

# Te Niwha Scholarship Summary for Final Report

## Research Title

**The COVID-19 Needle Length Study: A randomised controlled trial of the immunogenicity and reactogenicity of subcutaneous (SC) vs intramuscular (IM) administration of COVID-19 vaccination in community pharmacies in Aotearoa New Zealand.**

### Scholarship recipient:

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## Summary

mRNA COVID-19 vaccines are designed for deep intramuscular delivery, in Aotearoa/New Zealand (A/NZ) vaccination guidelines recommend the use of standard needle length of 25mm when administering deep intramuscular (IM) vaccines in most adolescents and adults, with the option of a longer 38mm needle for 'very large or obese persons'. These guidelines for vaccinators are non-specific and rely on clinical judgement of vaccinators to select which needle is appropriate to reach the muscle. Previous studies conducted out of the Medical Research Institute (MRINZ) show the standard needle length of 25mm is too short for deep IM deposition of the vaccine in a large proportion of adults with obesity, with up to 45% of their obese study population would not have received adequate IM deposition with 25mm needle. Obesity can increase the risk of severe illness from COVID-19 and decrease the chances of deep IM administration because of a thick subcutaneous (SC) fat layer. Obesity in adults is defined as a body mass index (BMI) of 30 kg/m<sup>2</sup> or more; one in three adults are classed as obese in A/NZ with Māori and Pacific Peoples having the highest prevalence. However only 2% of COVID-19 vaccines were administered with a longer 38mm needle, suggesting a significant rate of inadvertent SC vaccination.

The COVID-19 Needle Length Study is a randomised controlled trial of 400 participants comparing the immunogenicity (immune response) and reactogenicity (side effects) experienced when the COVID-19 booster (XBB.1.5 or JN.1) vaccine is administered SC versus IM in adults aged 18-75 years, with a BMI  $\geq 30.2\text{kg/m}^2$  (female) or  $\geq 37.3\text{ kg/m}^2$  (male). Participants were blinded and randomized to receive the COVID-19 booster either IM (38mm) or SC (12.7mm). To capture the side effects experienced participants completed surveys for the first seven days post vaccination, at day 28 and day 105. In addition, they completed COVID-19 Vaccine Hesitancy Scale surveys at screening and day 28 to assess vaccine hesitancy. To capture their immune response through neutralising antibody titers blood samples were taken before vaccination, day 28 and day 105.

Our study was coordinated out of the MRINZ office, Wellington Regional Hospital and conducted through the MRINZ New Zealand Pharmacy Research Network (PRN), a nationwide group of research trained pharmacists that can undertake RCTs. Pharmacists are highly accessible and well-established health providers which actively engage with their communities. The PRN utilises patient-pharmacist relationships to conduct research in under-served regions of A/NZ and is scalable to include any community pharmacy across NZ. Community pharmacies played a pivotal role

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during A/NZ's COVID-19 response, demonstrating the ability to rapidly implement novel services including vaccination, telehealth services, and supervised rapid antigen testing. This study has further developed pharmacist research capacity at PRN sites, ensuring the network of embedded community pharmacy research hubs across A/NZ are able to rapidly and efficiently respond when a new infectious disease threat emerges.

Since completing study recruitment in August 2025, we've analysed our reactogenicity data. Results show weak evidence of higher rates of moderate local reactions and association with a lower incidence of systemic reaction with SC administration. Local reactions were common in both groups and consistent with previous reports for mRNA COVID-19 vaccines. We are collaborating with Awanui labs for the analysis of immunogenicity; analysis will be complete in the first half of 2026. Once results are available, we will be able to describe the neutralising antibody response following SC administration relative to IM administration.

Our study aligns with Te Niwha's mission for infectious disease prevention in A/NZ and it will help to address whether IM deposition of the COVID-19 vaccine is critical to achieve immunity and reduce the severity of local reactions.