

Case Report			
Demographics			
522	\$22		s22
DOB	s22	Age	21
Gender	M	Indigenous status	s22
Case in Brief	1 1/1	indigenous status	322
Summary (case in < 30 words)	21 year old male had	d Pfizer vaccine dose	22
Background			
Past Medical History	s22		
Details of any previous reactions to vaccinations	Nil prior		
Vaccination history			
Vaccine	Pfizer Comirnaty	Pfizer Comirnaty	Bexsero
Date of vaccination	s22	s22	s22
Dose number	5	S	S
Place of vaccination	\$22	\$22	s22
Vaccine expiry			
Site of administration (if applicable)			
Situation		_	
Date of symptom onset	s22	Time of symptom onset	s22
Was the patient unwell prior to vaccination?	s22		
Description of clinical	 Pfizer dose 	22	
events	• s22		fever and 222
	s22		-
	• s22		
			, A
	• s22		

	• \$22 Time of death \$22 • \$22
Assessment	
Details of initial medical assessment	• \$22
Hospitalised? If yes include dates	s22
Investigations completed and results e.g. laboratory and imaging	Interview with patients GP \$22 • \$22 • \$22 • \$22 • \$22 • \$22 • Reviewed AIR and GP vaccination record. \$22 dose of Bexsero \$22 given \$22
Treatment provided (if relevant)	
Provisional diagnosis/outcome	Deceased 502
Outcome of AEFI	
Any other relevant info	rmation

Expert Panel Review - \$22



Minutes by 222

Participants		
\$22	s22	
\$22	s22	
s22	(Haematologist)	
\$22	(Haematologist)	
\$22	(Cardiologist)	
\$22	(Cardiologist)	
s22	(Toxicologist)	
\$22	(Infectious diseases physician, \$22	
s22	s22 GP, s22	
s22	Physician s22	
s <u>22</u>	s22	
s22	\$22	
s22	S22	
s22	(TGA)	
s22	(TGA)	
s22		

Apologies: None

- These documents represent a 'point in time' assessment of information available to the TGA on the date of assessment. They are subject to ongoing review as new information comes to light and do not represent a final conclusion or final decision. Even when the TGA does not have sufficient information to undertake a causality assessment at a particular point in time (WHO criteria = U or unassessable/unclassifiable), the TGA continues to code all reports with fatal outcome as "possibly" linked to COVID-19 vaccination. These cases are included in analyses of adverse event data to identify and investigate signals that may not be apparent through review of individual cases. This is consistent with the approach recommended by the WHO and used by other major global regulators and vaccine safety monitoring programs.
- The point-in-time causality decision included in these documents may be expressed in a variety of ways. In some documents, no decision has been made and the template text "causality" or text in square brackets remains. For other documents, WHO criteria is listed in the document and may be expressed as unassessable/unclassifiable (coded as "U") and "unlikely". This explanation has been included due to some misunderstandings about these words.
- The TGA released these documents to the FOI applicant but did not publish them in the disclosure log at the time given the sensitive nature of the documents. While personal information was redacted, it remains possible that a family member or of an individual may identify that the document relates to their family member. As such, a conservative approach to publishing the information in the disclosure log was taken, given the potential for causing distress to the family of the deceased. This approach was consistent with the TGA's obligations under the FOI Act as there are exemptions from publishing documents released under the FOI Act in appropriate circumstances. However, given that these documents have now been widely circulated in the community, we have re-considered our initial decision to include these documents on the disclosure log.