Post Vaccine Symptom Check report: 2023 concomitant Comirnaty bivalent COVID-19 and influenza 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 bivalent COVID-19, and influenza vaccines used in Aotearoa New Zealand.

On 1 March 2023, the Comirnaty bivalent COVID-19 vaccine replaced the existing Comirnaty vaccine used in New Zealand. On 1 March 2023, the influenza vaccine annual winter rollout also began. For 2023, concomitant administration (receiving both vaccines at the same time) of the bivalent and flu vaccines was offered by the immunisation programme to those who were eligible for both. The bivalent vaccine targets two strains of the COVID-19 virus (the original and the BA 4/5 Omicron subvariants), and the influenza vaccine targets four strains of influenza.

The 2023 Comirnaty bivalent COVID-19 vaccine PVSC campaign was conducted from 1 April 2023 through 17 October 2023. Health New Zealand | Te Whatu Ora sent text messages to a random sample of people who had received the bivalent 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 answered that they had experienced an adverse reaction were invited to complete 2 surveys, at 7 and 42 days following vaccination. The day 7 survey primarily focuses on collecting information on common adverse reactions within 7 days of vaccination. The day 42 survey primarily focuses on collecting information on serious suspected adverse reactions within 42 days of vaccination. Both surveys include health impact questions.

The information presented below is limited to those aged 18 years and older that were vaccinated with the Comirnaty bivalent COVID-19 vaccine, participated in the Comirnaty bivalent COVID-19 day 7 PVSC survey, and reported having at least one adverse reaction. This report includes responses from the day 7 survey only, as it is the only survey where the concomitant vaccine administration status of respondents is known. 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 a 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 when given alone or together with influenza 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. Among 25,536 respondents that reported having at least one adverse reaction following their vaccination, 10,558 (41%) had concomitant administration of the bivalent and influenza vaccine (<u>Table 1</u>). Uptake of concomitant administration was similar across gender, however it varied by ethnicity. Uptake was higher among Māori and Pacific Peoples and lowest among Asians.

The five most frequently reported adverse reactions were injection site reaction, fatigue, headache, flu symptoms, and chills (<u>Table 2</u>). These were the same regardless of if the vaccination was concomitant. These are common adverse reactions linked to the immune response following immunisation with many vaccines.

Of respondents, 3% indicated that they visited a doctor after receiving either a bivalent Comirnaty COVID-19 vaccine (3%) or concomitant bivalent and influenza vaccination (3%) (Figure 1).

The profile of reported adverse reactions to PVSC for Comirnaty bivalent COVID-19 vaccine and concomitant administration of the Comirnaty bivalent COVID-19 vaccine and influenza vaccine is similar to that reported for the Comirnaty (Pfizer) dose 1, 2 and booster PVSC campaigns.

Table 1: Type of vaccine administration among 25,536 respondents that reported having at least one adverse reaction following their vaccination by gender and ethnicity, 1 April through 17 October 2023

Demographic	Received Comirnaty bivalent and influenza vaccine		Received Comirnaty bivalent vaccine only					
	Number	Percentage	Number	Percentage				
Gender								
Male	3,301	43%	4,410	57%				
Female	7,254	41%	10,563	59%				
other	3	<1%	5	<1%				
Total	10,558	41%	14,978	59%				
Ethnicity								
Māori	1,127	54%	945	46%				
Pacific Peoples	259	53%	233	233 47%				
European or Other	8,418	41%	12,410	59%				
Asian	745	35%	1,390	65%				
Total	10,558	41%	14,978	59%				

Table 2: Most frequently reported adverse reactions among participants reporting at least one adverse reaction, 1 April through 17 October 2023

Adverse reaction	Comirnaty bivalent and influenza vaccine (n=10,558)		Comirnaty bivalent vaccine only (n=14,978)	
	Number	Percentage	Number	Percentage
Injection site reaction (pain, redness, swelling, itching at or near the injection site)	7,830	74%	10,760	72%
Fatigue or tiredness	7,598	72%	10,459	70%
Headache, muscle or body aches or pain	7,080	67%	9,993	67%
Flu symptoms	3,917	37%	5,142	34%
Chills (shivering or feeling cold)	2,705	26%	3,996	27%
Dizziness or feeling lightheaded	2,386	23%	3,159	21%

Figure 1: Number of people that completed a survey and visited a doctor after vaccination with Comirnaty bivalent vaccine only, or concomitant Comirnaty bivalent vaccine and influenza vaccine, 1 April through 17 October 2023

Of those who experienced an adverse reaction after receiving either the Comirnaty bivalent COVID-19 vaccine, or after concomitant administration of the Comirnaty bivalent COVID-19 and influenza vaccine, approximately three in every 100 people reported seeking medical advice in the days after their vaccination(s)

