Queensland Health

Attributing deaths to COVID-19 vaccines – a guide for medical practitioners

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While death following COVID-19 vaccination is not an expected outcome of health care, in practice not all post-vaccination deaths will be vaccine-related but rather as a result of the person's underlying health conditions. This document seeks to provide guidance for medical practitioners when certifying cause of death when a person has recently had a COVID-19 vaccine.

When is the death of a person who has received a COVID-19 vaccine reportable to the coroner?

The fact that a person received a COVID-19 vaccine some time prior to their death does not of itself make their death reportable to the coroner. The death of a person who has received a COVID-19 vaccination will **only** be reportable to the coroner if:

- the death may be vaccine-related (health care related); or
- the death is reportable for another reason (for example - the person died as a result of mechanical fall-related injury).

The legal threshold for issuing a cause of death certificate in Queensland is whether the certifying doctor can form an opinion as to the *probable cause* of death.[1]

This is a clinical assessment based on information about the patient's medical history and the circumstances of the death to arrive at an opinion about the most likely cause of death. For patients who have recently received a COVID-19 vaccine, this includes consideration about the vaccine's potential involvement within the context of the person's pre-existing comorbidities.

Doctors who are considering whether to issue a cause of death certificate for a patient who recently received a COVID-19 vaccine may find the below information useful for this process.

COVID-19 vaccine adverse effects

Despite provisional Therapeutic Goods Administration (TGA) registration in Australia, there is wealth of knowledge on adverse effects post COVID-19 vaccination locally and internationally. Adverse effects with mortality risk related to COVID-19 vaccination include:

- **Anaphylaxis**
- **Thrombosis with thrombocytopenia syndrome (TTS),** also known Vaccine Induced Immune Thrombotic Thrombocytopenia (VITT). No biological or other risk factors have been identified that predict who will develop TTS. It appears to be an idiosyncratic reaction. Cases have been reported in all ages and in both men and women. At the time

[1] Births, Deaths and Marriages Registration Act 2003, s.30

of publication, this syndrome appears to occur pr-dominantly following first dose of the COVID-19 Vaccine AstraZeneca (ChAdOx1-S).

Interim criteria have been developed for diagnosis of TTS/VITT. These are listed below, however, for the latest definition please consult the Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) COVID-19 Resources:

- COVID-19 vaccine 4-30 days previously
- venous or arterial thrombosis (often cerebral or abdominal)
- thrombocytopenia (<150x10^9) or falling platelet count AND high d-dimer (> 2 x ULN).
- In certain cases, anti-platelet factor 4 (anti-PF4 antibodies) have been found.

Symptoms of TTS/VITT occur 4-30 days after vaccination and can reflect the presence of blood clots in various organs. Reported symptoms include:

- severe headaches unresponsive to simple analgesia
- abdominal pain
- significant respiratory symptoms/distress
- visual changes
- vomiting
- seizures
- focal neurological deficits/changes
- confusion/encephalopathy

- Myocarditis and pericarditis which have been reported very rarely following vaccination with mRNA Covid-19 Vaccines. For the latest definition please consult the joint ATAGI and Cardiac Society of Australia and New Zealand (CSANZ) Guidance. For these adverse effects,
  - Symptoms typically appear within 1-5 days of vaccination, with most within 14 days after vaccination
  - more often after the second dose and in younger men (aged below 30 years)
  - Reported symptoms include:
    - chest pain, pressure or discomfort
    - palpitations (irregular heartbeat, skipped beats or 'fluttering').
    - syncope (fainting)
    - shortness of breath
    - pain with breathing.
- **An expected adverse drug effect (e.g. diarrhoea) may worsen an underlying medical condition and contribute to death in frail persons**. Further information on COVID-19 vaccine adverse drug effects can be found online:
  - Comirnaty vaccine phase III trial publication
  - COVID-19 AstraZeneca vaccine phase III trial publication
  - COVID-19 vaccination – ATAGI clinical guidance on COVID-19 vaccine in Australia in 2021

Additional adverse drug events of special interest being monitored for by the TGA for both vaccines that carry a mortality risk include:

- clotting disorders without thrombocytopenia (low platelets) including stroke, pulmonary embolism and deep vein thrombosis

- seizures
- acute cardiac injury, for example myocarditis and pericarditis, heart failure and cardiogenic shock, arrhythmia
- Capillary leak Syndrome
- Guillain-Barre syndrome.

Some of these adverse events are being monitored because of a theoretical link to COVID-19 disease such as stroke, pulmonary embolism and deep vein thrombosis. Other events, including Guillain-Barre syndrome, myocarditis and pericarditis and seizures, are being monitored because they have been observed with other vaccines.

Proximity of the vaccine to the death and the proposed mechanism of death must be considered (e.g. VITT typically occurs between 4-30 days, therefore if a person dies within six (6) hours of vaccine administration from a clot, then VITT is less likely to be the cause).

Doctors can also discuss their patient's circumstances with a forensic physician from the Queensland Health Clinical Forensic Medicine Unit during business hours on (07) 3405 5755 or after hours on (07) 3722 1300.

Ask yourself: "*Knowing everything you know about the patient and their pre-existing comorbidities and health risk factors; would you have expected the person to die regardless of having received the COVID-19 vaccination when they did?*"

Where the doctor is comfortable the death is from a natural cause unrelated to the COVID-19 vaccine, the doctor is encouraged to issue a cause of death certificate. The death does not need to be discussed with or reported to the coroner.

Doctors assessing if the death is from a natural cause unrelated to the COVID-19 vaccine should ask themselves these questions:

- *Has the vaccine directly caused the death?*
- *Has the vaccine caused a side effect or complication that has caused or significantly hastened the person's death?*
- *Is there a need to reference the COVID-vaccine and/or a vaccine-related complication on the cause of death certificate?*

If the answer to any of these questions is yes/possibly/probably/likely or unclear the doctor should seek advice from the Coronial Registrar, Coroners Court of Queensland during business hours on (07) 3738 7050 or after hours on (07) 3738 7166.

If the person dies in hospital, the body is to remain in the hospital morgue pending further advice from the Coroners Court. If the person dies in the community, the body may be transferred to the family's nominated funeral director pending further advice from the Coroners Court of Queensland.

Examples are provided in Appendix 1 to help certifying doctors determine when they should seek clinical or coronial advice about a patient death proximate to COVID-19 vaccination.

Resources

- When is the death of a person who has received a COVID-19 vaccination reportable to the coroner?
- Issuing cause of death certificates for apparent natural causes deaths - a guide for Queensland medical practitioners
- COVID-19 vaccination information for healthcare workers

Appendix

Appendix 1: Example COVID-19 Vaccination Cause of Death Cases

Case 1:
An 87yo man whose medical history includes ischaemic heart disease, prostate cancer (in remission), asthma and eczema died suddenly at home. He had received a COVID-19 vaccine six weeks earlier followed by the flu vaccine two weeks later. He had been well since then and had woken early that morning for his regular walk to buy the papers and returned home where he performed his morning meditation. His wife went back to bed and woke two hours later to find him slumped in the hallway near the bathroom showing no signs of life.

Recommendation: In this example, the combination of his age, comorbidities, recent wellness and time interval between vaccinations and death makes the death unlikely to be vaccine related. It is reasonable to issue a cause of death certificate based on his age and comorbidities.

Case 2:
An 83yo male residential aged care resident died the day after he received the second dose of a COVID-19 vaccine. He was being managed palliatively for an obstructing duodenal mass not amenable to surgical management with a life expectancy of weeks. He died peacefully in his sleep.

Recommendation: In this example, the combination of his age, limited life expectancy due to a known malignancy and brand of vaccine makes the death unlikely to be vaccine-related notwithstanding the time interval between the vaccine and death. It is reasonable to issue a cause of death certificate based on his pre-existing comorbidities.

Case 3:
A 73yo woman whose medical history includes uncontrolled hypertension, poorly managed Type 2 Diabetes Mellitus, supraventricular tachycardia/palpitations, haemochromatosis, osteoarthritis and right mastectomy from breast cancer in 2006, died in her sleep at home. She had received a COVID-19 vaccine four days prior to her death. According to her husband, she complained of mild flu-like symptoms after vaccination i.e. aches and pains and pain at the injection site. These symptoms resolved after 48 hours and by the day prior to her death.

Recommendation: In this example, the combination of her age and the absence of symptoms of anaphylactic reaction or symptoms associated with a clotting complication makes the death unlikely to be vaccine related notwithstanding the time interval between vaccination and death. It is reasonable to issue a cause of death certificate based on her pre-existing comorbidities.

Case 4:
An 83yo man with a significant medical history including severe Chronic Obstructive Pulmonary Disease (COPD) on home oxygen, pulmonary hypertension, bilateral femoral artery aneurysms, abdominal aortic aneurysm Type 2 Diabetes Mellitus, scleroderma, polymyalgia rheumatica and osteoarthritis died at home five days after receiving a COVID-19 vaccine. He had become lightheaded and acutely short of breath soon after receiving the vaccine and was transferred to hospital where he remained for three days with a working diagnosis of acute exacerbation of COPD before being discharged home for GP follow up.

Recommendation: In this example, the combination of his age, comorbidities and absence of symptoms of anaphylactic reaction or symptoms associated with a clotting complication make the death unlikely to be vaccine related notwithstanding the recency of the vaccine and his post-vaccine deterioration. It is recommended that the treating GP seek clarification from the hospital treating team about his condition on discharge home and speak with the family to

clarify his condition once he returned home. It is also reasonable for the GP to seek advice from the Coronial Registrar regarding whether a cause of death certificate can or should be issued.

Case 5:
A 91yo male residential aged care resident whose medical history includes chronic kidney disease, congestive cardiac failure, ischaemic heart disease, previous cerebrovascular accident, Type 2 Diabetes Mellitus and a recent hospital admission for urinary tract infection (treated with intravenous antibiotics) becomes acutely unwell several hours after receiving the first dose of a COVID-19 vaccine. Carers noted him to become pale, less alert and non-verbal, pooling fluids in his mouth and unable to swallow. His family did not wish for him to be transferred to hospital but wished for him to receive end of life care at the nursing home. He died that evening.

Recommendation: In this example, the time interval between the vaccination and his rapid deterioration is such that the vaccination cannot readily be excluded as directly contributing to his death notwithstanding his age, frailty, and comorbidities. It is recommended that the treating GP seek advice from the Coronial Registrar regarding whether a cause of death certificate can or should be issued.

Case 6:
A 57yo man with obesity, obstructive sleep apnoea and asthma died at home five days after receiving a COVID-19 vaccine. His family report he had become progressively unwell since receiving the vaccine but had not sought any medical care.

Recommendation: In this example, the time interval and deterioration after vaccination leading up to death raises a reasonable concern that the death may be vaccine related. It is reasonable for the treating GP to decline to issue a cause of death certificate and report the death to the Coroner.

Case 7:
A 73yo woman whose medical history included hypercholesterolaemia, left leg lymphoedema, gastro-oesophageal reflux disease, asthma and osteoarthritis collapsed at home after becoming acutely short of breath in the shower. She had received a COVID-19 vaccine eight days earlier. Six days after her vaccination she phoned her GP complaining of shortness of breath on exertion and an expiratory wheeze. She reported being afebrile with no cough or chest pain. She was prescribed a Ventolin (salbutamol) inhaler.

Recommendation: In this example the time interval and symptoms post-vaccination and shortly prior to death raises a reasonable concern that the death may vaccine-related. It is reasonable for the GP to decline to issue a cause of death certificate and report the death to the Coroner.

Case 8:
A 40yo man with chronic mental health issues and hepatitis C died suddenly at home six days after receiving the a COVID-19 vaccine. His mother found him dead in bed. She reported he had felt quite unwell since receiving the vaccine with fever, hot and cold flushes, night sweats and reduced appetite. He had been taking paracetamol to manage his symptoms.

Recommendation: In this example, the combination of his age and time interval from vaccination to death raises a reasonable concern that the death may be vaccine related. It is reasonable for the GP to decline to issue a cause of death certificate and report the death to the Coroner.