DAA Group

Focus on Quality

Review of Cold Chain Failure

COVID-19 Vaccination Programme

He Arotake ki te Paheke Tukunga Paemakariri

Kowheori -19 Tuku Rongoa Araimate

Southern DHB

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Karakia

Takina atu ki te Kawa nui [1]	Go fetch the great Dedication
Ki te Kawa roa	The long Dedication
Ki te Kawa tapu	The sacred Dedication
Ki te Kawa tiketike	The lofty Dedication
Ki te Kawa tuatahi	The first Dedication
Ki te Kawa tuangahuru	The tenth Dedication
Ki a Io-Matua-Nui	Of Io-the Great One
Ki a Io-Matua-Kore	Of Io-the Parentless One
Kia mau ki te Tika	Grasp that which is Right
Kia mau ki te Pono	Grasp that which is True
Kia mau ki te Aroha	Grasp that which is Compassion
Tihe Mauri Ora	It is the Breath of Life

He Mihi

Kia whakarangatira te Kingi, ko Tuheitia me te Kahui Ariki nui tonu. Ki a Ratou kua riro atu ki tua o te pae o te maumahara, haere atu, e moe. Ki a Tatou nga Kanohi Ora Tena Tatou katoa. Me mihi tenei ki te pae maunga ko Kawarau, otiia ko nga maunga katoa e tu rangatira ana. Ki te moana ko Wakatipu, he wai ora, he wai maori, he wai mana, me nga awa katoa Tena Koutou. Tena Koutou nga iwi ko Kai Tahu, ko Waitaha, ko Kati Mamoe, ko Kati Hawea, Koutou katoa nga mataa waka e noho na ahakoa nowhea. Ki te Roopu Marutau Ora, ESL e noho ana ki Tahuna, he mihi ake. Otiia ki a Koe e te Tumu Whakarae ko Chris Fleming o te Paoari-a-Rohe Southern District, korua ko te Hemana ko Pete Hodgson, Koutou nga Kaiwhakahaere Katoa o te Hauora-a-Rohe, me nga Kaiwhakautu ki nga patai, Tena Koutou, Tena Koutou, Tena Koutou Katoa.

Ko matou ko nga Kaiarotake o te Roopu Arotake ko DAA Group e mihi ana ki a Koutou. Matou ko Dr Jan Dewar te Poutoko, ko Lorraine Welman, Matatau Haumanu, ko Brian Te Rauroha Emery Kaumatua. No reira Tena Koutou, Tena Tatou Katoa.

We acknowledge King Tuheitia and his royal family. We mourn those who have passed over the horizon of remembrance. Them to Them, Us the Living to Us. We greet the mountain range of the Remarkables and all the mountains that stand on their authority. Lake Wakatipu, the life-giving water, the everyday water, the powerful water and all your tributary rivers we greet you. We greet the People who have mana over the land, waters and air and all residents of the districts. Especially we acknowledge the directors and staff of Engage Safety Limited who looked after us and responded willingly to this review. We greet the Chief Executive Officer Chris Fleming and Chair Mr Pete Hodgson of the Southern DHB and all the heads of departments, and people who spoke openly with us in this review. Greetings to you all.

We are the team appointed by the DAA Group: Dr Jan Dewar Team Leader; Lorraine Welman Technical Expert; and Brian Te Rauroha Emery Cultural Supporter for this review and we greet you all.

[1] Na Te Hira Moana

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Executive Summary – Tirohanga Whanui

Engage Safety Limited (ESL) is a private occupational health provider that practice in accordance to tikanga and embody the principles of Te Tiriti. ESL provide a range of services to the Central Otago community including 10 years administering workplace influenza vaccinations. On 7 August 2021, ESL gained a contract with the Southern District Health Board (SDHB) to administer Comirnaty (COVID-19) vaccinations.

On 2 March 2022 Southern District Health Board (SDHB) became aware of a potentially significant cold chain breach relating to the COVID-19 Vaccination Programme. Subsequently in consultation with the Immunisation Advisory Council (IMAC) and the Ministry of Health (MoH) a cold-chain failure was confirmed impacting a subset of COVID-19 vaccinations delivered by ESL.

ESL cold chain accreditation (CCA) expired in November 2021. At that time, the COVID-19 pandemic was dominating the health system, and there was a government directive to vaccinate all eligible people over the age of 18 in Aotearoa New Zealand. Ongoing attempts were made to arrange ESL renewal of CCA with no date agreed. In early February, a decision was made mutually by IC-A and ESL to delay CCA renewal until the installation of a new vaccine fridge - planned for later in the month in ESL's new premises at 18 Glenda Drive, Frankton, Queenstown. Prior to this, vaccines were kept in a vaccine fridge at the home of the directors of ESL.

The visit to renew the CCA occurred on 2 March 2022. There was an expectation that the renewal of accreditation visit would be routine, having successfully achieved CCA status in the past. Had the CCA renewal been completed in November 2021, the potential cold chain failure in December 2021 and January 2022 may not have been discovered at this time or at all. Equally, if all cold chain management processes were in place as required, downloading of data and appropriate action in early December would have prevented the resultant breaches.

Immunisation coordinator A (IC-A) downloaded the data from the fridge data loggers. It was then discovered that there were discrepancies with the fridge temperature monitoring over the previous two months. The ESL (lead) director appeared unaware that these breaches had occurred. IC-A and the ESL (lead) director attempted to find all related documentation to confirm vaccine fridge status. The complete manual record of vaccine fridge temperature monitoring prior to 4 January 2022 was missing.

SDHB worked closely with ESL, the Immunisation Advisory Council (IMAC) and the Ministry of Health (MoH) to identify if and when there had been compromised vaccines. During a period of missing data, and a further data period that showed numerous freeze/thaw cycles, affected batches of vaccine were identified from data held by SDHB. Members of the public affected were then notified of the issue and advised to have a replacement vaccination to increase immunity.

"Three key components (people, systems and process, and equipment) must be present and to a set standard to reduce risk and ensure vaccine viability through correct storage and follow-up of any deviations from the standards"[2]. This independent review focuses on systems and processes leading up to, during and following identification of a cold-chain failure.

[2] Ministry of Health. (2019). 2021 Addendum to National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition): COVID-19 Vaccination Immunisation Programme. Wellington: Ministry of Health

Recommendations – Nga Taunaki

Engage Safety Ltd

It is recommended that:

- appropriate delegations, close monitoring, and clear processes to meet reporting requirements are in place for any future contracts to provide vaccination services to the community.
- a continuous quality improvement system is developed within ESL.
- processes are implemented to ensure security of records, including electronic storage and retaining of records for 10 years as required.
- investment in remotely monitored loggers is considered so that fridge issues and alarms can be directed to an 'on call' person and managed in a timely way.
- staff resource and training are reviewed to enable ESL to consistently meet all requirements of future contracts.
- ESL and SDHB work towards communication that is open and transparent, proactive and timely with a culture of 'no surprises' and support.

Southern District Health Board - Poari Hauora-a-Rohe ki te Tonga

It is recommended that:

- immunisation coordinator (IC) resource is reviewed to ensure sufficient FTE to support providers is available.
- monthly reporting by ICs includes information about status of CCA and this is recorded in department governance meetings for action and follow up.
- the system to track CCA compliance across the SDHB region should be strengthened and included in the quality improvement programme for the DHB.
- processes are strengthened to ensure public safety is maintained during any period of CCA lapse/working towards renewal of CCA, in particular, where concerns or 'red flags' are raised by frontline staff.
- SDHB review the 'Cold chain provider non-compliance policy' and any related policy to ensure it is fit for purpose in a pandemic or another national emergency environment. This may include feedback to IMAC regarding actions and recommendations following this review.
- processes around introduction of new IT systems ensure that critical information and documentation is available to staff.

COVAX team SDHB - Roopu Whakamatautau Kowheori

It is recommended that:

- responsibilities for maintenance of national standards are clearly documented and understood by those responsible, particularly when new teams are developed.
- expertise of frontline staff is recognised and integrated into any new team structure, allowing transparent raising of issues to appropriate levels for action.

Background – Tuhinga o Mua

On 2 March 2022 Southern District Health Board (SDHB) became aware of a potentially significant cold chain breach relating to the COVID-19 Vaccination Programme. Subsequently in consultation with IMAC and the Ministry of Health a cold-chain failure was confirmed impacting a subset of COVID-19 vaccinations delivered by an occupational health provider Engage Safety Limited (ESL) in the Queenstown Lakes and Central Otago area.

Initial investigations 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. 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.

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.

1.0 Introduction – He Whakataki

Engage Safety Limited (ESL) is a private provider located in Frankton, Queenstown, providing occupational health and other health and social services to Queenstown Lakes and the wider Central Otago region. Currently services provided by ESL include COVID-19 swabbing, a community clinic at Glenorchy, social services, kai parcels (since 2019), COVID-19 kai parcels (for those isolating), first aid courses, respirator fit testing, a healthy heart well-being programme, annual health monitoring, health and safety planning, pre-employment health checks, drug testing, and up until 3 March 2022, vaccinating. The service has 10 years' experience providing influenza vaccination in workplaces.

Since late 2021, ESL have rapidly expanded to meet community needs. This included a large increase in provision of social supports, kai parcels to the community, employment of 25 additional staff and taking on the lease of a building, now functioning as a 'health hub' for the various services provided by ESL.

The team from the DAA Group reviewed ESL policies and records, SDHB policies and documentation in relation to the event, and national guidelines and policies in relation to cold chain accreditation. Interviews were held onsite with ESL staff and via Microsoft Teams with SDHB staff and follow up interviews as needed (see Appendix 3). A timeline of events was developed and confirmed with the ESL director (lead). A process of 'TapRoot' analysis was used to identify root causes with a focus on systems and processes.

2.0 Timeline – He Rarangi Wa (See Appendix 2 – Apitihanga 2)

A detailed timeline is included as Appendix 2. The timeline outlines a series of events alongside contextual factors in place at the time that may have influenced actions taken.

3.0 Engage Safety Limited (ESL) – He Roopu Marutau Ora

Whakataka te Hau [3]

Whakataka te hau ki te uru [4]	Get ready for the westerly
Whakataka te hau ki te tonga	Be prepared for the southerly
Kia makinakina ki uta	It will be icy cold inland
Kia mataratara ki tai	And icy cold on shore
E hi ake ana te atakura	May the dawn rise, red-tipped on ice,
He tio, he huka, he hauhunga	on snow, on frost
Haumie, hui e, taiki e	Remain united, gather together, bind it

ESL is a provider of occupational health and other services with a focus on Marutau Ora (safety and wellbeing). ESL is not a Kaupapa Māori Service Provider but demonstrate their commitment to tikanga and embody the principles of Te Tiriti. There were instances, as described below, where ESL, during the pandemic, worked as one would expect a whanau, hapu and marae to behave. Their tikanga mirrored those of hapu, marae throughout Aotearoa New Zealand who went out to the people including Māori and Pacifica. Every day ESL fed their staff and vaccinators who were manning the 'drive throughs' and outreaches.

ESL as an immunisation provider, took onboard the tikanga of tiaki tangata to care for people in their community. The timing of their entry as a provider occurred at the beginning of the national lockdown in August 2021. This was crucial when put together with community demands for vaccinations. These factors were not helpful in terms of putting pressure upon ESL to perform well in a pandemic.

There were some instances where tikanga were not followed and those had negative consequences too. Some are referred to below.

3.1 Data integrity – Raraunga Pono

The vaccine fridge(s) were kept in the home of the ESL directors until the lease on the building at 18 Glenda Drive was confirmed and a new fridge purchased in February 2022. Over the time of the identified breach December 2021 and January 2022, the pharmacist and the registered nurse vaccinator employed by ESL visited the fridge to obtain vaccine on approximately six occasions. Both reported that the vaccine fridge temperature monitoring documentation was present, and they did not note any discrepancies or issues. The fridge was also visited on one occasion by a SDHB vaccinator and IC-B together on one occasion who noted that the fridge monitoring paperwork was in place. IC-A reports visiting the fridge in the ESL directors home on a number of occasions with no issues with documentation noted. All vaccinators interviewed reported no issues with vaccine/chilli bin temperatures on arrival at 18 Glenda Drive from the home of the ESL directors (a five minute drive).

The data from the two fridge temperature loggers, downloaded after 3 March 2022, identified significant gaps in the data, different data on each logger, and the loggers showed a number of occasions when the temperature had fluctuated to the extent that, if that data is accurate (that is, the

[3] From He Mareikura na Pei Te Hurinui Jones

[4] ESL staff attended the opening of the Sudima Hotel in Frankston, Queenstown. The owner was asked if he would allow the karakia to be displayed in the hotel. He agreed. This karakia is shown on a wall at the main entrance of the hotel.

data loggers were in the fridge), the vaccines would have been exposed to more than the maximum number of freeze/thaw cycles to maintain vaccine integrity.

ESL reported that all data loggers are set up initially by a SDHB ICs with the expertise to do so. Once set up, the data loggers are described as easy to manage.

The SDHB reported that some Queenstown providers conveyed their concerns that ESL had not uploaded client information about clients' previous COVID-19 vaccinations to the COVID Immunisation Register (CIR). The tikanga here is that of tuku mohio whaiaro, the accurate uploading of personal information. There was an initial period where paper records were completed, and these were entered into the CIR by ESL staff or administration staff of the SDHB. Entering of data into the CIR during the initial weeks of the campaign did not meet the required standard. Elsewhere, under the same tikanga, there was a downside. The effects of the loss of the written records of fridge data during the breach period, can only be restored by location of the missing records, kia tika ai, to make it right.

3.2 Cold Chain Processes – Tukunga Paemakariri

From November 2021 onwards, both SDHB IC-A and ESL directors were aware that cold chain accreditation (CCA) had expired in November 2021. Several attempts were made to find a mutual time to review ESL cold chain processes and re-issue CCA. Messages were left by IC-A offering to make a pre-CCA visit to ensure all standards were in place prior to the CCA visit. Due to the pressure on vaccination teams to reach government targets to vaccinate the public, both ESL and ICs were very busy over this time. CCA is usually a straightforward process. In 2021 cold chain management was more complex due to introduction of a new vaccine (Pfizer COVID-19 vaccine) that had more complex storage requirements and complex reconstitution and administration timeframes.

There were two time periods when data downloaded from the fridge data loggers showed cold chain temperatures not maintained. This included a time with no data on two data loggers and another period with frequent freeze/thaw cycles. Over that period, the environment has been described as 'chaotic' with a large amount of activity within the business. The ESL director (lead) is an authorised vaccinator and the clinical site lead. The director (lead) took full responsibility for cold chain processes surrounding the fridge(s) kept at the director's home, and as a registered nurse provided clinical and professional oversight for the team.

Since installation of the new fridge in February 2022, a process has been in place for shared responsibility for maintaining cold chain processes for the vaccine fridge[5]. This includes the first vaccinator on each day being responsible for cold chain maintenance and recording. On Fridays this person is also responsible for the weekly logger download.

ESL had two data loggers and one temperature monitor on fridges in use for vaccine storage. ESL are unable to explain the discrepancies found in the data logger downloads. Several actions were taken over that time that may have contributed to the discrepancies in data produced from the fridge data loggers however none provide a rationale for the data discrepencies. These included:

- All cold chain activities were essentially being managed as off-site activities (and are still required to meet the standard).
- Data loggers needed to be transported from the ESL directors' home to the building at 18 Glenda Drive for downloading of data as this is where the computer and cradle for downloading data was kept.

[5] Engage Safety Ltd (2022). Cold chain policy for Engage Safety Ltd COVID-19 Community Vaccination Centre.

- The usual process was to download the data, place data logger on a desk ready to take back to the ESL directors' home to place back in the fridge.
- Data loggers may have been left on a desk or in a drawer at 18 Glenda Drive for the day or possibly several days and not returned to the fridge in the ESL directors' home.
- Data loggers may have been put in a bag with ice packs ready for return to the ESL directors' home at the end of the day.
- The bag with ice packs and data loggers may have been placed in the freezer at the ESL directors' home.
- The freezer at the ESL directors' home containing ice packs (and possibly the data logger(s)) was frequently accessed for other reasons (to get food out) which may have meant the temperature varied from the usual temperature of a freezer.
- Data loggers may have been left turned off.

At the time, very long hours of work were being recorded to keep all aspects of the business afloat; this was at times from 0600 hours to 2400 hours. This may have been a contributing factor to the situation described as 'chaotic' during the time of the drive through COVID-19 vaccination clinic. Essentially, a valid explanation for discrepancies on data loggers has not been found. Additionally, paper temperature monitoring (sighted by at least six staff including the ESL (lead) director), was unable to be located or provided to support the maintenance of vaccine fridge temperatures. Information was paper only and not kept in an electronic format.

The director (lead) at ESL had the tikanga of mana whakahaere or full authority, and overall management of the cold chain process for the organisation. I tona ngakau pono, and in her utmost sincerity, she said that during the entire breach period that she does not believe that the vaccines were compromised. The director (lead) accepts that the data loggers show a breach. The data from the data loggers show intermittent download of the data however on 3 March, the ESL director (lead) was not aware of the previous data discrepancies. However, kua huna, that truth is hidden and cannot be confirmed.

3.3 Staff Training – Whakangungu Kaimahi

All staff working with the CIR have completed the training to generate a login. In the week before the contract with SDHB commenced, all ESL staff completed privacy training. The review team sighted certificates for staff who had completed training attested by IMAC as vaccinators, CIR and BookMyVaccine for reception and admin staff course, and the Immunisation Support Worker course. Further training occurred on site by the ESL director and the COVID-19 immunisation coordinators.

A rapidly stood up drive through vaccination clinic commenced on 23 August after a nation-wide lockdown was announced. Initially record keeping was paper based due to the unavailability of the national system (CIR) at the drive through venue. Staff focused on manual recording of a contact phone number to be able to check details if necessary. This was necessary as many people requiring vaccination did not have a national health index (NHI) number or were migrants with unfamiliar names. The information was entered to the CIR after-hours by ESL administration staff[6]. Many errors were noted on later review by SDHB administration staff, and reported to SDHB by other providers trying to administer further doses.

[6] Ministry of Health. 2021. COVID-19 Vaccine Immunisation Programme Service Standards. Wellington: Ministry of Health.

The chaotic delivery of the initial "drive through" services resulted in incorrect processes and procedures being followed for entry of information into the CIR, this included too many vaccinations, insufficient testing of systems and failure (SDHB and ESL) to pause and regroup.

3.4 Reporting of Potential Failures – Whakamohio Paheke

IC-A, based in Alexandra, is identified as the first point of contact for any concerns by ESL. The contract was agreed between ESL and SDHB with the intention from ESL that outreach clinics would be held around the district in halls and other venues. ESL had no intention at that stage of a drive through clinic. Until the downloading of the data loggers on 2 March 2022, ESL was unaware that there had been a cold chain failure. This was based on the vaccine fridge located in the ESL Directors' home having a loud alarm to alert the household if the fridge temperature was below +2 degrees Celsius or above +8 degrees Celsius. ESL directors reported that the fridge(s) in the ESL directors' home did occasionally alarm and this was quickly dealt with, the alarm was described as very loud and impossible to ignore.

Under the tikanga of whakamohio paheke, it was not ESL who reported the breach. It was an immunisation coordinator (IC-A).

3.5 Culture -Tikanga

One important aspect of ESL's tikanga is the importance of whānau. Daily karakia were held prior to clinic commencement (whether in clinic or in the drive through). Some staff provided by SDHB to assist declined to attend karakia. Due to the strict protocols around drawing up the COVID-19 vaccine, staff may have been unable to attend immediately as they needed to complete this process before attending karakia.

3.6 Support - Tautoko

The ESL director reported support from IC-A based in Alexandra that was helpful and appreciated. Provision of an additional RN vaccinator and immunisation co-ordinator (IC-B) was also appreciated due to pressure on the service. Otherwise, ESL felt that the contract was provided 'reluctantly' to provide vaccination services.

While ESL operates in accordance to tikanga and embody the principles of Te Tiriti, there is a Kaupapa Māori Service in Queenstown called Te Kaika who now own Mountain Lakes Medical. Te Kaika provide swabbing and vaccination services.

3.7 Response from Community – Korero-a-Hapori

ESL reported very positive response from the Queenstown community following public notification of a cold chain failure. Feedback (comments, flowers, visits) from the community expressing appreciation and recognition of work completed within the community by ESL were received. In particular, recognition of 'making a huge difference' for the community, particularly in providing a 'safe space' for vulnerable members of the community, as well as outreach to hard-to-reach communities was expressed. The review team interviewed a leader from another service provider in the area who expressed appreciation and support for the community service focus of ESL and was positive about interacting with them.

3.8 Current state – Mahi Nonaianei

The ESL (lead) director recognises and takes responsibility for breaches that the data loggers show occurred, and for lack of available documentation. ESL now has improved processes in place including a new vaccine fridge placed in a central location, relevant policies and procedures and a building to work out of enabling delegation to registered staff to always share and clarify responsibilities for cold chain maintenance.

'Kitea te anga a te haku. See the driving force of the kingfish. A leader who shows immense energy and drive.' [7] ESL has contributed to its community in many ways including employment, through the leadership of the lead director. An inspirational leader grows her workforce through the tikanga of delegation or tuku mana. Given the pressures on the director specifically from August 2021, tuku mana (delegation) needed to happen and was not in place.

ESL has a commitment to keeping staff employed who would otherwise not have employment and is committed to completing any training or other requirements to continue to support the community. The staff at ESL are a committed team who are united and community focused. As a result of this breach and associated publicity and risk to the public, there are likely to be some issues around trust in the community (although not expressed to ESL, negative or concerned reactions from the public have been expressed to SDHB members of staff). ESL was described by staff interviewed as providing manaakitanga, feeling proud of achievements and reputation (especially being first in New Zealand to reach 90% of Māori vaccinated). Registered staff feel that ESL is now positioned well with processes in place for the future. In particular, having a building at 18 Glenda Drive, Frankton, Queenstown with a designated area for the new vaccine fridge, monitoring and maintenance of cold chain will be easier to manage. A Cold Chain Policy for Engage Safety Ltd Covid 19 Vaccination Centre is in place. The policy covers cold chain management, fridge management, vaccine receipt and storage, staff responsibilities and data logger download. A procedure clearly outlining responsibilities for cold chain management is also in place. Staff training records show up to date training completed by registered staff including Vaccinator authorisation, COVID-19 Vaccinator Education Course, Adoloescent – Adult Vaccinator update and Paediatric COVID-19 Vaccinator education.

Due to rapid expansion of the business, the administrator has now set up processes within the office to meet good office practice. All staff have signed contracts and have had health and safety training and confidentiality training. Performance reviews have been held with relevant employees and are on file.

ESL are not vaccinating at present. Meanwhile they continue to provide kai parcels to fifty whanau, support and manaaki to whanau and occupational health services.

3.9 Root Causes Engage Safety Ltd- Nga Matapuna

In summary, the following root causes for the cold chain failure, specific to ESL are:

- Procedures were not followed. The procedures required to maintain cold chain accreditation as per the contract were not followed through this time of rapid expansion of the business in the context of a national pandemic. This was the responsibility of the ESL director (lead).
- Work Environment was affected by rapid change. Factors such as rapid workforce expansion, implementation of new processes and procedures, public demand for vaccination and felt

[7] Nga Pepeha a Nga Tupuna. Mead and Grove. Page 222, number 1355. A leader

pressure through government and media information, provided an environment where cold chain processes around documentation, recording and reporting were not maintained

- Work Direction was unexpected. With the speed of set up of the COVID-19 vaccination drive through clinics it appears that preparation was lacking. Worker(s) worked long hours and were fatigued leading to errors. Many of the team were unfamiliar with health systems and processes, requiring support and training in a very short time.
- Quality Control needs improvement. Fridge temperature monitoring responsibility was not shared when the vaccine fridge was in a private home. Record keeping was not maintained as required by National Standards for Vaccine Storage and Transportation for Immunization Providers 2017. Records are required to be kept for 10 years however are not able to be accessed.

3.10 Recommendations Engage Safety Ltd - Nga Taunaki

It is recommended that:

3.10.1 appropriate delegations, close monitoring, and clear processes to meet reporting requirements are in place for any future contracts to provide vaccination services to the community.

3.10.2 a continuous quality improvement system is developed within ESL.

3.10.3 processes are implemented to ensure security of records, including electronic storage and retaining of records for 10 years as required.

3.10.4 investment in remotely monitored loggers is considered so that fridge issues and alarms can be directed to an 'on call' person and managed in a timely way.

3.10.5 staff resource and training are reviewed to enable ESL to consistently meet all requirements of future contracts.

3.10.6 ESL and SDHB work towards communication that is open and transparent, proactive and timely with a culture of 'no surprises' and support.

4.0 Southern District Health Board Implementation of National Standards for Vaccine Storage and Transportation for Immunization Providers 2017 (updated 2019): Te Whakahaere o te Poari Hauora-a-Rohe ki te Tonga o Nga Paerewa to te Tiaki me te Kawe o Nga Rongoa Araimate e Nga Rato Tuku Awhikiri 2017 (whakahou 2019)

SDHB contracts providers to provide vaccination services and is responsible for working with providers to achieve cold chain accreditation (CCA). In the context of a national pandemic, the number of contracted providers to deliver the COVID-19 vaccination campaign grew to 120 providers. Nationally CCA operates as a 'high trust' model and generally works well. In this example, it is clear that the system was not maintained in a crisis situation (a national pandemic).

4.1 Assessment, review, and administration of Cold Chain Accreditation (CCA) – Tiro Whanui ki te Paemakariri Whakamana

Under the tikanga of mana whakahaere the SDHB had the authority to assess, review and administer cold chain accreditations for providers, including ESL.

4.1.1 Assessment of CCA – Aromatawai ki te Paemakariri Whakamana

SDHB immunisation coordinators (ICs) work with providers to ensure standards are met for CCA. Once gained, accreditation is in place for up to two years. The national guidelines state that this can be up

to three years; however, SDHB has chosen re-accreditation earlier that that to maintain closer contact with providers[8]. Although the lapse in cold chain accreditation at ESL was known about, the issues raised about data monitoring occurred later than November. Had CCA taken place at ESL on time in November, the potential cold chain failures may not have been discovered for some time or at all. Equally, if all cold chain management processes were in place as required, downloading of data and appropriate action in early December would have prevented the resultant breaches.

Providers are required to meet all national standards for cold chain management and all staff must be responsible for cold chain management. At ESL, prior to February 2022, only one staff member was responsible for cold chain management due to the vaccine fridge being located in the directors' home. This reduced the ability for other members of staff to assist with maintenance of cold chain processes.

4.1.2 Review of CCA – Arotake ki te Paemakariri Whakamana

The IC team reported difficulty engaging with ESL to arrange a time for CCA. This was raised with the IC immediate manager, the COVAX team and the associate Māori health officer/relationship manager – equity perspective. Communication and response from ESL was reported as being slow.

Previous to this event, IC-A reports that ESL had always been able to provide information on request including cold chain records, daily minimum/maximum records, draw up records and vaccine registers. The director of ESL commented that processes for cold chain management were reviewed in August 2021 with IC-A, therefore it was perceived by ESL that there was no urgency to schedule renewal of CCA. IC-A confirms that a visit occurred in August to make sure everything was in place and to assure herself that ESL had a full understanding regarding COVID-19 vaccine requirements. It was noted at that time in the COVID-19 vaccination programme that there was high stress. IC-A commented in a written outline of events that they preferred to review ESL cold chain compliance more regularly than other providers in Central Otago citing a tendency for ESL to leave things to the last minute and difficulty finding mutual times to complete reviews. A data logger was left in the ESL fridge by IC-A in an effort to provide additional monitoring.

The SDHB cold chain provider non-compliance policy guides actions where a provider is unable to achieve the standard required for CCA or has cold chain breaches resulting in suspension of CCA. It does not specifically address actions to be taken where CCA renewal is not completed in a timely way. The national standards[9] detail expectations where a provider fails to meet the standard or is found to be non-compliant. This includes:

- development of a remedial plan with timeframes
- undertaking a CCA assessment
- following up if the provider does not meet requirements
- discussion of issues with the Immunisation Advisory Council (IMAC) regional immunisation advisor, medical officer of health and Primary Health Organisation (PHO) clinical lead
- formally notifying and making recommendations to the provider
- revoking the existing CCA and placing deliveries to the provider on hold.

It appears that late CCA renewal was not considered a situation of non-compliance by SDHB, therefore none of the recommended remedial actions had been taken.

[8] Wallace, E. (2022). SDHB Current state of provider cold chain accreditation (CCA). Service Manager Population Health, 6 March 2022.

[9] Ministry of Health. 2019. National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition). Wellington: Ministry of Health. URL: www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportationimmunisation-providers-2017

From the perspective of the quality lead, ongoing issues with ESL did not feature as a 'red flag'. The CIR was checked up to twice weekly by the SDHB staff based on the information available. The terms of reference for the COVID-19 immunisation programme (CIP) clinical governance committee (July 2021) state that the committee has within its scope effective clinical governance of cold chain information, training and compliance. Although there is a quality lead in the COVID-19 programme a coordinated system for tracking CCA was not in place. The lack of CCA across the SDHB district was not known or tracked within the quality improvement programme of the DHB.

4.1.3 Administration of CCA – Whakahaerenga ki te Paemakariri Whakamana

As part of 'business as usual', ICs provide a monthly report to their manager. The report includes work undertaken during the month but does not include lapsed CCAs and actions taken. During this time of pressure around administration of large numbers of COVID-19 vaccines and setting up new providers, monthly reporting lapsed so issues were not formally reported. A new clinical nurse coordinator began the role during 'lock down' in 2020 without orientation and clear direction as to responsibilities around CCA.

SDHB changed from use of a 'Y:Drive' to the use of Microsoft Teams for storing of information. Although there was an online Microsoft Teams orientation provided, team members may not have been able to prioritise this due to the pace of change and workload at the time. This led to documents either being incorrectly saved and difficult to find or being saved onto individual desktop computers. Organisation of team meetings was difficult due to deployments and availability of staff, with the introduction of a new Microsoft Teams system adding to the complexity.

4.2 Processes for managing reaccreditation – Tukunga Whakamanatanga

Kei a wai te mana kia tuku whakamanatanga - who had the responsibility to ensure that ESL was reaccredited? While there were contractual arrangements there were responsibilities to tikanga. Tikanga attributed responsibility to both ESL and the SDHB. It is related to the tikanga roles of manaaki and awhi as shown in relationships between tuakana and teina. One has the role to look after the other as in manaaki, and the other has the role to help the other as in awhi. That tikanga further expresses that success and failure are shared.

According to the Ministry of Health guidelines[10], reaccreditation for cold chain accreditation may be approved for up to three years. During this time, although immunisation coordinators may work closely with providers, the opportunity to pick up any issues essentially occurs at the time for renewal of CCA. Providers are responsible to inform IC's when new staff are employed or equipment is purchased requiring sign off.

During the period under review, with the establishment of a completely new COVAX team to manage the COVID-19 vaccination programme, responsibility for CCA and following up on expired CCA across the district was unclear. Although there was additional resource employed (additional ICs and vaccinators in the COVAX team), the responsibility for training new staff was supported by established ICs. With the 2.5 full-time equivalent (FTE) resource available in that team across the SDHB district, accuracy in all areas of training, monitoring and responding to issues may not have been achievable.

[10] Ministry of Health. 2019. National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition). Wellington: Ministry of Health. URL: www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportationimmunisation-providers-2017

4.3 Response to breach – Whakautu ki te Wawahi

4.3.1 Response by SDHB - Whakautu na Nga Kaimahi o te Poari Hauora

On discovery of missing data and/or data indicating cold-chain failure, IC-A immediately informed IMAC to decide next steps. SDHB reported the cold chain failure as a serious incident/adverse event to the Ministry of Health[11]. The report indicated that:

- IC-A performed a cold chain visit on 2 March 2022 and identified data logging excursions
- No prior notification had been made by ESL
- No maximum/minimum logging was provided
- No vaccine had been quarantined
- ESL cold-chain records for 18 December 2021 to 7 January 2022 indicated prolonged periods at temperatures below 2 degrees Celsius (as low as approximately -3.5degrees Celsius)
- There were gaps in temperature logging
- Assessment of the data also revealed that weekly downloading of data had not been occurring.
- There was one occasion when the fridge alarmed and ESL consulted with IC-A who checked with IMAC, the vaccine was approved to be used.
- A similar alarm happened on a few occasions and was corrected immediately (less than 30 minutes and not required to be reported). The ESL directors decided at that point to order a new vaccine fridge. Vaccine was moved from the problematic fridge to a secondary fridge on 4 February 2022 (loggers not moved with vaccine) and on 10 February 2022 a logger was placed with vaccine in the secondary fridge and showed acceptable readings.

A risk assessment was taken at the time and recorded as:

i. 1 December 2021 to 18 December 2022 - HIGH risk (no data available, temperatures out of range immediately following 18 December 2021)
ii. 7 January 2022 to 14 January 2022 - HIGH risk (logger appears out of fridge, temperatures out of range prior and after time period)
iii. 4 February 2022 to 10 February 2022 - LOW risk (logger appears out of fridge, fridge appears to have been performing well)

SDHB worked with the CIR data lead at the MoH to test the logic for recalling members of the public for further vaccination. Given the unavailability of daily fridge monitoring records and the lack of a definite explanation for the variations in temperature and the missing data logger information, IMAC, the Ministry of Health (MoH) with SDHB determined that members of the public vaccinated during the HIGH-risk periods were required to be notified of a cold-chain failure and advised to take action to ensure immunity to COVID-19 by accessing a replacement vaccination.

At the time of the discovery of the cold chain failure at ESL, it was later identified that there was a total of ten providers across the SDHB area with expired CCA who were at various stages of working through renewal of CCA[12].

[11] Wallace, E. (2022). SDHB Current state of provider cold chain accreditation (CCA). Service Manager Population Health, 6 March 2022.
[12] Wallace, E. (2022). SDHB Current state of provider cold chain accreditation (CCA). Service Manager Population Health, 6 March 2022.

4.3.2 Response by the public - Whakautungia e te Hapori

As a result of the breach identified there have been a small number of affected members of the public who have written complaints to SDHB. Anxiety and distress in the community, and a small number of angry and/or distressed consumers have come to the attention of SDHB staff interviewed. Introduction of the COVID-19 vaccine mandate was a driver for discovering poor data keeping at ESL. Members of the public came forward for subsequent vaccinations and vaccination providers found that the CIR did not have a record of their initial vaccination. This was happening across Aotearoa New Zealand, and while problematic, was not isolated to ESL. All vaccination providers in the SDHB region have since been advised to collect details from any member of the public who comes forward for vaccination and a record of previous vaccination is not on CIR.

4.4 Root Causes SDHB – Nga Matapuna

In summary, the following root causes for the cold chain failure, specific to SDHB are:

- System Quality control needs improvement. A system to connect all services/departments within SDHB that had an interest and a role to play in ensuring quality of cold chain processes was not maintained.
- Management systems were not responsive. A 'red flag' was raised by IC-A in several places (ESL expired Cold Chain Accreditation). No action was taken to restrict, assess or halt activities until CCA was renewed.
- Communication was not maintained. When new systems were introduced during a period of rapid change and pressure to perform, key information was not always passed on or understood. Responsibility for responding to CCA issues was not clear.

4.5 Recommendations SDHB - Nga Taunaki

It is recommended that:

4.5.1 immunisation coordinator (IC) resource is reviewed to ensure sufficient FTE to support providers is available.

4.5.2 monthly reporting by IC's includes information about status of CCA and this is recorded in department governance meetings for action and follow up.

4.5.3 a system is strengthened to track CCA compliance across the SDHB region and this is included in the quality improvement programme for the DHB.'

4.5.4 processes are strengthened to ensure public safety is maintained during any period of CCA lapse/working towards renewal of CCA, in particular where concerns or 'red flags' are raised by frontline staff.

4.5.5 SDHB review the 'cold chain provider non-compliance policy' and any related policy to ensure it is fit for purpose in a pandemic or another national emergency environment. This may include feedback to IMAC regarding actions and recommendations following this review.

4.5.6 processes around introduction of new IT systems ensure that critical information and documentation is available to staff.

5.0 Southern District Health Board COVID-19 Vaccination Programme - Te Hotaka Rongoa Araimate o te Poari Hauora-a-Rohe ki te Tonga

The SDHB COVAX team was set up specifically to manage the large-scale vaccination required in response to the COVID-19 pandemic, and the availability of a vaccine. The team included four senior team members, a CIR/IT lead, a quality improvement lead, Well South (PHO) representation and four project managers for the four portfolios of:

- Central lakes area lead
- Rural lead
- Pharmacy lead
- Disability sector lead

The pace of change was intense, and a large number of providers were contracted within a few weeks to deliver COVID-19 vaccinations. This included general practice providers, pharmacies, Pacific health providers and Māori health providers, described as a diverse model utilising 120 providers. Throughout August 2021 (when ESL became involved as a new provider), the context has been described by several SDHB staff as a period of 'huge pressure' to deliver the COVID-19 vaccine, with large numbers of people to vaccinate, and a context of fear and anxiety in the community.

The COVAX team was responsible for operations and delivery of the COVID-19 vaccination programme including keeping up with stock allocation and expiry and to maintain full visibility of the CIR. In regard to cold chain management, the team relied on the ICs to managed CCA, with each provider being responsible to maintain accreditation and monitor their own systems to ensure vaccine security.

The COVAX team attempted to be flexible and support providers as systems were being developed as the situation emerged and changed. The team had a particular emphasis on removing barriers for Māori providers. ESL are not a Kaupapa Māori provider, although were allocated to the team charged with supporting Kaupapa Māori providers. This may have contributed to perceived support issues. There were issues with IT systems and wifi availability, leading to a number of providers starting with a paper-based system, as ESL did.

The IC-A did raise concerns about difficulty setting a time with ESL to renew CCA. Additionally, four weeks after the initial drive through vaccination clinics, other providers from the Queenstown community flagged concerns regarding uploading to the CIR by ESL to the COVAX team. This was initiated when several members of the public began presenting for follow up vaccination to find that they were not recorded on the CIR, therefore follow up doses could not be administered without evidence of the first dose. This was a cause of frustration amongst providers and members of the public. This issue was noted across the country and although predominant, was not isolated to ESL.

5.1 Contract and relationship management – Kirimana me te Hononga

Project/relationship managers were put in place to work with providers and work with ICs to bring new providers through the process to enable sign on to the vaccination programme. Many providers were already vaccinators such as general practices, some pharmacies, some Māori providers who also had a general practice within them. This meant that they were able to upscale but were familiar with the vaccination programme.

The time when ESL joined the programme has been described as a particularly volatile time in the programme. ESL was signed off as having met all requirements and was given a contract for COVID-19 vaccination. At that time, there were ongoing challenges with vaccine supply and difficulty

predicting demand. Providers were often asked to release stock to other providers making it challenging to keep track of stock on hand and future needs. ESL was asked by the COVAX programme on a small number of occasions to relinquish excess stock that was about to expire.

During this time, the IC-A worked closely with ESL. A recommendation was made by IC-A to ESL to cap daily numbers for vaccine drive through on the first day to enable working within the capability of available staff. This did not occur and the number of people vaccinated was only limited by the number of vaccines supplied.

5.2 Communication pathways – Ara Whakapa

Communication between ESL and IC-A and managers at SDHB appears to have been intermittent and at times tense. Paperwork required by the Ministry of Health was perceived as slow to be completed by ESL. From the COVAX team perspective, support was provided to ESL from senior management and ICs and vaccinators at the site. An equity plan was developed and shared nationally. Meanwhile, the Associate Māori Health Officer was perceived as working well with ESL and providing support. Support was in place for ESL including additional staff as described, however staff provided understood their role as 'helping out where there were gaps' rather than any oversight or leadership role. Direct contact between ESL and management support was intermittent, slow and at times did not occur.

'Kei a koe tetehi kiwai, kei ahau tetehi kiwai. For you one handle of the basket, for me the other handle.' [13] A well-known tikanga in maintaining relationships is kanohi ki te kanohi, face to face. That did not occur between the equity lead for SDHB and ESL. That was a regret expressed by both parties.

5.3 Clinical Governance Structures and functions – Hanga Haumanu Kawanatanga

Under the tikanga of mana whakahaere, the SDHB had the authority to erect clinical governance structures or Hanga Haumanu Kawana. A clinical governance committee was set up specifically for this work. The group met every two or three weeks. COVAX operational meetings occurred frequently with daily 'stand-up' meetings held five days per week. ICs were specifically employed for this programme, however may not have had the expertise required as it takes several years to become an expert IC. ICs employed within Population Health were rarely included in these meetings; the pace of required change may have contributed to this. The COVID-19 vaccination programme was set up with many staff adding their role in the team to other roles they currently held.

The governance structure was set up for the programme, however opportunities for improvement have been identified. CCA status was not monitored through governance and the established ICs were not as involved as may have been desirable. A strengthened platform for ICs to raise issues for action and response would have assisted with early recognition and intervention.

- There was a disconnect between Population Health, the COVID-19 vaccination team, immunisation coordinators and the quality lead regarding cold chain accreditation and who held responsibility for this. The COVAX team did not have a process in place to monitor COVID vaccination providers CCA status (noting all COVAX providers requiring CCA also provide other vaccination services) for example ESL has historically provided flu vaccination for which they require CCA.

[13] Nga Pepeha a Nga Tupuna. Mead and Grove. Page 212 number 1295. A burden shared

5.4 Root Causes COVAX team SDHB – Nga Matapuna

In summary, the following root causes for the cold chain failure, specific to the SDHB COVAX team are:

- The management system was disconnected. There was a disconnect between Population Health, the COVID-19 vaccination team, immunisation coordinators and the quality lead regarding cold chain accreditation and who held responsibility for this.
- Quality control was lacking. No system was in place to scope and track ongoing work and ensure this was reflected in the SDHB quality improvement programme and overseen by quality leads.
- Communication and response was inadequate. Issues of CCA expiry were flagged by IC-A to the COVAX team (and others). Continued attempts were made to set a date for renewal of CCA however no other action was taken.

5.5 Recommendations COVAX team SDHB - Nga Taunaki

5.5.1 When a new team is set up, ensure that responsibility for maintenance of national and regional standards is clearly documented and understood by those responsible.

5.5.2 Ensure that expertise of frontline staff is recognised and integrated into a new team structure, allowing transparent raising of issues to appropriate levels for action.

6.0 Discussion – Korero Whakawhiti

There is an opportunity for improvement to systems and processes both at ESL and within SDHB. This event should be considered within the context of a national pandemic, and at a particular stage in the pandemic where services were rapidly set up or scaled up to meet the requirements of the Ministry of Health to offer COVID-19 vaccines to the community. Within that context, a large number of consumers were safely administered COVID-19 vaccines by ESL. It has become clear that administration of contracts, response to non-reporting, and communication systems across departments within SDHB could be improved.

In regard to national learning from this review, the following comments are made. There was devolved responsibility to providers for the provision of vaccination to the population across the country and pressure from central government, the DHB and the community to provide COVID-19 vaccination. This meant that providers were managing a complex vaccine within a cold chain process that had to be implemented at scale. The national standards provide succinct information to providers on IMAC information sheets which are a valuable resource. The process of achieving CCA can be daunting to providers suddenly expected to provide a program at scale. The review team recommends that the national standards be enhanced for providers providing programmes at scale, perhaps at the governance level, given that failure has potentially harmful consequences.

Appendix 1 Glossary – Values – Apitihanga 1 – Kuputaka - Nga Tikanga

Huna = hidden, to conceal
Manaakitanga = support, hospitality, protect, respect
Mana whakahaere = authority, governance, management, power
Mohio whaiaro = personal information
Ngakau pono = sincerity, integrity, dependable
Pono = true, valid, honest
Tiaki tangata = caring for people
Tika = correct, right, withstand scrutiny
Tumu whakarae = chief executive, leader

Appendix 2 – Timeline – Apitihanga 2 – Rarangi Wa

The following timeline has been discussed and confirmed with ESL Ltd (ESL). The timeline includes events and contextual/environmental factors.

Date	Event	Contextual/Environmental Factors
Prior to 2018	Older fridge in ESL directors' home	Fridge was reliable, used for vaccines for occupational health clients, small number of vaccines.
2018/2019	New fridge purchased on advice from 2 pharmacies, placed in directors' home alongside older fridge	New fridge an industry medication fridge as recommended by 2 pharmacies consulted. Occasionally alarmed, dealt with quickly. Reporting felt to be unnecessary as always dealt with and temperature returned within 30 mins as per the regulations.
June 2021	ESL director spent 8-9 weeks in Invercargill working with Ngā Kete to ensure upskilling on all aspects of vaccination	ESL (lead) director had previously worked with Ngā kete and had established relationships there. Alongside this she completed Adolescent-Adult vaccinator update (21/06/21) and COVID-19 vaccinator education course (20/06/21). Has also completed Vaccinator authorisation (24/09/21) and paediatric COVID-=19 vaccinator education (07/01/22)
August 2021	Audit of ESL practices by Immunisation Coordinator (IC-A) SDHB	Check of cold chain processes completed by IC-A and ESL (lead) director. Comment made by IC to ESL director that ESL was 'the most audited clinic in the area'. IC-A checked that processes at that time were meeting standard required for cold chain.
August 2021	ESL was offered the use of the building at 18 Glenda Drive, short term use for 3 months	New building offer accepted. Building needed setting up to be office space and spaces for seeing clients; time consuming to make building fit for purpose.
07/08/21	Contract for outreach vaccination clinics commences	Plan to offer outreach clinics only in venues such as halls around the Central Otago area.
16/08/21	ESL employ 16 new staff on 3-month temporary contracts	Very busy period of employing and training new staff who did not have backgrounds in healthcare.
17/08/21	Lockdown announced	No plan for drive through clinics at this stage. Idea put forward to use Events Centre Support for this from Queenstown Lakes Council. Pressure from the community, Ministry of Health and government for the public to get vaccinated and for providers to scale up.
20/08/21	Paperwork for site set up received by SDHB from ESL	Paperwork fast tracked by SDHB to enable vaccinating to begin as soon as possible
23/08/21	First drive through clinic held by ESL	Extreme pressure to vaccinate large numbers, described as 'chaotic' by several people. Very brief run through then rapid scaling up due to pressure from the public for vaccinations.

		First 2 weeks using manual paperwork to record patient details, with information entered in the CIR after hours. Issues getting on and staying on national booking system. Associate Māori Health Officer assisted with issues around booking system (noted to be very busy). No written production plan supplied or agreed with ES NZ Ltd (vaccine volumes)– rather verbal understandings with SDHB team members to support the roll out of the drive through option. Specifically, SDHB agreed to source at short notice a "conservative" volume of vaccine to allow for the initial operation of the drive through on Monday 23 and Tuesday 24 August. The "conservative" volume of vaccines was in line with managing a new Covid vaccination provider with a graduated set up and new delivery model.Run sheets and 'some' weekly reports kept; ESL unsure who to send them to. SDHB supplied RN vaccinator and IC–B to assist.
25/08/21	Incident with NZ couriers, ESL attempts to fast-track vaccine supply from courier	ESL required additional vaccine. Vaccine being 'hubbed' from Queenstown. Local knowledge meant that ESL were aware of this and had been able to intercept vaccines this way in the past. Efforts were being made by SDHB to access additional vaccine elsewhere however ESL was unaware of this.
September 2021	Outreach clinics continue to businesses, individual homes and outlying areas	Some businesses coming through a special lane at drive through clinic. After initial rush of drive through clinic, business settled to maintain outreach clinics and in-home visits across the Queenstown Lakes and Central Otago area.
29/09/21	Issue with cold chain fridge in house reading -3 degrees	Brief incident, ESL reported to IC-A. Issue: vaccines too close to the back of the fridge; IC-A discussed with IMAC and advice received that vaccine not compromised and to continue.
Oct/Nov/Dec 2021; Jan 2022	'Occasional' alarms on fridge at home, (approximately 4 times)	ESL director reports there is always someone home. Not reported as vaccines thought to not be compromised and did not meet the threshold required by national IMAC policy (more than 30 mins[14]). Support workers trained in anticipation of flu vaccine roll out. ESL asked to pilot MMR roll out planned to start in March. Daily fridge checks completed, sighted by the pharmacist on a 'handful' of occasions over Dec/Jan,

[14] Ministry of Health. 2019. National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition). Wellington: Ministry of Health. URL: www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportationimmunisation-providers-2017

		also sighted by ESL RN vaccinator when removing vaccines from the fridge, also sighted by SDHB vaccinators (2) on one occasion. All staff spoken to confirm no issues with temperature on chilli bins on arrival at 18 Glenda Drive from ESL Directors' home (approximately a 5 minute drive). SDHB vaccinator (V-1) assisting 3-4 days per week as needed.
Christmas 2021 / early January 2022	Occasional fridge alarm	Vaccines moved back to older fridge. Although this fridge was old, it had no previous issues keeping temperature within the +2 to +8 degrees required. Change of fridge not reported.
November 2021	Cold Chain Accreditation expires	Communication between IC-A and ESL by text regarding need to renew cold chain accreditation. ESL understood this was due, did not feel urgency due to having been seen by IC-A in August.
Mid December 2021	ESL (lead) director returned to Ngā kete to learn swabbing technique with a view to taking up swabbing service	Multiple staff training and being supervised by ESL director. ESL (lead) director ensuring a change in culture around PPE, serious IPC requirements, swabbing protocols, staff safety (most staff had not come from a health background). ESL negotiating lease of 18 Glenda Drive. ESL putting together a business structure to support 25 new staff with purposeful jobs. ESL managing kai parcels to up to 44 whānau (unfunded). Assigning responsibilities, completing unfunded work such as employment of a Māori pharmacist to provide a medication reconciliation service.
February	Cold Chain Accreditation remains outstanding	ESL discussed with IC-A in early February, new fridge had been ordered, decision by IC and ESL to delay accreditation renewal visit until new fridge in place (late February).
25/02/22	Purchase of new vaccine fridge, placed in designated internal room at 18 Glenda Drive	3 loggers placed in new fridge to check for accuracy of temperature control prior to placing vaccines, this included x1 temperature logger belonging to IC-A.
02/03/22–1300hrs	IC-A visits ESL for cold chain accreditation renewal visit	Cold chain breaches identified as data downloaded. On checking back further IC-A discovered more breaches and missing data. Daily fridge check information not able to be located from house site, this may have been accidentally discarded when getting ready for visitors to stay, or when moving paperwork from directors' home to new premises. Fridge temperature manual monitoring information is available from 4 January 2022 onwards. This shows fridge temperature above 8 degrees (upper limit) between 25/01/22 and 30/01/22.

03/03/22	Notification of potential breach made to SDHB	Senior members of the COVAX team, as well as Associate Māori Health Officer/Relationship Manager – Equity perspective informed of potential breach.
04/03/22	Visit by Southland IC	Visited ESL to locate relevant records following notification of a breach. Assisted by ESL director (lead), found all available information at that time. Vaccines uplifted.
03/03/22 to 07/03/22	SDHB worked with IMAC and Ministry of Health to assess next steps	SDHB attempted to gain all information possible to enable a risk assessment to the public. Advice from IMAC concluded that there were 2 periods of time that were of particular interest. This was either when no information was available, or data loggers noted the number of freeze/thaw cycles exceeded recommendations obtained directly from Pfizer. Stock supply information from SDHB was used to assess which members of the public may have been affected.
07/03/22	Affected Members of the public notified of breach	Members of the public vaccinated during the time period identified were advised to present for a further COVID-19 vaccination to ensure protection against COVID-19. At time of writing 61% of people have re-presented.
08/03/22	ESL visited for the first time by Associate Māori Health Officer/Relationship Manager – Equity perspective and A WellSouth representative	During pandemic SDHB had travel restrictions in place. No face to face visits occurred between August 2021 when contract began and March 2022. All vaccines removed from ESL fridge at 18 Glenda Drive to be returned to SDHB and discarded. Fridge temperature logger belonging to IC returned to IC.
After 08/03/22	SDHB accessed all records held by ESL	Retrospective assessment of all documentation by SDHB administration staff, found a large number of errors during the initial set up time including: • Information recorded late to CIR • Information absent from CIR • Information on paper file not matched to CIR documentation Impression that ESL did not have resources of capability to correct all records. Ongoing issues reported such as: • Wrong dose in wrong interval • Early doses • Wrong age groups However, errors were assessed as being no higher than other providers and were not unusual.

Appendix 3 – Staff Interviewed – Apitihanga 3 – Korero a Nga Kaiwhakautu

Debbie Swain-Rewi	Director (Lead) ESL, registered nurse, vaccinator
Darren Rewi	Director ESL,
Zahra Nadal	Registered Nurse, vaccinator, ESL
Brendon McIntosh	Pharmacist, ESL
Diane Payne	Registered Nurse, paramedic, vaccinator
Trish	Administrator, ESL
Ebony Webster	COO, Mana Tahuna (contracts to ESL for kai parcels)
Nancy Todd	Associate Māori Health Officer/Relationship Manager – Equity Perspective
Emma McDonough	COVAX programme manager
Andrew Barry	Operations Manager – COVID-19 workforce, pharmacist
Karl Metzler	COVAX SRO
Rebecca Buchan	Clinical nurse co-ordinator, SDHB
Judy Walker	SDHB COVID-19 vaccination programme quality lead
Mary Millen	Registered Nurse, vaccinator, SDHB
Meg Paulin	Clinical Immunisation Co-ordinator (IC-A),
Fran Hunt	Clinical Immunisation Co-ordinator (IC-B) SDHB

Appendix 4 – Documentation Reviewed – Apitihanga 4 – He Tuhinga i Kitea

1. **Engage Safety Ltd Documents reviewed**

Document	Comments
Engage Safety Roles and Responsibilities – Clinical Lead	
Cold Chain Management Policy for Immunisation Services	Not signed
Engage Safety Individual Employment Agreement (per employee)	
Engage Safety Limited Job Title – COVID vaccination programme	Job description
Engage Safety Limited: Level 3 and Level 4 Vaccination Delivery	Plan for Drive through clinic: Queenstown Events Centre
Engage Safety Limited : New Staff Orientation • Responsibility of vaccinator(s) on duty for daily and weekly data download • Vaccine management – recording and rotation of stock • Cold Chain orientation guide / checklist for new staff • COVID-19 Vaccinations 5-11 year olds, resource folder	
Engage Safety Limited: Cold Chain Policy for Engage Safety Ltd Covid-19 Community Vaccination Centre • Cold chain management • Fridge Management • Vaccine receipt and storage • Staff responsibilities • Data logger and download Additionally • Details around COVID-19 Vaccination programme	Dated 27/02/2022
Cold Chain Management: 18 Glenda Drive (procedure)	
Engage Safety Ltd Production Plan	30/08/2021
Engage Safety Ltd – first quarter stats 2022	Detail on aspects provided to the community by ESL
Engage Safety Training and Professional Development Record – certificates and records sighted	

2. **SDHB Documents reviewed**

Document	Comments
SDHB Cold Chain Provider Non-compliance Policy	Provider may be referred for competence review by their regulatory body, particularly relevant where a cold chain failure could have been prevented if action had been taken
COVID-19 Programme (CIP) Clinical Governance Committee Terms of Reference (District) July 2021	See point 3 … monitor the programme's clinical quality & safety measures Responsible for effective clinical governance of:

	• cold chain information • Training and compliance
SDHB Current State of Provider Cold Chain Accreditation (CCA)	6 March 2022
Time line for events leading up to uncovering the cold chain failure at Engage Safety	Comments on lead up to the incident and current state
2021-06-02_COVID-19_reponse_structure v10.1	
CC breach MedPro Cromwell June 2021	
Central Otago Immunisation Coordination August Monthly Report 2021	
Central Otago Immunisation Coordination July Monthly Report 2021	
Central Otago Immunisation Coordination September Monthly Report 2021	
CFA Immunisation Coordination Service Report Jan 2022	
Cold Chain Breach MLMC May 2021	
Covid-19 Vaccination Programme Maori plan	
Response Deliverable and Action Tracker	
IncidentReviewEngageSafetyLtd-Judy FINALDRAFT 31August2021	
EngageSafetyColdChainManagementChillyBin31March22	
Serious-incident-adverse-event-notification-form-ENGAGE SAFETY feb2022	
Southern DHB CCA Audit confirmation March 2022	
Engage Safety Delivery Report email, which has IM All Transactions by Stock-2022-03-14-15-37-43 spreadsheet	
Engage Safety data logger record	
Invercargill to Stewart Island 15 03 2022	
Production Plan 30.8.21 Engage Safety	

3. Other information reviewed

Cold Chain info from Immunisation Advisory Centre Cold Chain | Immunisation Advisory Centre (immune.org.nz)
Annual Cold Chain Management Record
Immunisation Handbook 2020 Immunisation Handbook 2020 online | Ministry of Health NZ
COVID-19 Vaccine Immunisation Programme Service Standards covid-19-vaccine-immunisation-programme-service-standards-29oct2021.docx (live.com)
Operating Guidelines for DHBs & Providers - COVID-19 Vaccine Immunisation Programme MoH covid-19-vaccine-operating-guidelines-3sep2021_0.docx
COVID-19 Vaccine Use and Waste Policy StatementCOVID-19 Vaccine and Immunisation Programme MoH covid-19-vaccine-use-waste-policy-statement-17aug2021.pdf