Post Vaccine Symptom Check report: 2022 Comirnaty COVID-19 paediatric 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 paediatric vaccine used in Aotearoa New Zealand.

The 2022 Comirnaty COVID-19 paediatric vaccine PVSC campaign was conducted from 28 January 2022 through 31 October 2022. Health New Zealand | Te Whatu Ora sent text messages to a random sample of parents/caregivers whose tamariki had received the Comirnaty COVID-19 paediatric vaccine. The text messages asked parents/caregivers if their tamariki 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. Parents/caregivers of tamariki who chose to participate completed a day 7 survey to provide more information about their tamariki's vaccination experience or adverse reactions.

The information presented below is limited to those aged 5 through 11 that were vaccinated with the Comirnaty COVID-19 paediatric vaccinations and parents/caregivers whose tamariki participated in the Comirnaty COVID-19 paediatric PVSC survey. It does not represent the total number of tamariki who were vaccinated nor the total number of tamariki 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 (<u>CARM</u>).

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 a 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 2022 Comirnaty COVID-19 Paediatric PVSC campaign we have not identified any new safety concerns for the Comirnaty COVID-19 Paediatric 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 28 January 2022 through 31 October 2023, text messages were sent to the parents/guardians 7 days following their tamariki receiving a Comirnaty COVID-19 paediatric vaccination, asking if their tamariki 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 5,055 consumers responded, 'Yes' and 19,558 responded 'NO' to experiencing any adverse reactions and a further 387 responded 'Stop'. The response rate was 47% (Table 1). More dose 2 consumers participated in the survey than dose 1 consumers (Table 2), and European or Other was the ethnicity most respondents identified as (Table 3).

Of the consumers that responded, 21% experienced at least one adverse reaction within 7 days of vaccination. The proportion of adverse reaction reporting was similar across ethnicities (<u>Table 3</u>).

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

Of the consumers who completed the day 7 survey, very few reported missing school or other daily activities (<u>Table 5</u>). Of those who indicated they missed school on the day 7 survey, the majority missed one day or less, and less than 1 percent of people indicated that they visited a doctor after their vaccination (<u>Figure 1</u>).

Campaign	Text messages sent	Responses received	Percentage of responses received
Comirnaty COVID-19 paediatric	52,919	24,623	47%

Table 1: Summary of day 7 text message responses, from 28 January 2022 through 31 October 2022

Table 2: Responses by vaccine dose and adverse reaction,	28 January 2022 through 31
October 2022	

		Did not report an adverse reaction			at least one reaction
Dose	Responded	Number	Percentage	Number	Percentage
Dose 1	9,152	7,526	82%	1,626	18%
Dose 2	15,461	12,032	78%	3,429	22%
Total ^a	24,613	19,558	79%	5,055	21%

a: A small number of texts were sent out for dose 3 immunocompromised tamariki: 34 texts were sent, and 10 responses were received. Due to low numbers, analysis of these 10 responses is not shown to protect privacy. Therefore, the sum of the responses in this table is different from the other tables.

Table 3: Responses by ethnicity and adverse reaction, 28 January 2022 through 31 October 2022

			ort an adverse		at least one reaction
Ethnicity	Responded	Number	Percentage by ethnicity	Number	Percentage by ethnicity
Māori	3,148	2,501	79%	647	21%
Pacific peoples	1,394	1,131	81%	263	19%
Asian	5,798	4,872	84%	926	16%
European or Other	14,281	11,060	77%	3,221	23%
Total ^a	24,621	19,564	79%	5,057	21%

a: A small number of responses did not contain ethnicity data and are not shown here to protect privacy. Therefore, the sum of the responses in this table is different from that shown in the other tables.

Table 4: Most frequently reported adverse reactions among total responses by dose,	28
January through 31 October 2022	

	Dose 1 ((n=9,152)	Dose 2 (ı	า=15,461)
Reported reaction	Number	Percentage	Number	Percentage
Injection site reaction	715	8%	1,646	11%
Tiredness	501	6%	1,031	7%
Headache, muscle/body aches	336	4%	810	5%
Stomach symptoms	138	2%	319	2%
Fever	133	2%	283	2%
Chills	68	<1%	260	2%
Swollen lymph node(s)	29	<1%	136	<1%
Rash (not at injection site)	19	<1%	33	<1%

Table 5: Proportion of tamariki that missed school or other daily activities among total 24,613 responses received, 28 January 2022 through 31 October 2022

Dose	Missed school or activity		
	Number	Percentage	
Dose 1	231	1%	
Dose 2	584	2%	

Figure 1: Tamariki that visited a doctor after vaccination, by dose, 28 January 2022 through 31 October 2022

Dose 1	Dose 2
Less than 1 in 100 (0.28%) of tamariki	Less than 1 in 100 (0.42%) of tamariki
reported a visit to a doctor in the days after	reported a visit to a doctor in the days after
the first dose	the second dose



