

# **Research Project Impact Case Study**

Randomised controlled trial evaluating immunogenicity and reactogenicity of subcutaneous versus intramuscular COVID-19 vaccination

**COVID-19 Needle Length Study** 

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# Te Niwha Research Project - Impact Case Study

#### Introduction

COVID-19 vaccines are intended for injection into the deltoid muscle in the arm. However, previous research identified standard 25mm needles are inadequate to ensure intramuscular injection in 45% of adults with obesity. Currently, vaccination guidelines provide non-specific advice about needle selection, and less than 2% of COVID-19 vaccinations in Aotearoa being delivered with a longer 38mm needle. Therefore, a significant population in Aotearoa are inadvertently receiving their COVID-19 vaccines into the subcutaneous tissue. For some vaccines, subcutaneous administration can increase the risk of injection site reactions and reduce immune response. However, it is currently unknown if delivery location for COVID-19 vaccines influences the immune response or the severity of adverse reactions following vaccination.

This randomised controlled trial compares immunogenicity and reactogenicity of subcutaneous versus intramuscular injection of the COVID-19 vaccine. In total, 400 adults will be recruited from community vaccinating pharmacies in Aotearoa to receive the COVID-19 booster via a 12.7mm or 38mm needle and are followed up over 15 weeks.

Research partners include community pharmacies across Aotearoa, Pacific Health Services Hutt Valley and Mareroa Marae Health Clinic. This project develops pharmacist research capacity, ensuring the network of embedded community pharmacy research hubs across A/NZ can rapidly and efficiently respond when a new infectious disease threat emerges.

## **Results**

To date, recruitment is currently 72% complete and on track to be complete by August 2025. Immunogenicity and reactogenicity outcomes will be analysed in Q1 2026 once final participant visit is complete. This research has resulted in students and community pharmacists taking part in clinical research and developing clinical trial capacity.

## **Impact**

This study will provide information as to whether intramuscular delivery of COVID-19 vaccines is essential to achieve full therapeutic effect, and whether inadvertent subcutaneous delivery may increase reactogenicity.

Ensuring vaccines are delivered effectively is crucial for public health. This study will provide essential data on whether needle length influences immune response and side effects, helping shape vaccination guidelines for better health outcomes. If a difference is identified between intramuscular and subcutaneous delivery, this will inform vaccination guidelines in Aotearoa and internationally to ensure vaccines are delivered in a method that is safe and effective for all body types. Immunisation Advisory Centre, Health New Zealand, the Māori Health Authority, and the Ministry of Health will be closely informed of the progress of the study, as findings can inform vaccination guidelines.

This research project has opened the door for future research in this area. The research framework and infrastructure are currently being developed for a future project for subcutaneous versus intramuscular randomised controlled trial investigating influenza vaccination. This project is currently being designed for a 2025/2026 HRC project grant.