Post Vaccine Symptom Check report: 2023 Comirnaty bivalent COVID-19 vaccine survey

Health New Zealand | Te Whatu Ora and Medsafe advises people NOT to make any decisions about vaccination based only on the information contained in this report. If you have questions or concerns about receiving a vaccine, please speak to a health care professional.

Introduction

The information from the Post Vaccine Symptom Check (PVSC) survey supports ongoing safety monitoring of the Comirnaty COVID-19 vaccine used in Aotearoa New Zealand.

The Comirnaty bivalent COVID-19 vaccine PVSC campaign was conducted from 1 March 2023 through 17 October 2023. Health New Zealand | Te Whatu Ora sent text messages to a random sample of consumers who had received the Comirnaty Bivalent COVID-19 vaccine. The text messages asked consumers if they had experienced an adverse reaction after their vaccination, and if they would like to participate in the survey. Consumers could reply STOP to this text message if they wished to opt out of the survey. Consumers who chose to participate completed a day 7 and day 42 survey to provide more information about their vaccination experience or adverse reactions.

The information presented below is limited to those aged 18 years and older that were vaccinated with the Comirnaty bivalent COVID-19 vaccine and participated in the 2023 Comirnaty bivalent COVID-19 PVSC survey. It does not represent the total number of people who were vaccinated nor the total number of people who experienced an adverse reaction after their vaccination. Not everyone will report an adverse reaction to the vaccine through the PVSC survey, some might submit a report to the Centre for Adverse Reactions Monitoring (CARM).

The number of vaccine adverse reaction reports in a PVSC campaign can be influenced by; the number of participants, the nature of the symptoms (e.g., how painful the vaccination was), and other factors (e.g., concurrent viral infection or other medicines taken), which vary over time.

PVSC survey answers may come from one person, but that person may report more than one adverse reaction. As with any adverse reaction, some may be associated with the vaccine or may be coincidental and due to other reasons.

PVSC surveys do not specifically ask for the reason why the person sought medical care in the days following vaccination. Therefore, medical attendance reported may or may not be related to any reported adverse reactions.

Based on data collected from the 2023 Comirnaty bivalent COVID-19 PVSC campaign, we have not identified any new safety concerns for the Comirnaty bivalent COVID-19 vaccine. Collected data is in line with data collected from clinical trials and from other post-marketing surveillance in New Zealand and overseas.

Survey results

From 1 March 2023 through 17 October 2023, text messages were sent to consumers 7 days following their Comirnaty bivalent COVID-19 vaccination, asking if they had experienced any adverse reactions, to which they could respond 'Yes' if they had or 'No' if they had not. They could reply 'Stop' if they did not wish to participate. A total of 46,955 consumers responded, 'Yes' and 158,129 responded 'NO' to experiencing any adverse reactions and a further 13,259 responded 'Stop'. The response rate was 66% (Table 1). A further 40,136 participants completed a follow up survey, 42 days after their vaccination. More females participated in the survey than males, and most respondents identified as European or Other (Table 2).

Of the consumers that responded, 23% experienced at least one adverse reaction within 7 days of vaccination (Table 3). The proportion of adverse reaction reporting was similar across ethnicities.

The five most frequently reported adverse reactions for the day 7 survey were: injection site reaction, fatigue or tiredness, head or muscle aches, flu symptoms, and chills (Table 4). These are common adverse reactions linked to the immune response following immunisation with many vaccines.

In the follow up day 42 survey, participants that reported experiencing an adverse reaction in the day 7 survey, were asked if their symptoms were resolved. A large majority of people (97%) were no longer experiencing their reported day 7 symptoms.

Of the consumers who completed the day 7 and 42 surveys, very few reported missing work or other daily activities. Of those who indicated they missed work on the day 7 survey, approximately 60% missed one day or less, and less than one percent (0.4%) of people indicated that they visited a doctor after their vaccination (Figure 1). Of those who indicated they missed work on the day 42 survey, 44% were reported to have missed one to two days, 25% missed three to five days and 26% missed six days or more (5% answered that they were unsure).

Medical advice was sought by 3% of people, this could include seeking care from a GP clinic, phone advice from a helpline (e.g., Healthline), visiting a hospital emergency department, rangoā clinic, Whānau Ora navigator, or a Marae.

Table 1: Summary of text message responses, 1 March 2023 through 17 October 2023

Survey	Text messages sent	Responses received	Response Rate (%)
Day 7 survey	310,574	205,423	66%

Table 2: Summary of day 7 and day 42 text message responses by demographic, 1 March 2023 through 17 October 2023

Demographic	Comirnaty Bivalent COVID-19 day 7 survey		Comirnaty Bivalent COVID-19 day 42 survey	
	Responses received	Percentage	Responses received	Percentage
Gender				
Male	87,008	42%	59,195	42%
Female	118,355	58%	82,455	58%
Other[a]	60	<1%	31	<1%
Total	**205,423**	**100%**	**141,681**	**100%**
Ethnicity				
Māori	19,269	9%	13,116	9%
Pacific Peoples	5,600	3%	3,220	2%
Asian	18,323	9%	10,154	7%
European or Other	162,231	79%	115,191	81%
Total	**205,423**	**100%**	**141,681**	**100%**

a: For both day 7 and day 42 surveys, less than 1% of respondents were unknown, and less than 1% of respondents were gender diverse.

Table 3: Percentage of people that reported an adverse reaction following the Comirnaty Bivalent COVID-19 vaccine, within ethnicities, 1 March through 17 October 2023

Ethnicity	Total Responses	Reported an adverse reaction	
		Number	%
Māori	19,269	4,293	22%
Pacific peoples	5,600	1,284	23%
Asian	18,323	4,965	27%
European or other	162,231	36,413	22%
Total	205,423	46,955	23%

Table 4: Type of reported adverse reaction following Comirnaty Bivalent COVID-19 vaccine among all 205,423 responses received, 1 March through 17 October 2023

Adverse reaction	Number	Percentage out of all responses (n=205,423)
Injection site reaction (pain, redness, swelling, itching at or near the injection site)	18,921	9%
Fatigue or tiredness	18,363	9%
Headache, muscle or body aches or pain	17,360	9%
Flu symptoms	9,238	5%
Chills (shivering or feeling cold)	6,815	3%
Dizziness or feeling lightheaded	5,647	3%

Figure 1: People that sought medical advice after vaccination with the bivalent COVID-19 vaccine, 1 March through 17 October 2023

Bivalent COVID-19 vaccine day 7 survey	**Bivalent COVID-19 vaccine day 42 survey**
Fewer than 1 in 100 people (<1%) reported seeking medical advice in the 7 days after their bivalent vaccination	Fewer than 3 in 100 people (3%) reported seeking medical advice in the 42 days after their bivalent vaccination