Summary of COVID-19 Vaccine Adverse Events Noti

Notification rate≠incidence rate

The number of notifications of adverse events alone cannot explain or be used to derive the existence, severity, and severity of vac

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

Preface

- Since March 22, 110, the COVID-19 vaccination plan has started. As of **October 6, 110** ,
  The total number of COVID-19 vaccines administered nationwide was **17,226,370,** and the notification c
  There were **8,807** incident notifications **,** and the average **number of notifications per 1,000 injections v**

- Notification of adverse vaccine events refers to the **initiative of the** informant at any time after vaccinatio
  Report any incidents related to the administration of the vaccine due to suspicion or failure to rule
  Born after vaccination, but it does not mean that it is caused by vaccination . Autonomous Notificati
  In the establishment of a systematic vaccine safety database, the changes that affect vaccine safety (such a
  Adverse event symptoms... etc.) to be statistically evaluated and analyzed in order to detect potential safe

2

Data cut-off point: 110/10/6

Page 3

Accumulated domestic adverse event notifications

Classification of the severity of the notified case	Number of notified cases				total
	0 to <18 years old	18 to <50 years old	50 to <65 years old	≧65 years old	
die	0	58	124	665	848 *
strict life threatening	0	36	41	63	140
Heavy Cause permanent disability	0	0	0	0	0
Do not					#

goodCongenital malformations of the fetus thing	0	0	0	0	1
Causes the patient to be hospitalized or prolongs the patient's hospital stay. Pieces	40	414	268	501	1,223
Other events of clinical significance	96	952	453	434	1,935
Non-serious adverse events	242	2,856	914	647	4,660 §
total	**378**	**4,316**	**1,800**	**2,310**	**8,807**
Number of inoculants	904,534	7,774,489	3,881,740	4,665,607	17,226,370
Notification rate (pieces/thousand doses)	0.4	0.6	0.5	0.5	0.5
Report rate of serious adverse events (pieces/thousand doses)	0.2	0.2	0.2	0.4	0.2

*Includes a notification case where a mother was vaccinated and breast-fed a female baby on the same day, and the baby died the next day. Such adverse events after breastfeeding will be analyzed separately, so they are not included in the statistics of reported cases f
#It contains 1 case of a baby with a physical defect a few months after the mother was vaccinated. Such adverse events will be analyzed separately, so they are not included in the statistics of the number of reported cases for each age group.
§Includes 1 reported case of unknown age

Data cut-off point: 110/10/6

Accumulated domestic adverse events of special concern (AESI) no

Adverse Event of Special Interest	Number of notified cases	Case age range	Time to onset
Allergic reaction (anaphylaxis)	30	18.8 ~ 73.7 years old	5 minutes to 1 day
Arrhythmia (arrhythmia)	twenty one	18.6 ~ 94.2 years old	<1~44 days
Acute myocardial infarction	123	37.9 ~ 96.4 years old	<1~ 90 days
Myocarditis/pericarditis	27	13.9 ~ 85.8 years old	1~29 days
Cerebrovascular stroke	316	19.4 ~ 96.4 years old	<1~108 days
Facial palsy	75	16.9 ~ 88 years old	<1~49 days
Seizure/convulsion	35	14.4 ~ 74.7 years old	<1~26 days
Transverse myelitis (transverse myelitis)	2	41.3 ~ 61.4 years old	20~23 days
Acute diffuse encephalomyelitis (ADEM)	3	25.8~ 57 years old	<1 ~17 days
Guillain-Barre Syndrome (GBS)	17	35.1 ~ 84.8 years old	2~63 days
Myelitis (myelitis)	2	36.6~77 years old	4~6 days
Encephalitis	2	27.4 ~ 76.6 years old	9~14 days

Optic neuritis (optic neuritis)	7	28.3 ~ 60 years old	1~35 days
Acute pancreatitis (acute pancreatitis)	5	49.8 ~ 82.3 years old	2~41 days
Acute kidney injury	5	75.5 ~ 90.2 years old	1~70 days
Acute liver injury	6	46.4 ~ 70.7 years old	<1~27 days

Note: The number of cases in each category is based on the statistical evaluation results of the notification information obtained before the data cutoff point. The follow-up may change due to case tracking, investigation or clinical re

Data cut-off point: 110/10/6

Page 5

Accumulated domestic adverse events of special concern (AESI) no

Adverse Event of Special Interest	Number of notified cases	Case age range	Time to onset
Erythema multiforme	5	30 ~ 67.7 years old	4~27 days
Vasculitis	6	37 ~ 69.6 years old	2~49 days
Rhabdomyolysis	8	32.7 ~ 83.7 years old	1~36 days
Arthritis	5	37.9 ~ 69.9 years old	2~52 days
Spontaneous abortion	8	26.8 ~ 38.1 years old	<1~40 days
Stillbirth	8	25.7 ~ 41 years old	5~25 days
Preterm birth	2	31.9~34.2 years old	1~5 days
Idiopathic thrombocytopenic purpura (ITP)	42	19.4 ~ 100.7 years old	<1~86 days
Thrombosis and Thrombocytopenia Syndrome (TTS)	78	20.3 ~ 95.7 years old	0~96 days
Thrombosis related disorders			
Retinal vein occlusion (RVO)	12	25.6 ~ 81.3 years old	1~64 days
Retinal artery occlusion (RAO)	8	44.5 ~ 71 years old	1~57 days
Retinal vascular occlusion	3	56.1 ~ 78.7 years old	1~28 days
Deep vein thrombosis	61	23.8 ~ 91.4 years old	<1~98 days
Pulmonary embolism (pulmonary embolism)	56	24.5 ~ 94.1 years old	<1~64 days
Cerebral venous sinus thrombosis	14	30.7 ~ 71.1 years old	<1~72 days
Other thrombotic disorder (other thrombotic disorder) #	20	21.6 ~ 88.8 years old	<1~75 days

#Notified symptoms include left renal infarction, ischemic intestinal disease, hepatic portal vein thrombosis and intestinal veins, intestinal vein thrombosis, upper mesenteric artery thrombosis, renal vein thrombosis, splenic infarction, acute venous thromboembolism of unspecified upper extremities and lowe

Note: The number of cases in each category is based on the statistical evaluation results of the notification information obtained before the data cutoff point. The follow-up may change due to case tracking, investigation or clinical re

Page 6

Thrombosis with thrombocytopenia syndrome (TTS)

- TTS is known to be vaccinated with adenovirus vector COVID-19 vaccine (AstraZeneca and Janssen brand COVID-19 vaccine)
  Very rare adverse reactions. Recently, a case report of TTS after mRNA vaccination has been published. But clinically
  There is still some speculation and uncertainty in the diagnosis of the TTS case. The international Brighton Collaboration TTS c
  International Society on Thrombosis and Haemostasis (ISTH)
  The diagnostic and treatment guidelines issued are still interim guidance

- As of October 5, 110, a total of 78 cases of suspected TTS notifications have been received in China (17 cases have been reviewe
  The cases comply with the definition of individual cases, but have yet to be reviewed by the expert meeting), of which 72 cases
  The notification rate was about 7.6 cases/million doses, another 5 cases were vaccination of Moderna brand vaccines, and 1 case

- Comparing the TTS notification rate and notification situation of various countries, the TTS notification rate of European and Ar
  The notification rate is higher in relatively young people (under 50 or 60 years old)

Data cut-off point: 110/10/6

Analysis of death notification cases (847 cases)

- The case included 485 men and 362 women, with a median age of 79 years (range: 26 to 101 years old)

- Death notification rate by age group:

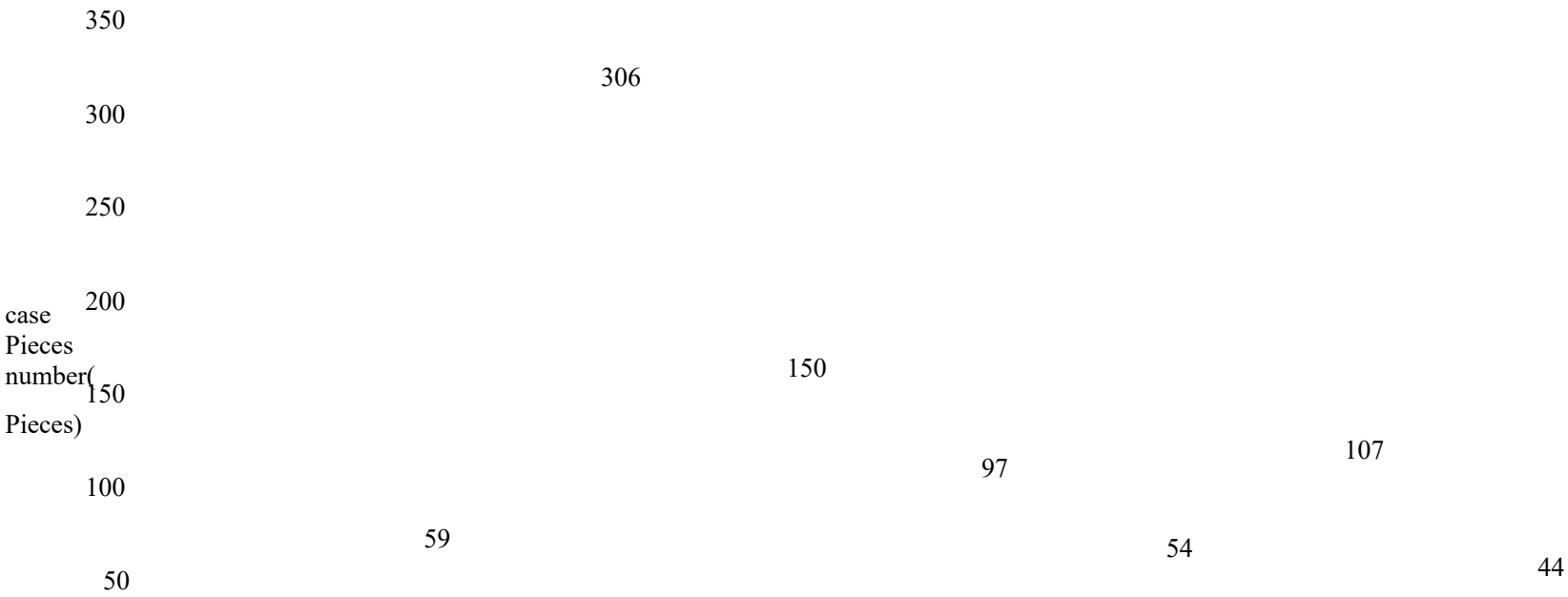
age range	Number of inoculations	Number of death notification cases	Death notification rate (cases/100,000 doses)

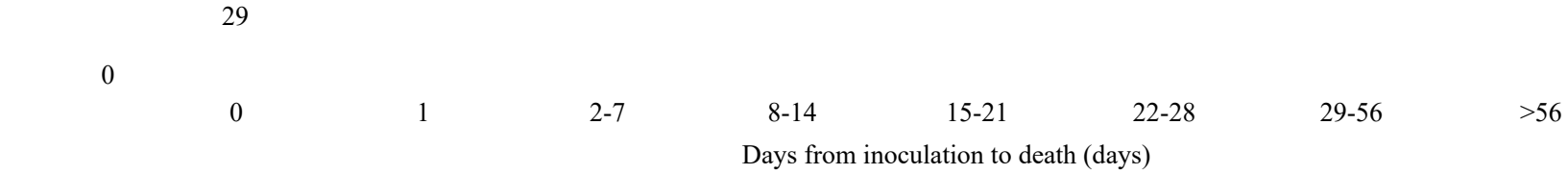
<18 years old	904,534	0	0.0
18-49 years old	7,774,489	58	0.7
50-64 years old	3,881,740	124	3.2
65-79 years old	3,607,313	254	7.0
80-89 years old	907,178	282	31.1
≥90 years old	151,116	129	85.4

Note: This is the analysis result of an adverse event notification case that died after COVID-19 vaccination. As of October 6, 110, another case was received for a mother who was vaccinated with breastfeeding a female baby on the same day
Reported cases, such adverse events after breastfeeding will not be combined with general cases for statistical analysis.

Data cut-off point: 110/10/6

Distribution of days from inoculation to death (847 ca





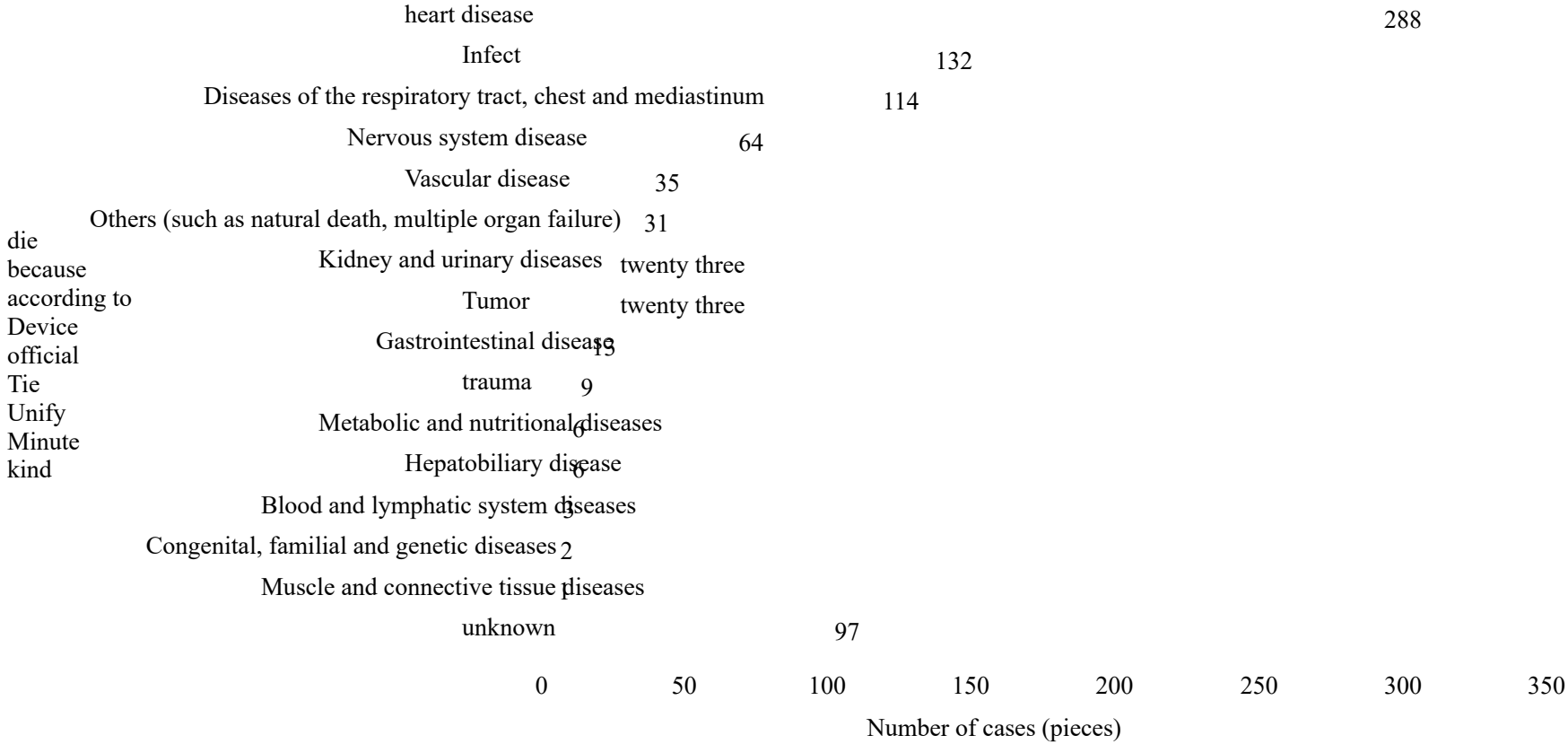
Note: The date of death in 1 case is not yet known

8

Data cut-off point: 110/10/6

Page 9

Analysis of causes of death (classified by organ system)



Note: 183 cases are analyzed based on anatomical data, and the remaining 664 cases are analyzed based on the cause of death described in the preliminary notification content

9

Data cut-off point: 110/10/6

Page 10

Past/existing medical history of death

- Analyze according to 724 cases where relevant information is provided in the notification cases of vaccine

Organ System Classification	Number
Vascular diseases (such as hypertension, arteriosclerosis... etc.)	**358**
Metabolic and nutritional diseases (such as diabetes, hyperlipidemia, gout, etc.)	**296**
Heart disease (such as heart disease, coronary heart disease, heart failure... etc.)	**224**
Nervous system diseases (such as dementia, cerebrovascular accident, Parkinson's disease..., etc.)	**219**
Kidney and urinary diseases	133
Surgery and medical treatment (such as hemodialysis)	121
Tumor	86
Diseases of the respiratory tract, chest and mediastinum	65
Bedridden	41
No known medical history	39
Infect	37
mental illness	32

Organ System Classification	Number
Gastrointestinal disease	25
Hepatobiliary disease	twenty two
Trauma (e.g. falls, fractures)	20
Reproductive system and breast diseases	19
Musculoskeletal system and connective tissue diseases	15
Endocrine disease	12
Eye diseases	11
Blood and lymphatic system diseases	7
Congenital, familial and genetic diseases	6
Abnormal laboratory test values	4
Skin and epidermal tissue diseases	3
Others (such as dying cases)	1

Note: A single case may have more than one past/existing medical history

10

Data cut-off point: 110/9/22

Page 11

Analysis of reported value and background expected

- **Reported value:**
  - death of adverse events: After our vaccine adverse event reporting system as of September 22 of 110 vaccinated COVID-19 **Number** of **death notification cases**

- Other adverse events of special concern: China's vaccine adverse event notification system is vaccinated with COVID-19 as **Number of reported cases** of **adverse events** after vaccination

- **Background Expected Value** = [Background Incidence Rate] * [Accumulated Observation Time (person
  - Calculate the cumulative observation time of the vaccinated person based on the number of daily doses of the COVID-19 va Time and background rate of domestic adverse events to calculate the expected number of events
    - Cumulative observation time: Calculate the observation time contributed by the vaccinators based on the number of daily doses provided by the Department of
    - Background incidence rate: the incidence rate calculated based on the 2016-2019 health insurance data of the Health and Welfare Data Science Center
- **The ratio of reported value to background expected value (OE ratio) = [reported value]/[backgroun**

List of other Adverse Events of Special Concern (AESI)

- Observation time:

Compare the reported value with the expected value from **0 to 2 days** after vaccination (1 AESI in total)

Anaphylaxis

Compare the reported value with the expected value from **0 to 7 days** after vaccination (1 AESI in total)

Seizure

Compare the reported value with the expected value from **1 to 42 days** after vaccination (a total of 20 AESIs)

Acute aseptic arthritis	Deep vein thrombosis (DVT)	Pulmonary embolism (PE)
Acute liver injury	Encephalitis/myelitis	Retinal artery occlusion (RAO)
Acute myocardial infarction (AMI)	Erythema multiforme	Retinal vein occlusion (RVO)

Acute pancreatitis	Facial palsy	Rhabdomyolysis
Arrhythmia	Guillain-Barre syndrome (GBS)	Stroke
Cerebral venous sinus thrombosis (CVST)	Myocarditis/pericarditis	Vasculitis
Immune thrombocytopenic purpura (ITP)	Optic neuritis (ON)	

12

Data cut-off point: 110/9/22
Page 13

Analysis result of reported value and background expec

- **Death adverse events:**

  The number of reported deaths (reported value) of men and women of all ages regardless of the label and individual label is not

  Number of events (expected background value)

- **Other Adverse Events of Special Concern (AESI):**

  The reported value is not higher than the background expected value (the ratio of the reported value to the background exp

Acute aseptic arthritis	Encephalitis/myelitis	RVO
Acute liver injury	Erythema multiforme	Rhabdomyolysis
AMI	Facial palsy	Stroke
Acute pancreatitis	GBS	Seizure
Arrhythmia	ON	Vasculitis
ITP	PE	
DVT	RAO	

13

Data cut-off point: 110/9/22
Page 14

Analysis result of reported value and background expec

Other Adverse Events of Special Concern (AESI):

Part of the age and gender stratification observed that the **reported value is higher than the background expected value**

Allergic reactions (anaphylaxis), cerebral venous sinus thrombosis (CVST),
Myocarditis/pericarditis

- **Anaphylaxis:**

  Since anaphylaxis is a known adverse reaction that may occur after vaccination, and the notification rate in China is not higher than that in foreign countries,

  It is recommended to continue monitoring.

  - As of 110/9/22, the anaphylaxis notification rate of AZ vaccine in the UK is 16.8 cases per million doses, and in Taiwan it is 2.1 cases per million doses;

    The anaphylaxis notification rate for Moderna vaccine in the UK is 15.4 cases per million doses, and in Taiwan it is 2.1 cases per million doses

  - The frequency of anaphylaxis after other vaccinations: 1-10 cases/million doses for measles vaccine, 1-6 cases/million doses for tetanus vaccine Doses, 1.35 pieces/million doses of seasonal flu vaccine

14

Data cut-off point: 110/9/22

Page 15

Analysis result of reported value and background expec

Other Adverse Events of Special Concern (AESI):

Part of the age and gender stratification observed that the **reported value is higher than the background expected value**

Allergic reactions (anaphylaxis), cerebral venous sinus thrombosis (CVST),

Myocarditis/pericarditis

- **Cerebral venous sinus thrombosis (CVST):**

  Because other possible causes or diagnoses cannot be completely ruled out, there is no clear conclusion yet, and monitoring will continue.

- **Myocarditis/pericarditis (myocarditis/pericarditis)**

  - According to the international post-marketing data of vaccines, extremely rare cases of myocarditis and pericarditis have occurred after vaccination with mRNA
    Occurs within 14 days after vaccination, more commonly after the second dose and young men.

  - Consideration results may be affected by surveillance bias (such as medical staff's alertness to myocarditis after vaccination), and
    In the past, the number of people receiving mRNA vaccination among young people and the number of people receiving the second dose is still relatively sma
    Line monitoring.

15

Page 16

in conclusion

- Integrating the assessment results of the current vaccine adverse event notification data, it **has not been ol**
  Shi Zhi's safety concerns . The Food and Drug Administration of the Ministry of Health and Welfare an
  Continue to conduct safety signal detection for vaccine adverse event notifications to actively implement
  System to ensure the safety of people’s medication.

16