



Government of Western Australia  
Child and Adolescent Health Service



# Western Australian Vaccine Safety Surveillance (WAVSS) system Clinical Pathway

Judy Mathews - CNM Immunisation Service PCH  
November 2023

Compassion

Excellence

Collaboration

Accountability

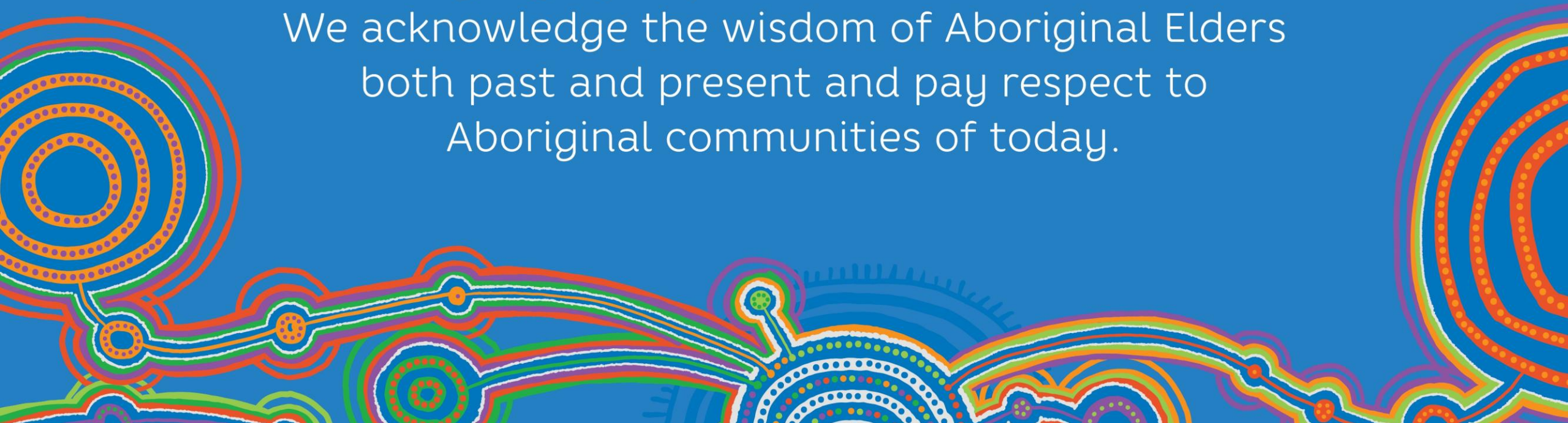
Equity

Respect

# Acknowledgement of Country

The Child and Adolescent Health Service acknowledge Aboriginal people of the many traditional lands and language groups of Western Australia.

We acknowledge the wisdom of Aboriginal Elders both past and present and pay respect to Aboriginal communities of today.



# History of WAVSS & CAHS

- WAVSS established in 2011 to better track AEFIs in response to H1N109 vaccine reactions causing febrile seizures
- Reporting to DOH with clinical follow up at PMH
- Clinical follow up mostly children on NIP (~30/month) so in 2019, WAVSS moved from DOH to PCH



# WAVSS

## Objectives & Outcomes

- What is the function of WAVSS?
- What is an AEFI?
- How does WAVSS receive reports?
- What is the clinical pathway for management of reports?



# WAVSS Function

WA Vaccine Safety Surveillance (WAVSS) system is a state-wide comprehensive surveillance system that allows close monitoring of adverse events following immunisation (AEFI) including uncommon AEFI, safety signal detection, and causality assessment of severe AEFI (SAEFI) and adverse events of special interest (AESI).



# Adverse Event Following Immunisation

- An AEFI is any unwanted or unexpected event that follows immunisation and does not necessarily confirm a causal relationship to vaccine administration.
- AEFI also includes incorrect handling or administration of a vaccine.
- Most adverse events are mild, such as low-grade fever, and pain or redness at the injection site. These should be anticipated and do not require reporting.



# Mechanisms to report to WAVSS

## Passive and Active reporting

- Reports can be submitted via the online portal SAFEVAC at any time.
- Members of the public can report AEFI that they, or a child/family member have experienced.
- Passive reports are also received from immunisation providers, health care providers and reports received directly by the TGA.
- Immunisation providers and medical practitioners in WA have a statutory requirement to report AEFI to the WA DOH through WAVSS (Public Health Act 2016<sup>1</sup> and the Public Health Regulations 2017<sup>2</sup>).
- Active reporting methods include “SmartVax” and data linkage repositories.

1. “Public Health Act 2016”, Government of Western Australia, [https://www.legislation.wa.gov.au/legislation/statutes.nsf/main\\_mrtitle\\_13791\\_homepage.html](https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13791_homepage.html)

2. “Public Health Regulations 2017”, Government of Western Australia, [https://www.legislation.wa.gov.au/legislation/statutes.nsf/law\\_s49088.html](https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_s49088.html)



# SAFEVAC Reporting

- Health professionals and the public can report a possible AEFI using the online portal at the SAFEVAC website <https://www.safevac.org.au/>
- Click on the Register tab if this is the first time using the system or the Log in tab if you have already registered.
  - Security code will be sent to your nominated number
- Collecting as much information at the time of reporting ensures early detection of possible problems with vaccines or systems.
- WAVSS provides advice to clinicians regarding AEFIs but does not provide acute management advice to patients.





# Possible serious AEFI

A serious AEFI (SAEFI) is defined as an event that<sup>3</sup>:

- results in death
- is life threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- results in a congenital anomaly/birth defect

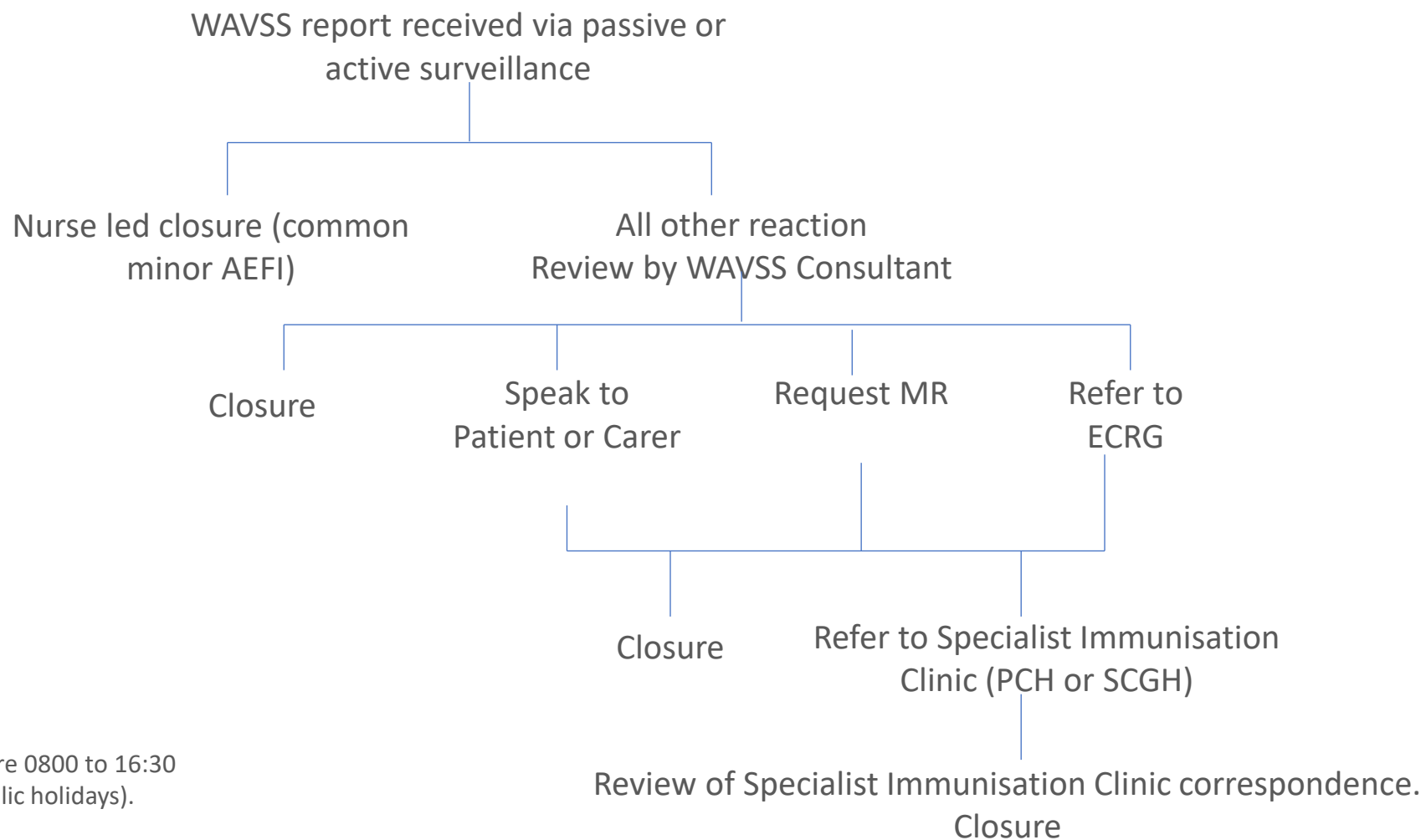
or

is deemed medically serious by WAVSS clinicians.

3. CIOMS/WHO Working Group on Vaccine Pharmacovigilance, Definition and application of terms for vaccine pharmacovigilance (Geneva: Council for International Organizations of Medical Sciences, 2012), [https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/cioms\\_report\\_wg\\_vaccine.pdf](https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/cioms_report_wg_vaccine.pdf)



# Clinical Workflow for WAVSS team



\*WAVSS team operating hours are 0800 to 16:30  
Monday to Friday (excluding public holidays).

# WAVSS Team

- Based at PCH
- 1 CNM, and pool of CNs and RNs who review reports
- Admin support
- Medical oversight from GP, Infectious Diseases and Immunology Specialists
- Complex cases discussed by ECRG in monthly meeting



# Expert Clinical Reference Group (ECRG)

- ECRG is a specialist subcommittee of the WA Vaccine Safety Advisory Committee (WAVSAC).
- It is comprised of clinicians with expertise in vaccine safety, public health and other specialities related to AEFI.
- The group reviews all serious AEFI, safety signals, other surveillance issues and relevant clinical and research updates.



# Specialist Immunisation Clinic

- Specialist Immunisation Clinics are available at PCH and SCGH via CRS and eReferrals systems.
- Clinicians review the AEFI and assign causality based on World Health Organization (WHO) criteria<sup>4</sup> and provide further vaccination advice.
- All correspondence is then reviewed by WAVSS staff for SAFEVAC report closure, auditing and data collection purposes.

# National Collaborations

- WAVSS Clinicians meet regularly with vaccine safety teams from other jurisdictions to discuss:
  - Safety signals, SAEFI, AESI and unusual cases
  - Surveillance processes
  - Research collaborations
- Formal groups established for this purpose are:
  - TGA Jurisdictional Immunisation Coordinator (JIC) meeting (monthly)
  - AEFI-CAN (AEFI-Clinical Assessment Network) meeting (monthly)

