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110/11/16 COVID-19 Notification of adverse events after vaccination

110 Update on November 17,

Vaccine adverse event notification means that at any time after vaccination, the informant proactively reports any event related to vaccine administration due to suspicion or failure to rule out. These notified events occurred after vaccination in time sequence, but they do not mean that they were caused by vaccination. Vaccine Adverse Event Notification System (VAERS) Is a passive monitoring system. The number of notifications of adverse events cannot be explained by itself or used to derive the existence, severity, and severity of vaccine-related problems.

The conclusion of frequency or incidence should be explained in the context of other scientific information.

VAERS The notification information received is entrusted to the Drug Hazard Relief Foundation/The National Adverse Drug Reaction Reporting Center analyzes and detects safety signals. When safety concerns arise, they must be further clarified and approved by the Food and Drug Administration of the Ministry of Health and Welfare COVID-19 Summary report for notification of adverse vaccine events. That As of 11 moon 03 day Analysis of the reported value and background value (O/E analysis) In, observed Anaphylaxis (Severe allergic reaction) Number of reported

incidents observed in some age and gender stratification (Reported value) Higher than expected number of events (Background expected value) due to anaphylaxis. It is a known adverse reaction that may occur after vaccination, and the notification rate in my country

Compared with foreign notification rates, it is not high, so continuous monitoring is recommended. (AZ Vaccine Canada the notification rate for anaphylaxis is 7.5 per million doses and Taiwan is 1.7 per million doses; Moderna Vaccine Canada' s anaphylaxis notification rate is 7.8 per million doses and Taiwan' s is 1.6 per million doses; BioNTech Vaccine Canada anaphylaxis notification rate per million doses 10.0 Pieces, Taiwan is per million doses 0.6 Pieces). In the analysis results of death cases, no specific or abnormal patterns of clinical symptoms, adverse events, and causes of death before and after vaccination were not observed in the case series analysis. In addition, the number of reported deaths of men and women of all ages regardless of the label and individual label (Reported value) none higher than the expected number of deaths (Background expected value). Based on the assessment results of the current vaccine adverse event notification data, no safety concerns that require immediate measures have been observed. COVID-19 For the latest information of the Vaccine Adverse Event Notification Summary Report, please refer to the "Drug Safety Information" published by the Food and Drug Administration every week.

https://www.fda.gov.tw/TC/siteList.aspx?sid=1571.

The following table shows the Department of Disease Control 110 From March 22 to November 16, information about the number of notifications of adverse events, the number of serious adverse events, and the number of deaths and adverse events reported at 16:00. The classification of adverse events requires waiting time to track and collect information, which may change at any time based on subsequent information obtained.

move. As of November 16 a total of 28,161,546 doses of vaccine were vaccinated, of which 13,666,214 doses were vaccinated for AZ, Moderna Vaccination 6,749,900 High-end vaccination 1,419,736 Agent, BioNTech Vaccination 6,325,696 Agent.

Table, Notification of Adverse Events after COVID-19 Vaccination

(Deadline for notification: 110/11/16 16:00)

Vaccine Brand		Adverse events after vaccination	Non-serious adverse events after vaccination	Suspected serious adverse events after vaccination			
				Subtotal	die[a]	Suspected severe allergic reaction[b]	Other suspected serious adverse events[c]
total	2021/11/16 Add	120	51	69	7	0	62
	2021/3/22~11/16 Grand total	12,929	6,625	6,304	1,090	35	5,179
AstraZeneca	2021/11/16 Add	41	17	twenty four	4	0	20
	2021/3/22~11/16 Grand total	7,735	3,967	3,768	767	twenty two	2,979
Moderna	2021/11/16 Add	twenty three	10	13	1	0	12
	2021/6/8~11/16 Grand total	2,268	914	1,354	264	9	1,081
High-end	2021/11/16 Add	3	1	2	0	0	2
	2021/8/23~11/16 Grand total	528	278	250	31	1	218
BioNTech	2021/11/16 Add	53	twenty three	30	2	0	28
	2021/9/22~11/16 Grand total	2,398	1,466	932	28	3	901

[a] 2021 year11 moon 16 Daily addition 4 example (2 Female 2 male) AstraZeneca Adverse events of death after vaccination, age 47 Years old 93 Years old, after vaccination 4 Day to 59 Occurs during the day; added during the same period1 example (1 Female) Moderna Adverse events of death after

vaccination, age 70 Years old, after vaccination 30 Occurred every day; added during the same period 0 Cases of adverse events resulting from death after high-end vaccination; newly added during the same period 2 example (1 Female1 male) BNT Adverse events of death after vaccination, age 42 Years old 81 Years old, after vaccination 10 Day to 14 Daytime happen. Accumulated so far 1,090 example (454 Female 636 male) COVID-19 Adverse events of death after vaccination, age 0 Months to 101 Years (of which 578 Artificial 75 Elders over the age of), until the day after vaccination 144 Occurs during the day, among them 767 Example is vaccination AstraZeneca, Have 264 Example is vaccination Moderna, Have 31 Examples are high-end vaccination, there are 28 Example is vaccination BNT. According to the analysis by the National Adverse Drug Reaction Notification Center 11 moon 03 Daily reported value and background value (O/E analysis) The safety signal detection results show the number of reported deaths of men and women of all ages regardless of the label and individual label (Reported value) None higher than the expected number of deaths (Background expected value).

[b] According to the National Adverse Drug Reaction Notification Center "COVID-19 Vaccine Adverse Event Notification Summary Report"(Statistics as of 11 moon 10 day), In line with the definition of allergic reaction in total 36 Pieces of which 1 Cases reported as adverse events of death and also suspected of severe allergic reactions, have been counted into the adverse events of death in this table.

[c] 2021 year 11 moon 16 Daily addition 20 example (9 Female 11 male) AstraZeneca Suspected of other serious adverse events after vaccination, deducting deaths and deducting the number of serious adverse events suspected of severe allergic reactions or the number of important clinically significant notifications, the age is 31 Years old 80 From the day after vaccination to 56 Occurs during the day; added during the same period 12 example (6 Female 6 male) Moderna Suspected of other serious adverse events after vaccination, age 28 Years old 69 From the day after vaccination to 95 Occurs during the day; added during the same period 2 example (1 Female 1 male) Suspected other serious adverse events after high-end vaccination, age 42 Years old 61 Years old, after vaccination 7 Day to twenty one Occurs during the day; added during the same period 28 example (16 Female 12 male) BNT Suspected of other serious adverse events after vaccination, age 12 Years old 60 From the day after vaccination to 51 Occurs during the day.