IMSURE ACTIVE SURVEILLANCE PROGRAMME :

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) POST COVID-19 VACCINATION AMONG TWO-DOSE VACCINE RECIPIENTS IN MALAYSIA

KEMENTERIAN KESIHATAN MALAYSIA
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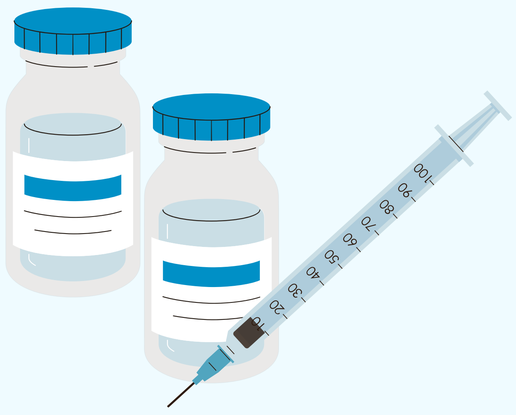


INTRODUCTION

- The COVID-19 vaccination provides different levels of protection against SAR-CoV-2 infection to vaccine recipients.
- Post-Vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE) is a surveillance programme initiated in conjunction with the COVID-19 National Immunization Program for monitoring immunity and the occurrence of COVID-19 post vaccination.
- This study aims to analyse the adverse event following immunization (AEFI) among two-dose vaccine recipients in Malaysia.

METHODOLOGY

- This is a sentinel surveillance study that applied a prospective cohort design to monitor and follow-up selected vaccine recipients (18 years and above) at nine (9) vaccination administration centres (PPV) nationwide.
- AEFI was recorded using questionnaire from National Pharmaceutical Regulatory Agency (NPRA) as Self-administered Questionnaire (SAQ) at two time-points; 1) Second dose appointment; 2) 14 days after the complete dose of Comirnaty, CoronaVac and Vaxzevria.
- Descriptive analysis was done to describe AEFI by different types of vaccines and logistic regression was conducted to identify the factor associated with AEFI.

RESULTS

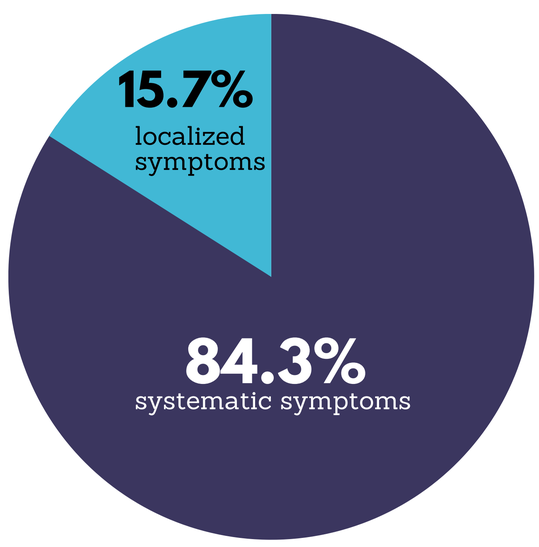
Table 1: Percentage of AEFI / AESI (symptom and no symptom) by type of vaccines.

Type of vaccine	Dose	AEFI				AESI			
		Symptom		No symptom		Symptom		No symptom	
		count, n	%	count, n	%	count, n	%	count, n	%
Comirnaty	1st dose	178	31.3	390	68.7	2	0.4	566	99.6
	2nd dose	205	40.4	302	59.6	1	0.2	506	99.8
CoronaVac	1st dose	160	28.9	393	71.1	1	0.2	552	99.8
	2nd dose	133	27.3	354	72.7	4	0.8	483	99.2
Vaxzevria	1st dose	335	59.5	228	40.5	2	0.4	561	99.6
	2nd dose	142	29.2	344	70.8	0	0	486	100

Table 2: Factor associated with AEFI among two-dose vaccine recepients.

Variables	Unadjusted			Adjusted		
	β	95% CI	*p-value*	β	95% CI	*p-value*
Vaccine types						
Comirnaty	3.219	2.521, 4.111	≤0.05	2.415	1.709, 3.413	<0.01
CoronaVac	3.609	2.813, 4.630	≤0.05	1.926	1.315, 2.819	<0.01
Vaxzevria	ref					
Sex						
Male	1.49	1.224, 1.812	≤0.05	1.425	1.158, 1.754	0.01
Female	ref					
Ethinicity						
Melayu	0.595	0.211, 1.678	0.326	-	-	-
Cina	0.421	0.146, 1.213	0.109	-	-	-
India	0.623	0.209, 1.853	0.395	-	-	-
Bumiputera Sabah	0.865	0.181, 4.141	0.856	-	-	-
Bumiputera Sarawak	1.667	0.427, 6.499	0.462	-	-	-
Others	ref					
Citizenship						
Malaysian	0.833	0.278, 2.497	0.745	-	-	-
Non-Malaysian	ref					
Age						
18-39	ref					
40-59	1.355	1.000, 1.837	0.050	2.415	1.709, 3.413	<0.01
≥ 60	1.178	0.844, 1.644	0.336	1.926	1.315, 2.819	0.01
BMI						
Underweight	1.286	0.810, 2.041	0.286	1.186	0.723, 1.946	0.499
Normal	0.975	0.759, 1.252	0.843	1.079	0.824, 1.413	0.579
Overweight	0.765	0.592, 0.988	0.040	0.811	0.617, 1.066	0.133
Obese	ref					
Comorbidity						
Yes	1.153	0.944, 1.408	0.164	-	-	-
No	ref					
Covid-19 History						
Yes	1.002	0.604, 1.661	0.995	-	-	-
No	ref					

Figure 1: Percentage of systematic and localized symptoms reported by all type of vaccines.



- The study analysed 1684 recipients, comprised of Comirnaty (n=568), CoronaVac (n=553) and Vaxzevria (n=563).
- Reported AEFIs for the first and second doses by types of vaccines: Comirnaty (31.3% and 40.4%); CoronaVac (28.9% and 27.3%); Vaxzevria (59.5% and 29.2%) (Table 1).
- Most reported AEFIs were systematic symptoms (84.3%) such as headache, fever and muscle pain and localized symptom (15.7%) mostly, pain at injection site. Reported AESI for all types of vaccines were very low (⩽ 0.8%) (Figure 1).
- Main reported AEFIs for Comirnaty were fever, headache and pain at injection; CoronaVac were fever and headache; and Vaxzevria were fever, headache and muscle/body pain.
- Adjusted for confounders, the factors found to be significantly associated with AEFI were Comirnaty vaccine [aOR: 2.415 (95% CI: 1.709, 3.413)], male [aOR: 1.425 (95% CI: 1.158, 1.754)] and 40-59 age group [aOR: 2.415 (95% CI 1.709, 3.413)] (Table 2).

DISCUSSION & CONCLUSION

- This findings aligned with NPRA ADR/AEFI report which stated that the majority of reports received, at 93%, were non-serious, short-term, and did not pose any potential risk to the health of the vaccine recipients and only 7% of the total AEFI reports received were categorised as serious AEFIs.
- As a conclusion, this study demonstrated that the majority of reported AEFIs were not serious, suggesting that the benefit-to-risk ratio of COVID-19 vaccines remains favourable.

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