

## Terms of Reference Cold Chain Failure – COVID Vaccination Programme (Provider- Engage Safety)

<b>Review</b>	Cold Chain Failure – COVID Vaccination Programme (Provider- Engage Safety)
<b>Sponsor</b>	Chief Executive Officer
<b>Responsible Manager</b>	Executive Director Planning, Funding and Population/Public Health
<b>Background</b>	<p>On 2 March 2022 Southern District Health Board became aware of a potentially significant cold chain breach relating to the COVID Vaccination Programme. Subsequently in consultation with IMAC and the Ministry of Health a cold-chain failure was confirmed impacting a subset of COVID vaccinations delivered by an occupational health provider (Engage Safety) in the Queenstown Lakes and Central Otago area.</p> <p>Initial investigations have identified 1601 affected doses of the COVID-19 Pfizer vaccine given to 1571 people at various locations in Queenstown Lakes and Central Otago between 1 December 2021 and 28 January 2022.</p> <p>As of 7 March 2022 the affected vaccine recipients have been advised to receive a replacement vaccination to ensure they benefit from a high level of immunity against Covid-19.</p> <p>This is a large scale adverse event affecting significant numbers of COVID-19 vaccine recipients in the context of the COVID-19 pandemic and an active and expanding disease outbreak.</p> <p>The purpose of this review is to identify what has happened including contributing factors and root causes and make appropriate recommendations to ensure effective action can be taken to minimise the risk of <del>prevent</del> similar events happening again.</p> <p>The terms of reference have been developed by the Southern DHB Planning, Funding and Population/Public Health Directorate.</p> <p>The final report will be provided to the Chief Executive Officer.</p>
<b>Method</b>	<p>The review shall be undertaken following tikanga for the rohe. The review team shall be culturally appropriate.</p> <p>The purpose of this review is to identify what has happened including contributing factors and root causes and make appropriate recommendations to ensure effective action can be taken to prevent similar events happening again.</p> <p>The reviewers will identify and gather appropriate information about key events, create a timeline of the event, identify, and review all relevant policies, procedures and guidelines.</p> <p>The reviewers will use relevant Southern DHB adverse event manuals and procedures to support the review process.</p>

	Conduct interviews with relevant Southern DHB staff, contracted provider/s and related agencies.
<b>Deliverables</b>	<p>The review will:</p> <p>1.0 Review the COVID-19 vaccination services provided by Engage Safety to all the affected vaccine recipients, including:</p> <ul style="list-style-type: none"> <li>the management and delivery of all vaccination services and related matters leading up to and subsequent to the cold chain failure. This will include data integrity relating to the administration of the COVID Vaccination Register (CIR) and all cold chain processes and staff training, as well as the providers obligations to report any potential failures to the Southern District Health Board</li> <li>This will generally involve a member of the review team interviewing the provider and relevant staff members who were directly involved in the vaccination service.</li> </ul> <p>2.0 Review Southern District Health Boards implementation of the “National Standards for Vaccine Storage and Transportation for Immunization Providers 2017” including:</p> <ul style="list-style-type: none"> <li>the assessment, review and administration of Cold Chain Accreditation and Cold Chain Compliance processes as provided by the Southern District Health Board Population Health Service.</li> <li>Processes for managing reaccreditation and relevant actions where accreditation has lapsed.</li> </ul> <p>3.0 Consider the role and responsibilities of the Southern DHB COVID Vaccination Programme as it relates to this adverse event.</p> <ul style="list-style-type: none"> <li>This will include (but not be limited to) provider contract and relationship management and communication pathways and related clinical governance structures and functions.</li> </ul> <p>A draft report will be provided to all engaged in the review with the ability for feedback to be provided to the reviewers for consideration before producing the final report.</p> <p>The final report will be provided directly to the Chief Executive Officer</p>
<b>Professional Standards</b>	<p>Reviewers will act professionally, impartially, and ethically throughout the review.</p> <p>Reviewers will display independence, abide by the Southern DHB codes of conduct and confidentiality and agree to the terms of engagement. Any identified risks will be escalated upon discovery if appropriate.</p> <p>The reviewers will not release the report or comment publicly on the review unless approved by the Chief Executive or delegate.</p>
<b>Review Team</b>	Tbd

<b>Timing</b>	To commence 28 March 2022, complete end of April 2022