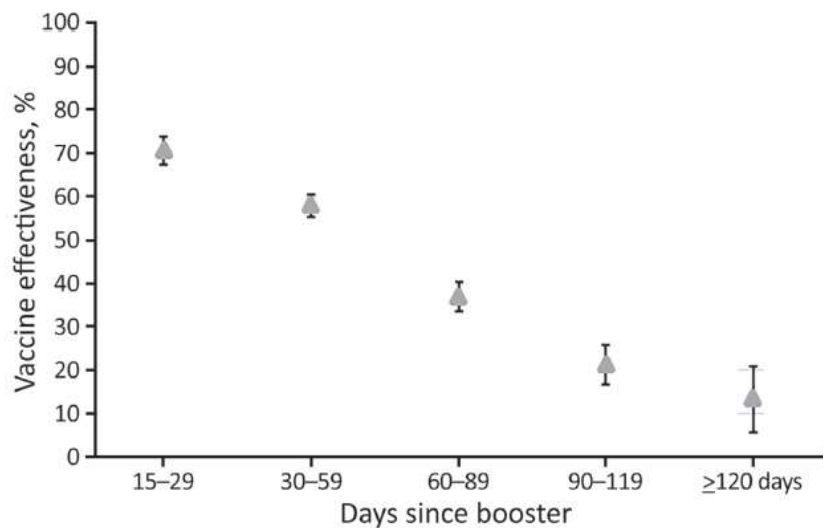


Figure 4. Vaccine effectiveness against breakthrough infection of any severity, by time since first booster dose versus unvaccinated controls, Western Australia, Australia, February 1–May 31, 2022. Error bars indicate 95% CIs.

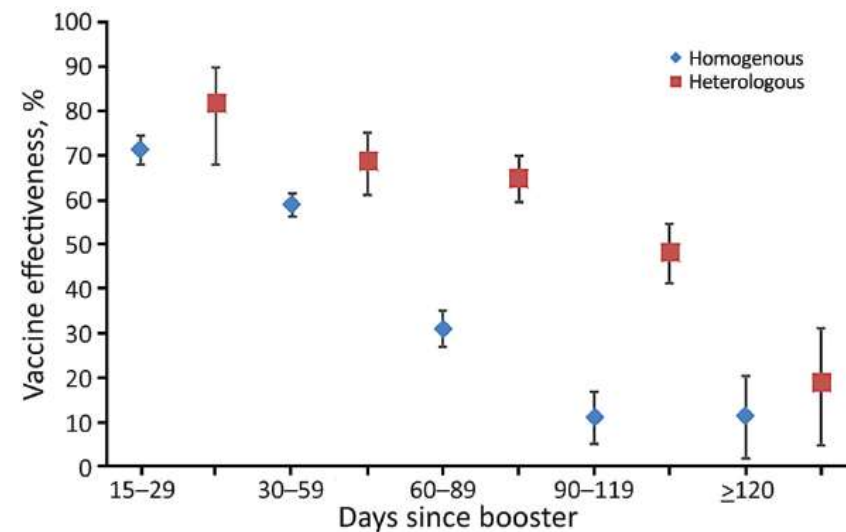
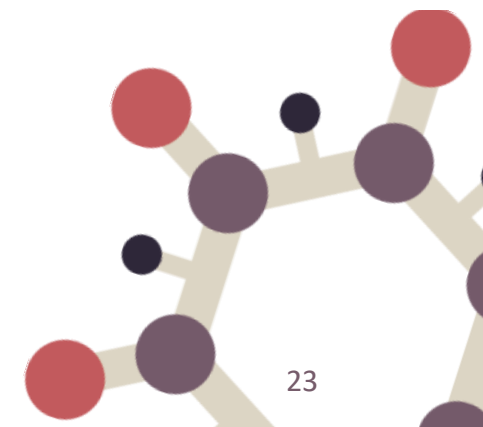


Figure 5. Vaccine effectiveness against breakthrough infection of any severity, by time since booster vaccination, for homologous (all mRNA vaccines) versus heterologous (ChAdOx1 primary, mRNA booster) vaccination series, Western Australia, Australia, February 1–May 31, 2022. Error bars indicate 95% CIs.



VACCINE SAFETY AND VE – FUTURE

- Safety signals and data linkage – incorporate into ‘BAU’ and continue case finding and RCA for ‘new’ vaccines e.g.
 - Seasonal flu
 - RSV
 - Shingrix
- VE for seasonal influenza – propose to compare three methods
 - Retrospective cohort
 - TND (PathWest only)
 - Test-ORV+ (Flu, COVID, RSV)

THANK YOU

WA Health Linkage for Immunisation

- Gemma Cadby
- Sera Ngeh
- Paul Effler

Data Linkage

WA Health Data Linkage Team, Death Registrations, COVID-19 Pathology Data Collection, Hospital Morbidity Data Collection, and AIR for providing linked health data

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THANK YOU

Thank you to our speakers and the audience for engagement and questions.

The next / final event in our 2023 webinar series will be “*Title of Webinar*” on DATE, presented by Presenter Name, so make sure you **subscribe to the Immunisation Coalition Newsletters for more information.**

There will be a very short survey coming after the event closes and we look forward to hearing your feedback.

Good evening and stay safe.