Queensland Government

Post COVID-19 Vaccination Suspected Anaphylaxis Case Reporting Form

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

The Queensland Vaccine Command Centre (VCC) has developed this form to assist Public health Units (PHU) to capture details on anaphylaxis following COVID-19 vaccine administration, that are aligned to the Brighton Collaboration's Anaphylaxis Case definition. The Brighton Collaboration aims to standardise collection and assessment of immunization safety data to improve comparability of data across different data sources.

Please complete this form when reporting a **suspected anaphylactic reaction** following vaccination. The form should be completed by a health professional and submitted to the local PHU. This form is to be used in addition to a Queensland Government Adverse Event Following Immunisation (AEFI) form which all Queensland vaccine providers are required to submit under the *Public Health Act 2005* and the COVID-19 Vaccination Code.

The information provided will be used to investigate the reported AEFI and will be submitted to the Therapeutics Goods Administration to support vaccine safety surveillance.

Patient Details

Surname:	First name:
Date of birth:	Gender:
Address:	
Vaccine administered:	Date:

Risk History

1. Significant past medical history:
   ☐ Asthma ☐ Pulmonary disease ☐ Mastocytosis ☐ Thyroid disease ☐ Coronary artery disease
   ☐ Ischemic dilated cardiomyopathy ☐ Other *(specify)*:

2. Does the person have a history of acute illness prior to vaccination? ☐ Yes *(specify below)* ☐ No

3. Has the person had previous allergic reactions?
   ☐ Yes *(specify type and provide details of the name, date and details of reaction)* ☐ No
   a. Drugs (including vaccines):

   b. Food:

   c. Atopy (e.g. asthma, eczema or allergic rhinitis):

   d. Other *(specify)*:

DO NOT WRITE IN THIS BINDING MARGIN

POST COVID-19 VACCINATION SUSPECTED ANAPHYLAXIS CASE REPORTING FORM

v1.00 - 07/2021
SW1125

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Risk History *(continued)*

4. Details of any other potential exposures 24 hours before and after immunisation (e.g. foods, environmental):

5. Current medications (include blood thinners, steroids, diabetic medications, over the counter medications, inhalers, topical, eye drops, pain relievers, herbal medication). Include dose and frequency.
   If you have a medication list, please attach it to this form.

Adverse Event Following Immunisation Details

6. Date of COVID-19 vaccination: ..... Time of COVID-19 vaccination (24hr): .....

7. Date of onset of symptoms: ..... Time of onset of symptoms (24hr): .....

8. Was there a **sudden onset** of signs and symptoms? ☐ Yes ☐ No

9. Was there **rapid progression** of signs and symptoms? ☐ Yes ☐ No

10. Is the AEFI associated with an administration error? ☐ Yes *(specify below)* ☐ No

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Adverse Event Following Immunisation Details *(continued)*

Clinical Features

Body system	B. Major criteria	C. Minor criteria
11. Dermatologic/skin or mucosal	☐ Generalised urticaria (hives) ☐ Generalised erythema ☐ Angioedema* (general or localised including lip) ☐ Generalised pruritus with skin rash **Excluding hereditary angioedema*	☐ Localised injection site urticaria ☐ Red AND itchy eyes ☐ Generalised prickle sensation ☐ Generalised pruritus withOUT skin rash ☐ Other *(describe)*:
12. Respiratory (RESP)	☐ Bilateral wheeze (bronchospasm; by stethoscope) ☐ Stridor ☐ Upper airway swelling (tongue, throat, uvula, larynx) ☐ ≥2 indicators of respiratory distress: ◯ Tachypnea ◯ Cyanosis ◯ Grunting ◯ Chest wall retractions ◯ Increased use of accessory ◯ Respiratory muscles	☐ Persistent dry cough ☐ Hoarse voice ☐ Sensation of throat closure ☐ Sneezing *OR* rhinorrhoea ☐ Difficulty breathing withOUT wheeze or stridor ☐ Other *(describe)*:
13. Cardiovascular (CV)	☐ Measured hypotension Specify BP: ..... ☐ ≥3 signs of uncompensated shock: ◯ Tachycardia Specify rate: ..... ◯ Capillary refill >3 seconds ◯ Reduced central pulse volume ◯ Decreased level or loss of consciousness	☐ ≥2 signs of reduced peripheral circulation: ◯ Tachycardia ◯ Capillary refill >3 seconds ◯ Decreased level of consciousness ☐ Other *(describe)*:
14. Gastrointestinal (GI)	☐ None	☐ Nausea ☐ Diarrhoea ☐ Abdominal pain ☐ Vomiting
15. Laboratory	☐ None	☐ Elevated mast cell tryptase (> upper normal limit for laboratory doing test) Specify level: .....

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Management

16. Treatment provided:
    - ☐ Adrenaline (specify dose, frequency and route): .....
    - ☐ Oxygen
    - ☐ Other *(specify)*:

17. Investigations (if any):
    - ☐ Nil
    - ☐ Tryptase level (specify time from event to collection): .....
    - ☐ Other (specify and include time from event to collection where relevant):

18. Highest level of care:
    - ☐ GP assessment
    - ☐ Emergency department attendance
    - ☐ Hospital admission (specify dates): .....
    - ☐ Unknown
    - ☐ Other *(specify)*:

19. Details of last observation recorded – Date: ..... Time (24hr): .....

20. Outcome:
    - ☐ Full recovery
    - ☐ Recovered but symptoms ongoing
    - ☐ Death
    - ☐ Unknown

    Comments (include date of outcome if known):

21. Referred for further follow-up for future vaccinations?
    - ☐ Yes (specify where): ..... ☐ No

Completed by (print name):	Designation:	Signature:	Date:

Submit form | Reset form

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TGA or PHU Use Only: Level of Diagnostic Certainty

Level of certainty	Logic to reach level of certainty for anaphylaxis
Level 1, 2 and 3	Must meet both of the following criteria (if one or both not met, it is not a case – level 5): ☐ Sudden onset of symptoms/signs ☐ Rapid progression of symptoms/signs
Use the pattern of MAJOR and minor criteria met for skin, respiratory, cardiac and gastrointestinal (GI) systems and laboratory result from the table above to determine the highest level of diagnostic certainty (with level 1 > level 2 > level 3).	
Level 1	≥1 skin MAJOR *AND* (≥1 respiratory MAJOR *AND/OR* ≥1 cardiac MAJOR)
Level 2 *NOTE: 4 different ways to meet level 2.*	1. ≥1 skin MAJOR *AND* (≥1 respiratory minor *AND/OR* ≥ 1 cardiac minor)
	2. ≥1 respiratory MAJOR *AND* ≥1 cardiac MAJOR
	3. ≥1 respiratory MAJOR *AND* ≥1 minor from a different system (skin, cardiac, GI, lab)
	4. ≥1 cardiac MAJOR *AND* ≥1 minor from a different system (skin, respiratory, GI, lab)
Level 3 *NOTE: 2 different ways to meet level 3.*	1. ≥1 respiratory minor *AND* ≥1 minor from each of 2 different systems (skin, cardiac, GI, lab)
	2. ≥1 cardiac minor *AND* ≥1 minor from each of 2 different system (skin, respiratory, GI, lab)
Level 4	Reported anaphylaxis with insufficient evidence to meet any of levels of diagnostic certainty.
Level 5	**Not a case of anaphylaxis:** If unable to check 1.1 and 1.2 (i.e. onset not sudden and did not progress rapidly).

Event Meets Case Definition

☐ **Level 1:** Criteria as specified in the anaphylaxis case definition
☐ **Level 2:** Criteria as specified in the anaphylaxis case definition
☐ **Level 3:** Criteria as specified in the anaphylaxis case definition

Event Does NOT Meets Case Definition

☐ **Level 4:** Reported anaphylaxis with insufficient evidence to meet the case definition
☐ **Level 5:** Not a case of anaphylaxis

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The *Information Privacy Act 2009* sets out the ways in which a health agency can collect personal information for the purpose of reporting Adverse Events Following Immunisation (AEFI). Authorised Queensland Health staff may access the information for the purpose of clinical follow up and monitoring. Personal information will not be accessed by or given to any other person or organisation without permission unless permitted or required by law. For information about how Queensland Health protects personal information, or to learn about the right to access your own personal information, please see our website at www.health.qld.gov.au.
All reports are provided to the Therapeutic Goods Administration (TGA) to be entered into the TGA's Australian Adverse Drugs Reactions System (the ADRS). Information about how the TGA uses adverse event information that is reported is available at: www.tga.gov.au/safety/problem.htm.

Glossary of Terms	Source Gold et al (Vaccine 28, 2010)
Term	**Definition**
Accessory muscles	Muscles, primarily in the neck (sternocleidomastoid which elevates sternum; scalene group which elevates upper ribs) which assist but don't play a primary role in breathing. When used at rest they indicate a level of respiratory distress or increased work of breathing.
Angioedema	Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and usually not itchy. (Reported symptoms of "swelling of the tongue" or "throat swelling" should not be documented as angioedema unless there is visible skin or mucosal swelling). *NOTE: hereditary angioedema, usually with a history of recurrent episodes of swelling, should be excluded (affects 1 in 50,000).*
Capillary refill time	The time required for normal skin colour to reappear after a blanching pressure is applied for 5 seconds. Usually assessed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue indicated by a pink colour returning to the nail. It normally takes <3 seconds.
Cyanosis	A dark bluish or purplish discolouration of the skin and/or mucous membranes due to lack of oxygen in the blood.
Dry cough	Rapid expulsion of air from the lungs and not accompanied by expectoration/sputum (a non-productive cough).
Erythema	Abnormal redness of the skin without any raised skin lesions.
Generalised	Involving >1 body site – that is each limb is counted separately as is the abdomen, back, head and neck.
Grunting	A sudden and short noise with each breath when breathing out.
Hoarse voice	An unnaturally harsh cry in an infant or vocalisation in and adult or child.
Hypotension	An abnormally low blood pressure (BP) documented by appropriate measurement. For infants and children: age specific systolic BP <3–5th percentile *OR* >30% decrease from that person's baseline. For adults: Systolic BP of <90mmHg *OR* >30% decrease from that person's baseline.
In-drawing or retractions	Inward movement of the muscles between the ribs (inter-costal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing which results in increased use of 'accessory respiratory muscles' (sternocleidomastoid and intercostal).
Injection site urticaria	Urticaria which is continuous with the injection site or involves other aspects of the injected limb.
Localised	Involving one body site only.
Loss of consciousness	Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual or painful stimulus.
Mast cell tryptase	Inflammatory mediator released by mast cells during acute anaphylaxis. Typically levels peak between 15 and 120 minutes after onset; samples for measurement should be taken within 6 hours of onset of signs/ symptoms.
Prickle sensation	An unpleasant skin sensation that provokes the desire to run and/or scratch to obtain relief.
Pruritus	Itchiness.
Red and itchy eyes	Redness of the whites of the eyes (sclera) with sensation that provokes the desire to rub and/or scratch to obtain relief.
Retractions	Indrawing of skin while breathing in (implies an obstruction to breathing); may be supraclavicular (above the collarbone), suprasternal (above the sternum), intercostal (between the ribs), substernal (below the sternum) or subcostal (abdomen just below the rib cage).
Rhinorrhoea	Discharge of thin nasal mucus.
Sensation of throat closure	Feeling or perception of throat closing with a sensation of difficulty breathing.
Sneezing	An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.
Stridor	A harsh and continuous sound made on breathing in.
Tachycardia	Faster than normal heart rate which varies by age.
Tachypnoea	Faster than normal respiratory rate which varies by age.
Urticaria	Localised redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours).
Wheezing	A whistling, squeaking, musical or puffing sound made on breathing out.