SESLHD BUSINESS RULE SESLHDBR/096

Name	Reporting of notifiable Adverse Events Following Immunisation (AEFI) – local reporting process for COVID-19 Vaccination		
What it is	An outline of the process for the local reporting and escalation requirements for those who present with a serious reportable adverse reaction following COVID-19 vaccination		
Risk Rating	High	**Review Date**	June 2024
What it is not	It is not a guide to the appropriate clinical management for patients who present to South Eastern Sydney Local Health District (SESLHD) facilities with an adverse event following COVID-19 vaccination.		
Who it applies to	This business rule applies to all staff who are responsible for treating patients who present to SESLHD facilities with a serious reportable adverse reaction following COVID-19 vaccine (up to 42 days post).		
Why the rule is necessary	Vaccine safety surveillance in Australia aims to monitor vaccine program safety and to detect population specific, rare, late–onset or unexpected adverse events. In response to the COVID-19 global pandemic, an enhanced surveillance process has been implemented as a result of the rapid rollout of the COVID-19 vaccination program across Australia. The agency responsible for this process is the Therapeutic Goods Administration (TGA), who are required to monitor and respond to any emerging safety concerns relating to the COVID-19 vaccines. In particular, any adverse events following immunisation (AEFI). Whilst the reporting process to the TGA is well defined, SESLHD facilities do not currently have a clearly documented and consistent process for reporting patients who present to our facilities with suspected serious AEFI related to the COVID-19 vaccine. This highlights a number of risks, most notably, delayed investigation or missed reporting of AEFI to the TGA. The National COVID-19 Vaccination Program is increasing momentum, with thousands of Australians being vaccinated against COVID-19 each day. This highlights the importance of rapidly detecting and reporting this data, in an effort to keep our community safe and to identify any emerging at risk groups. For this reason, a district wide framework for local reporting and escalating AEFI relating the COVID-19 vaccine is imperative.		
Background	As at June 2021, two COVID-19 Vaccines have been approved for use by the TGA, including: - COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE (Pfizer) - COVID-19 Vaccine AstraZeneca (ChAdOx1-S)		

	As with any vaccine, there are a number of common and expected reactions in the 72 hours following vaccine administration, such as fever, injection site reaction, headache, myalgia or lethargy. It is **not** necessary to report these to the Public Health Unit. Clinicians or patients may report common, expected reactions directly to the TGA. Any serious or unusual reactions to COVID-19 vaccination **must** be reported to the Public Health Unit. Serious AEFIs include events that: - Result in death - Are life-threatening - Require hospitalisation - Result in persistent or significant disability - Are unexpected reactions for that vaccine. Patients presenting with the following significant but rare syndromes following vaccination must also be reported: - disorders of clotting and haemostasis - anaphylaxis - Bell's palsy - persistent lymphadenopathy - other new onset neurological disorder
When to use it	This business rule should be used for scenarios where a patient presents to a SESLHD facility or is an in-patient with a suspected or confirmed serious adverse event following COVID-19 vaccination administration (up to 42 days post)
How to use it	The following steps outline the local process for reporting a suspected or confirmed **serious** AEFI relating to the COVID-19vaccine. The process should be followed by staff across SESLHD facilities who may be presented with this scenario. **For suspected Thrombosis with Thrombocytopenia Syndrome (TTS), death or other life-threatening event** suspected to be related to COVID-19 vaccination: 1. Admitting Medical Officer/ Medical Officer in Charge to telephone the Public Health Unit on 9382 8333 from 08:30 to 20:00 hours; outside of hours contact PHU On Call via Prince of Wales Hospital (POWH) switch or Staff Specialist on 0418 843 120 2. Complete the NSW Health AEFI notification form, or have required information available for PHU. Form to be submitted to the SESLHD Public Health Unit via SESLHD-PublicHealthUnit-IDOpsLead@health.nsw.gov.au. 3. Admitting Medical Officer/ Medical Officer in Charge to notify Nurse Manager/AHNM 4. Nurse Manager to notify facility Executive/Executive On Call 5. Treating team to document incident via IMS+ with reference to AEFI and details of the type of COVID-19 vaccine (type, dose (1 or 2), date administered etc.). QRG Notifying a Vaccine Related Incident in ims+. Location in IMS+ should be the Department/Ward at the facility where adverse event identified.

	6. PHU will investigate the event and advise the Ministry of Health via MOH- covidaefi@health.nsw.gov.au. In turn, the Ministry will notify the TGA.

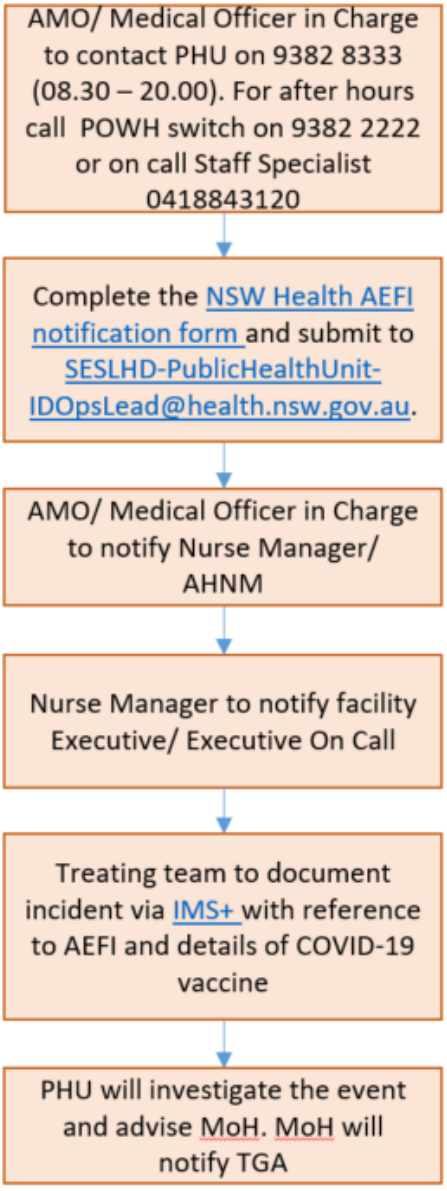
	For other serious events related in time to COVID vaccination e.g. anaphylaxis, new onset neurological symptoms, or any other serious illness that develops within six weeks of COVID vaccination: 1. Admitting Medical Officer/ Medical Officer in charge to complete the NSW Health AEFI notification form. Form to be submitted to the SESLHD PHU via SESLHD-PublicHealthUnit-IDOpsLead@health.nsw.gov.au within 24 hours of recognition. 2. Admitting Medical Officer/ Medical Officer in charge to notify Nurse Manager/AHNM 3. Nurse Manager to notify facility Executive team 7. Treating team to document incident via IMS+ with reference to AEFI and details of the type of COVID-19 vaccine (type, dose (1 or 2), date administered etc.). QRG Notifying a Vaccine Related Incident in ims+. Location in IMS+ should be the Department/Ward at the facility where adverse event identified. 4. PHU will investigate the event and advise the Ministry of Health via MOH- covidaefi@health.nsw.gov.au. In turn, the Ministry will notify the TGA.
Who is responsible	This outlines the actions that are required of those responsible for enacting this business rule.
Functional Group(s)	Infection Control, Clinical Governance
Executive Sponsor	Dr. Marianne Gale, Director Population and Community Health, SESLHD
Author	Dr. Vicky Sheppeard, Director Public Health Unit, SESLHD

Revision and Approval History

Date	Revision Number	Author and Approval
July 2021	1	Approved by Dr Marianne Gale, Director Population and Community Health, SESLHD.
July 2021	1	Published on Draft for Comments page. No feedback received.
August 2021	2	Final version approved by Executive Sponsor.
September 2021	2	Approved at Quality Use of Medicines Committee meeting noting 'will require update when Modern vaccine available.'
November 2021	2	Approved at October Clinical and Quality Council meeting.

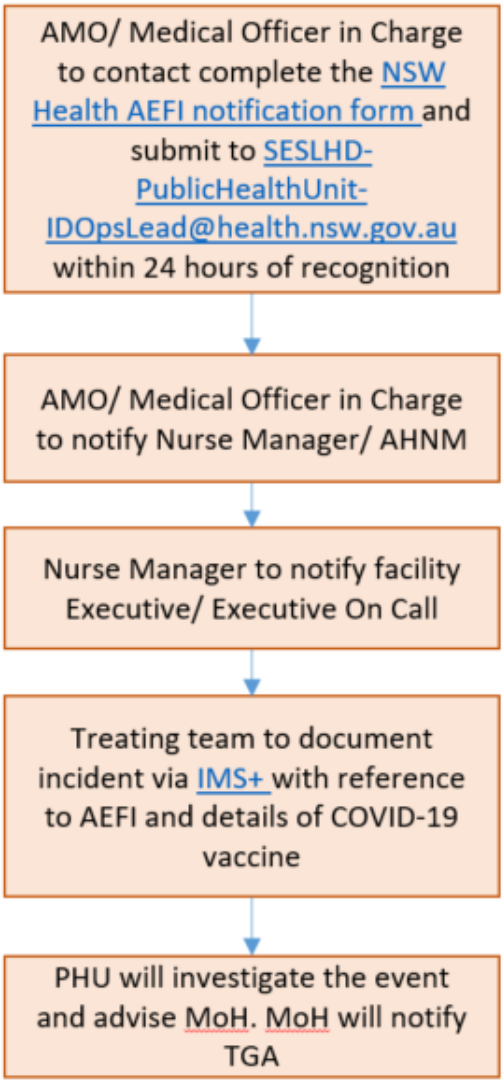
APPENDIX A:

Flowchart for reporting suspected Thrombosis with Thrombocytopenia Syndrome (TTS), death or other life-threatening event suspected to be related to COVID-19 vaccination:



APPENDIX B:

Reporting of other serious events related in time to COVID vaccination e.g. anaphylaxis, new onset neurological symptoms, or any other serious illness that develops within six weeks of COVID vaccination



APPENDIX C: NSW Health Adverse Event Following Immunisation (AEFI) Form

COVID-19 vaccine:

NSW Health adverse event following immunisation case notification form

Instructions

- This form has been designed to collect initial clinical information regarding an Adverse Event Following Immunisation (AEFI) related to COVID-19 vaccination.
- The information provided will be used to investigate the reported adverse event following immunisation and will be reported to the Therapeutics Goods Administration to support vaccine safety surveillance.
- The form should be completed by a health professional and submitted by email on MOH-covidaefi@health.nsw.gov.au. Alternatively, cases can be notified by phone to the local Public Health Unit on **1300 066 055**.
- The Public Health Unit may contact you during business hours for further information regarding this case notification.

Vaccinated person's details		
Surname		
First name		
Date of birth		
Age		
Gender	Male	☐
	Female	☐
	Other	☐
Street address		
Postcode		
Suburb		
State		
Phone number		
Aboriginal status: Is the person of Aboriginal or Torres Strait Islander origin?	☐ No ☐ Yes, Aboriginal ☐ Yes, Torres Strait Islander ☐ Yes, both Aboriginal and Torres Strait Islander	

Reporter details	
Surname	
First name	

Practice name (if relevant)		
Street Address		
Suburb		
Postcode		
Phone – Landline (incl. area code)		
Mobile phone		
Email address		
Fax		
Date of report		
Reporter type	Medical practitioner	☐
	Register nurse	☐
	Vaccinated person	☐
	Parent/guardian	☐
	Other (specify)	
Is the reporter the vaccination provider	No	☐
	Yes	☐

Vaccine details (if known)							
Vaccine (brand name)	Dose no.	Batch number	Date given	Time given	Route of administration	Injection site	
					IM ☐ SC ☐ ID ☐	RL ☐ RA ☐	LL ☐ LA☐
					IM ☐ SC ☑ ID ☐	RL ☐ RA ☐	LL ☐ LA☐

Adverse Event Details		
Date of onset		
Time of onset		
Description of events, including timeline		
Management of event (tick as many as apply)	None	☐
	Nurse assessment	☐
	GP assessment	☐
	Hospital emergency department	☐

	Hospital admission (specify number of days and date of discharge)		
	Unknown	☐	
	Other (describe)		
Please specify the treatment/care provided (e.g. antibiotics, adrenaline, advice, counselling, etc.):			
Outcome			
Have the symptoms resolved?	Yes (specify date and time resolved)	Date	
		Time	
	No (Symptoms are ongoing as of)	Date	
		Time	
		Describe	
	Unknown	☐	