110/10/28 COVID-19 Notification of adverse events after vaccination

110 year10 moon29 Daily update

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 10 moon 6 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 China compared with foreign notification rates, it is not high, so continuous monitoring is recommended. (AZ Vaccine UK anaphylaxis Notification rate per million doses 16.8 Pieces, Taiwan is per million doses 2.0 Pieces Moderna Vaccine UK anaphylaxis Notification rate per million doses 15.4 Pieces, Taiwan is

per million doses 1.7 Pieces BioNTech Vaccine UK anaphylaxis Notification rate per million doses 11.5 Pieces, Taiwan is per million doses 1.2 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 to be taken have not 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 October 28 Information on the cumulative 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 **10** moon **28** day Cumulative vaccination 24,048,734 Dose of vaccine, of which AZ Vaccination 12,100,866 Agent, Moderna Vaccination 5,919,909 High-end vaccination 1,382,354 Agent, BioNTech Vaccination 4,645,605 Agent.

Table, Notification of Adverse Events after COVID-19 Vaccination

(Deadline for notification: 110/10/28 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	2021/10/28 Add	116	68	48	4	0	44
	2021/3/22~10/28 Grand total	10,925	5,584	5,341	982	32	4,327
AstraZeneca	2021/10/28 Add	38	20	18	3	0	15
	2021/3/22~10/28 Grand total	7,167	3,720	3,447	720	21	2,706
Moderna	2021/10/28 Add	22	11	11	1	0	10
	2021/6/8~10/28 Grand total	1,861	740	1,121	221	7	893
High-end	2021/10/28 Add	5	4	1	0	0	1
	2021/8/23~10/28 Grand total	478	265	213	29	1	183
BioNTech	2021/10/28 Add	51	33	18	0	0	18
	2021/9/22~10/28 Grand total	1,419	859	560	12	3	545

[a] 2021 year 10 moon 28 Daily addition 3 example (3 male) AstraZeneca Adverse events of death after vaccination, age 59 Years old 86 Years old, after vaccination 1 Day to twenty three Occurs during the day; added during the same period 1 example (1 male) Moderna Adverse events of death after vaccination, age 66 Years old, after vaccination 1 Occurred every day; added during the same period0 Cases of adverse events resulting from death after high-end vaccination; newly added during the same period0 example BNT An adverse event of death occurred after vaccination. Accumulated so far 982 example (418 Female 564 male) COVID-19 Adverse events of death after

vaccination, age 2 Months to 101 Years (of which 541 Artificial 75 Elders over the age of), until the day after vaccination 142 Occurs during the day, among them 720 Example is vaccination AstraZeneca, Have 221 Example is vaccination Moderna, Have 29 Examples are high-end vaccination, there are 12 Example is vaccination BNT. According to the analysis by the National Adverse Drug Reaction Notification Center 10 moon 6 Daily reported value and background value (O/E analysis) The security signal detection, the result shows the number of reported deaths of men and women of all ages regardless of 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 10 moon 20 day), In line with the definition of allergic reaction in total 33 Pieces of which 1 The 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 10 moon 28 Daily addition 15 example (12 Female 3 male) AstraZeneca Suspected of other serious adverse events after vaccination, deducting the number of deaths and serious adverse events of suspected severe allergic reactions or the number of important clinically significant notifications, the age is 26 Years old 87 Years old, from the day after vaccination to 58 Occurs during the day; added during the same period 10 example (5 Female 5 male) Moderna Suspected of other serious adverse events after vaccination, age twenty one Years old 72 Years old, from the day after vaccination to 34 Occurs during the day; added during the same period 1 example (1 male) Suspected other serious adverse events after high-end vaccination, age 41 Years old, after vaccination 2 Occurred every day; added during the same period 18 example (12 Female 6 male) BNT Suspected of other serious adverse events after vaccination, age 12 Years old 58 Years old, from the day after vaccination to 32 Occurs during the day.