



# Safety monitoring of COVID-19 vaccination among adolescents aged 12 to 17 years old in the Republic of Korea

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## ABSTRACT

**Objectives:** This study aimed to disseminate information on coronavirus disease 2019 (COVID-19) vaccine safety among adolescents aged 12 to 17 years in the Republic of Korea.

**Methods:** Two databases were used to assess COVID-19 vaccine safety in adolescents aged 12 to 17 years who completed the primary Pfizer-BioNTech vaccination series. Adverse events reported to the web-based COVID-19 vaccination management system (CVMS) and collected in the text message-based system were analyzed.

**Results:** From March 5, 2021 to February 13, 2022, 12,216 adverse events among 12- to 17-year-olds were reported to the CVMS, of which 97.1% were non-serious adverse events and 2.9% were serious adverse events, including 85 suspected cases of anaphylaxis, 74 suspected cases of myocarditis and/or pericarditis, and 2 deaths. From December 13, 2021 to January 26, 2022, 10,389 adolescents responded to a text message survey, and local/systemic adverse events were more common after dose 2 than after dose 1. The most commonly reported events following either vaccine dose were pain at the injection site, headache, fatigue/tiredness, and myalgia.

**Conclusion:** The overall results are consistent with previous findings; the great majority of adverse events were non-serious, and serious adverse events were rare among adolescents aged 12 to 17 years following Pfizer-BioNTech COVID-19 vaccination.

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## Introduction

Coronavirus disease 2019 (COVID-19) vaccination has been available since February 26, 2021 in the Republic of Korea (ROK) to prevent the occurrence of severe cases leading to hospitalization and death by reducing the risk of infection and transmission [1]. To date, only the Pfizer-

BioNTech mRNA COVID-19 vaccine has been authorized for use in adolescents aged 12 to 17 years by the Korea Ministry of Food and Drug Safety (MFDS), on the basis of safety and efficacy data from controlled trials conducted in the United States (US) [2,3]. The Korea MFDS initially approved the use of the Pfizer-BioNTech vaccine for persons aged  $\geq 16$  years on March 5, 2021 [4], and expanded it to include adolescents aged  $\geq 12$  years on July 16, 2021 [5]. Following the 19th Korea Advisory Committee on Immunization Practices (KACIP), the Pfizer-BioNTech vaccine was offered to adolescents aged 16 to 17 years starting on October 18, 2021 and to adolescents aged 12 to 15 years starting on November 1, 2021, with a 3-week interval between dose 1 and dose 2 [6,7].

Since then, COVID-19 vaccines have been widely distributed to adolescents aged 12 to 17 years across the nation, and vaccination coverage in this population trended upward, reaching 46.9% for dose 1 and 24.9% for dose 2 as of December 1, 2021 [8]. To make COVID-19 vaccinations more accessible and boost the vaccinations rate for adolescents, the Korea Disease Control and Prevention Agency (KDCA) announced a 2-week mass vaccination strategy during December 13–24, 2021, to vaccinate adolescents aged 12 to 17 years at schools, vaccination centers, public health centers in cooperation with the Korea Ministry of Education [8]. In addition, a text message survey for those aged 12 to 17 years was launched when the mass vaccination strategy was initiated to monitor and investigate adverse events or health conditions after COVID-19 vaccination.

As information on COVID-19 vaccine safety for adolescents aged 12 to 17 years is currently limited in real-world settings, this study aimed to identify and disseminate information on COVID-19 vaccine safety for adolescents aged 12 to 17 years in the ROK who completed the primary Pfizer-BioNTech vaccination series, including the first and second doses. This study analyzed data on adverse events reported to the COVID-19 vaccination management system (CVMS; a web-based passive vaccine safety surveillance system) and the text message-based vaccine safety surveillance system.

## Materials and Methods

### COVID-19 Vaccination Management System

In order to monitor adverse events following immunization (AEFIs) and identify potential safety signals for further evaluation, the KDCA manages the CVMS, in which doctors and forensic pathologists can report AEFIs regardless of a causal association between the events and the vaccines in accordance with the Infectious Disease Control and Prevention Act [9]. From March 5, 2021 to February 13, 2022, a total of 4,340,710 primary doses of the Pfizer-BioNTech

vaccination series were administered to adolescents aged 12 to 17 years in the ROK, and 12,216 adverse events after vaccination were reported to the CVMS. Data on an additional dose (dose 3) and vaccines other than the Pfizer-BioNTech vaccine were excluded as they were not authorized for use in adolescents aged 12 to 17 years during the study period in the ROK. Adverse events reported to the CVMS are classified into non-serious and serious events as per the Guidelines for Adverse Events Following COVID-19 Immunization in the ROK [9]. Non-serious events include common symptoms, such as redness at the injection site, pain, swelling, myalgia, fever, headache, chills, and others. The following adverse events are classified as serious: death, suspected anaphylaxis, adverse events of special interest (AESIs), intensive care unit admission, life-threatening events, permanent disability or sequelae, and others. The characteristics of adverse events reported in the CVMS among adolescents aged 12 to 17 years were stratified by sex, age groups, and vaccine doses, and the types of symptoms and signs reported as adverse events were described in descending order of the number of cases. Since adverse events reported to the CVMS are suspected cases, the events do not indicate medically confirmed diagnoses.

### Text Message-Based Vaccine Safety Surveillance System

The KDCA operates a text message-based vaccine safety surveillance system that surveys adverse events and health conditions after COVID-19 vaccination for specific population groups, such as pregnant women who consent to receive text message surveys through their smartphones on the day of their first vaccination [9]. Text messages were sent on a daily basis until day 7 post-vaccination to check health conditions. In total, 10,398 adolescents aged 12 to 17 years in the ROK who received the primary series of the Pfizer-BioNTech vaccine responded to text message surveys from December 13, 2021 to January 26, 2022. The surveys included questions about any health problems experienced after vaccination, fever, local and systemic adverse events, limits to normal daily activities, and visits to medical facilities. The respondents were able to report multiple adverse events on various days. The characteristics of 10,398 respondents aged 12 to 17 years were described according to sex and age, and adverse events and health conditions were assessed in terms of age groups and vaccine doses.

SAS ver. 9.4 (SAS Institute Inc., Cary, NC, USA) was used to conduct all the analyses in this study. The passive surveillance activity was conducted and authorized by the KDCA; the study was not subject to the institutional review board approval under government regulations. The study with the

text message-based surveillance was exempted from review by the Korea Public Institutional Review Board designated by the Ministry of Health and Welfare (P01-202203-01-035).

## Results

### COVID-19 Vaccination Management System

From March 5, 2021 to February 13, 2022, the CVMS confirmed 12,216 adverse events among adolescents aged 12 to 17 years after primary doses of the Pfizer-BioNTech vaccination series (Table 1); 11,867 (97.1%) were non-serious and 349 (2.9%) were serious. Serious adverse events included death (2, 0%), suspected anaphylaxis (85, 0.7%) and major adverse events, including AESIs for COVID-19 vaccines (262, 2.1%). In total, 4,340,710 doses were administered to adolescents aged 12 to 17 years during the study period and the overall reporting rate per 100,000 doses was 281.4 (295.8 after receipt of dose 2 and 268.1 after receipt of dose 1). The reporting rate per 100,000 doses after the primary vaccination series was 271.5 in males and 291.9 in females, and 16- to 17-year-olds (370.0) showed a higher reporting rate than 12- to 15-year-

olds (224.6). Two deaths were reported in males aged 16 to 17 years after receipt of dose 2. Among 11,867 (97.1%) non-serious adverse events, the most commonly reported symptoms based on the reporting rate per 100,000 doses were headache (74.0), chest pain (72.0), myalgia (42.5), dizziness (39.9), and nausea (36.2) (Table 2). Among 349 (2.9%) serious adverse events, acute cardiovascular injury (2.1), including 74 cases of suspected myocarditis and/or pericarditis, showed the highest reporting rate per 100,000 doses, followed by anaphylaxis, including anaphylactoid reactions (2.0), convulsions or seizures (0.9), acute paralysis (0.8), and vaccine-associated enhanced disease (0.7).

### Text Message-Based Vaccine Safety Surveillance System

From December 13, 2021 to January 26, 2022, a total of 10,389 adolescents aged 12 to 17 years responded to at least 1 text message survey on days 0 to 7 after Pfizer-BioNTech COVID-19 vaccination (Table 3); 8,909 (85.8%) were 12- to 15-year-olds and 1,480 (14.2%) were 16- to 17-year-olds. Among them, 4,828 (46.5%) were male and 5,561 (53.5%) were

**Table 1.** Characteristics of adverse events reported to the CVMS for adolescents aged 12 to 17 years after Pfizer-BioNTech COVID-19 vaccination, Republic of Korea, March 5, 2021 to February 13, 2022

Variable	Number of doses administered	Adverse events (n = 12,216) <sup>a)</sup>					
		Total	Non-serious adverse events <sup>b)</sup>	Serious adverse events <sup>c)</sup>			
				Sub-total	Death	Anaphylaxis	Others
Total	4,340,710	12,216 (281.4)	11,867 (273.4)	349 (8.0)	2 (0)	85 (2.0)	262 (6.0)
Dose 1	2,254,487	6,044 (268.1)	5,845 (259.3)	199 (8.8)	0	71 (3.1)	128 (5.7)
Dose 2	2,086,223	6,172 (295.8)	6,022 (288.7)	150 (7.2)	2 (0.1)	14 (0.7)	134 (6.4)
Sex							
Male	2,229,864	6,055 (271.5)	5,854 (262.5)	201 (9.0)	2 (0.1)	38 (1.7)	161 (7.2)
Dose 1	1,158,684	2,915 (251.6)	2,809 (242.4)	106 (9.1)	0	30 (2.6)	76 (6.6)
Dose 2	1,071,180	3,140 (293.1)	3,045 (284.3)	95 (8.9)	2 (0.2)	8 (0.7)	85 (7.9)
Female	2,110,846	6,161 (291.9)	6,013 (284.9)	148 (7.0)	0	47 (2.2)	101 (4.8)
Dose 1	1,095,803	3,129 (285.5)	3,036 (277.1)	93 (8.5)	0	41 (3.7)	52 (4.7)
Dose 2	1,015,043	3,032 (298.7)	2,977 (293.3)	55 (5.4)	0	6 (0.6)	49 (4.8)
Age (y)							
12–15	2,644,362	5,940 (224.6)	5,762 (217.9)	178 (6.7)	0	42 (1.6)	136 (5.1)
Dose 1	1,424,052	3,026 (212.5)	2,918 (204.9)	108 (7.6)	0	36 (2.5)	72 (5.1)
Dose 2	1,220,310	2,914 (238.8)	2,844 (233.1)	70 (5.7)	0	6 (0.5)	64 (5.2)
16–17	1,696,348	6,276 (370.0)	6,105 (359.9)	171 (10.1)	2 (0.1)	43 (2.5)	126 (7.4)
Dose 1	830,435	3,018 (363.4)	2,927 (352.5)	91 (11.0)	0	35 (4.2)	56 (6.7)
Dose 2	865,913	3,258 (376.3)	3,178 (367.0)	80 (9.2)	2 (0.2)	8 (0.9)	70 (8.1)

Data are presented as n (per 100,000): the reporting rate of adverse events per 100,000 doses administered.

CVMS, COVID-19 vaccination management system; COVID-19, coronavirus disease 2019.

<sup>a)</sup>Data were calculated using the information on suspected adverse events after COVID-19 vaccination reported by medical facilities or doctors. The results do not indicate an accurate diagnosis or causality between the events and the vaccines. <sup>b)</sup>Non-serious adverse events include common symptoms such as redness at the injection site, pain, swelling, myalgia, fever, headache, chills, and others. <sup>c)</sup>Serious adverse events include the following: death, suspected anaphylaxis and major adverse events including adverse events of special interest, intensive care unit admission, life-threatening events, permanent disability or sequelae, and others.

**Table 2.** Types of symptoms and signs reported to the CVMS for adolescents aged 12 to 17 years after Pfizer-BioNTech COVID-19 vaccination, Republic of Korea, March 5, 2021 to February 13, 2022

Symptoms and signs ( <i>n</i> = 12,216) <sup>a)</sup>	Case (per 100,000)
Non-serious adverse events ( <i>n</i> = 11,867)	
Headache	3,214 (74.0)
Chest pain	3,127 (72.0)
Myalgia	1,845 (42.5)
Dizziness	1,732 (39.9)
Nausea	1,573 (36.2)
Fever	1,183 (27.3)
Vomiting	754 (17.4)
Abdominal pain	748 (17.2)
Allergy reactions	745 (17.2)
Chills	692 (15.9)
Pain, redness or swelling at the injection site within 3 days after	455 (10.5)
Diarrhea	451 (10.4)
Lymphadenitis	381 (8.8)
Abnormal uterine bleeding	130 (3.0)
Cellulitis	58 (1.3)
Arthritis	44 (1.0)
Severe local adverse events	29 (0.7)
Abscess at the injection site	2 (0)
Systemic disseminated Bacillus Calmette-Guerin infection	1 (0)
Severe adverse events ( <i>n</i> = 349) including reports of death	
Acute cardiovascular injury	90 (2.1)
Anaphylaxis (including anaphylactoid reactions)	85 (2.0)
Convulsions or seizures	40 (0.9)
Acute paralysis	33 (0.8)
Vaccine-associated enhanced disease	30 (0.7)
Acute respiratory distress syndrome	14 (0.3)
Encephalopathy or encephalitis	11 (0.3)
Thrombocytopenic purpura	6 (0.1)
Thrombocytopenia	5 (0.1)
Acute kidney injury	4 (0.1)
Osteitis or osteomyelitis	4 (0.1)
Erythema multiforme	3 (0.1)
Coagulation disorder	3 (0.1)
Thrombosis with thrombocytopenia syndrome	3 (0.1)
Anosmia or ageusia	3 (0.1)
Acute liver injury	2 (0)
Meningoencephalitis	2 (0)
Multisystem inflammatory syndrome	2 (0)
Single organ cutaneous vasculitis	2 (0)
Acute disseminated encephalomyelitis	1 (0)
Chilblains	1 (0)
Guillain-Barre syndrome	1 (0)

Data are presented as *n* (per 100,000): the reporting rate of adverse events per 100,000 doses administered.

CVMS, COVID-19 vaccination management system; COVID-19, coronavirus disease 2019.

<sup>a)</sup>Data were calculated using the information on suspected adverse events after COVID-19 vaccination reported by medical facilities or doctors. The results do not indicate an accurate diagnosis or causality between the events and the vaccines.

**Table 3.** Characteristics of adolescents aged 12 to 17 years<sup>a)</sup>

Characteristic	Dose 1 (n = 10,389)	Dose 2 (n = 3,147)
Sex		
Male	4,828 (46.5)	1,436 (45.6)
Female	5,561 (53.5)	1,711 (54.4)
Age (y)		
12–15	8,909 (85.8)	2,744 (87.2)
12	1,948 (18.8)	639 (20.3)
13	2,432 (23.4)	766 (24.3)
14	1,857 (17.9)	584 (18.6)
15	2,672 (25.7)	755 (24.0)
16–17	1,480 (14.2)	403 (12.8)
16	864 (8.3)	247 (7.8)
17	616 (5.9)	156 (5.0)

Data are presented as n (%).

COVID-19, coronavirus disease 2019.

<sup>a)</sup>Adolescents aged 12 to 17 years who completed at least 1 text message-based survey on days 0 to 7 following Pfizer-BioNTech COVID-19 vaccination, Republic of Korea, December 13, 2021 to January 26, 2022.

female. During days 0 to 7 post-vaccination, health problems among those aged 12 to 15 years were more common after dose 2 (58.9%) than after dose 1 (53.9%) (Table 4). The reporting trend was similar for those aged 16 to 17 years: health problems were reported by 58.1% of respondents after dose 2 and 51.8% after dose 1. Fewer than one-quarter of adolescents in both age groups reported fever or a sensation of heat after dose 2. Among those aged 12 to 15 years, local adverse events (53.2%) and systemic adverse events (52.3%) were reported more frequently after dose 2 than after dose 1. The reporting trends were similar for those aged 16 to 17 years, of whom 52.6% reported local adverse events and 53.8% reported systemic adverse events after dose 2. The most commonly reported adverse events among both age groups following either dose 1 or dose 2 were as follows: pain at the injection site, headache, fatigue or tiredness, myalgia, and fever or a sensation of heat. Almost one-fifth

**Table 4.** Adverse events and health conditions reported by adolescents aged 12 to 17 years following Pfizer-BioNTech COVID-19 vaccination, Republic of Korea, December 13, 2021 to January 26, 2022

Events <sup>a)</sup>	Age group (12–15 y)		Age group (16–17 y)	
	Dose 1 (n = 8,909)	Dose 2 (n = 2,744)	Dose 1 (n = 1,480)	Dose 2 (n = 403)
Health problems <sup>b)</sup>	4,803 (53.9)	1,617 (58.9)	766 (51.8)	234 (58.1)
Fever or sensation of heat	694 (7.8)	634 (23.1)	103 (7.0)	89 (22.1)
Local adverse events	4,323 (48.5)	1,460 (53.2)	686 (46.4)	212 (52.6)
Pain	3,978 (44.7)	1,346 (49.1)	634 (42.8)	200 (49.6)
Redness	195 (2.2)	88 (3.2)	39 (2.6)	20 (5.0)
Swelling	843 (9.5)	316 (11.5)	130 (8.8)	55 (13.6)
Itching	232 (2.6)	95 (3.5)	44 (3.0)	12 (3.0)
Urticaria	42 (0.5)	13 (0.5)	9 (0.6)	1 (0.2)
Others	506 (5.7)	164 (6.0)	86 (5.8)	31 (7.7)
Systemic adverse events	3,736 (41.9)	1,434 (52.3)	615 (41.6)	217 (53.8)
Chills	494 (5.5)	386 (14.1)	102 (6.9)	66 (16.4)
Headache	1,455 (16.3)	853 (31.1)	262 (17.7)	146 (36.2)
Joint pain	218 (2.4)	146 (5.3)	48 (3.2)	35 (8.7)
Myalgia	2,070 (23.2)	729 (26.6)	404 (27.3)	136 (33.7)
Fatigue or tiredness	1,753 (19.7)	748 (27.3)	338 (22.8)	144 (35.7)
Nausea	577 (6.5)	267 (9.7)	103 (7.0)	55 (13.6)
Vomiting	35 (0.4)	24 (0.9)	12 (0.8)	4 (1.0)
Diarrhea	188 (2.1)	68 (2.5)	36 (2.4)	13 (3.2)
Abdominal pain	326 (3.7)	145 (5.3)	53 (3.6)	26 (6.5)
Rash	25 (0.3)	11 (0.4)	10 (0.7)	5 (1.2)
Armpit tenderness	347 (3.9)	286 (10.4)	65 (4.4)	41 (10.2)
Others	450 (5.1)	152 (5.5)	73 (4.9)	28 (6.9)
Unable to perform normal daily activities	867 (9.7)	510 (18.6)	185 (12.5)	103 (25.6)
Visits to medical facilities	100 (1.1)	39 (1.4)	16 (1.1)	5 (1.2)
Emergency department visit	15 (0.2)	6 (0.2)	3 (0.2)	1 (0.2)
Hospitalization	2 (0)	0	0	0
Clinic visit	87 (1.0)	34 (1.2)	13 (0.9)	5 (1.2)

Data are presented as n (%): the percentage of respondents who reported health problems and adverse events at least once during days 0–7 post-vaccination. COVID-19, coronavirus disease 2019.

<sup>a)</sup>Events were reported by respondents who completed at least 1 text message-based survey on days 0 to 7. They could report multiple adverse events on various days. <sup>b)</sup>The proportion of respondents who answered that they had experienced any health problems after vaccination.

(18.6%) of adolescents aged 12 to 15 years responded that they were unable to perform normal daily activities after dose 2. This reporting rate was slightly higher in those aged 16 to 17 years (25.6%). More than 1% of adolescents aged 12 to 17 years visited medical facilities, including emergency departments, clinics, or hospitals, during days 0 to 7 after receiving either dose.

## Discussion

The results of the text message survey on AEFIs and subjective health problems among adolescents aged 12 to 17 years after the primary series of Pfizer-BioNTech COVID-19 vaccination are consistent with the safety data including adolescents aged 12 to 17 years reported in the US [10] and a controlled trial [2]; local and systemic adverse events, including fever, following vaccination were more common after dose 2 and were mostly mild and did not limit daily activities. Moreover, similar to the findings reported in the US and a controlled trial [2,10], the most common local adverse event was pain at the injection site, and the most common systemic adverse events were headache, fatigue, and myalgia in this study. Those adverse events were more frequently reported in 16- to 17-year-olds than in 12- to 15-year-olds in both the ROK and the US [10].

Among the adverse events reported to the CVMS for adolescents aged 12 to 17 years after Pfizer-BioNTech COVID-19 vaccination, 97.1% were non-serious and 2.9% were serious. These proportions are slightly different from those in safety data in adolescents reported in the US, where 90.7% were non-serious reports and 9.3% were serious reports [10]. This might be attributed to different standards used in the 2 surveillance systems to assess and define non-serious and serious adverse events. However, the great majority of adverse events reported by adolescents aged 12 to 17 years following vaccination were non-serious in both the ROK and the US.

Based on the early safety monitoring for adolescents aged 12 to 17 years after Pfizer-BioNTech COVID-19 vaccination, serious adverse events, including 85 cases of suspected anaphylaxis (2.0 cases per 100,000 doses administered) and acute cardiovascular injury (including 74 cases of suspected myocarditis and/or pericarditis; 1.7 cases per 100,000 doses administered) appear to be rarely reported. Reviewing these 2 major serious adverse events, the number of suspected anaphylaxis reports in adolescents after vaccination was greater after dose 1 (71, 83.5%) than after dose 2 (14, 16.5%), but similar between females (47, 55.3%) and males (38, 44.7%). In previous reports from the ROK and the US, most cases of confirmed anaphylaxis based on the Brighton

Collaboration case definition criteria among all age groups after Pfizer-BioNTech COVID-19 vaccination were reported in women (70.9%–93.6%) [11,12]. Moreover, the number of suspected myocarditis and/or pericarditis reports was higher in males (59, 79.7%) than in females (15, 20.3%), and after dose 2 (50, 67.6%) than after dose 1 (24, 32.4%) in this study; these findings are consistent with a meta-analysis showing that the incidence of myopericarditis was significantly higher in males and after receiving dose 2 [13]. However, since the current study is based on reports of suspected cases including anaphylaxis and myocarditis and/or pericarditis due to limited information available in early safety monitoring, diagnostic bias might exist and the assessment of causality between adverse events and vaccines is constrained at this stage. Therefore, we suggest that follow-up work should be conducted with the confirmation of suspected cases in adolescents after COVID-19 vaccination for further evaluation.

Although a few COVID-19 vaccine-associated myocarditis and/or pericarditis cases have been reported among adolescents aged 12 to 17 years, predominantly among males, after dose 2 of Pfizer-BioNTech vaccination, most cases were mild [14–18]. Since those cases are rarely reported and patients can recover quickly if responded to and treated well, the benefits of COVID-19 vaccination, including for adolescents, are considered to outweigh the risks of myocarditis and/or pericarditis [19–22]. Furthermore, a systematic review concluded that the COVID-19 vaccine for children and adolescents is effective with no major safety issues based on 36 clinical studies [23], and a meta-analysis also demonstrated that the incidence of myopericarditis after COVID-19 vaccination was not higher than that reported after other standard vaccinations including smallpox and influenza vaccines [13]. In this respect, this study does not support actions to exclude adolescents aged 12 to 17 years from vaccination; instead, we recommend that adverse events, including myocarditis and/or pericarditis after COVID-19 vaccination, should be closely monitored to respond and provide further information on COVID-19 vaccine safety [24].

The number of deaths reported among adolescents aged 12 to 17 years after Pfizer-BioNTech COVID-19 vaccination was 2, and both were among males aged 16 to 17 years after receipt of dose 2 in this study. For rapid responses in the ROK, the Vaccine Injury Investigation Committee (VIIC) has been reviewing all death reports to evaluate the causality between death and vaccination [11]. These 2 deaths were assessed not to be associated with the vaccination based on medical records, death certificates, autopsy, and epidemiological investigation results.

This study has some limitations. First, data were calculated using information on suspected adverse events after COVID-19 vaccination; thus, the results do not indicate an accurate diagnosis or causality between the events and the vaccines. Second, since adverse events reported to the CVMS are based on persons who visit medical institutions, the reports might have been subject to underreporting. Third, the results of text message surveys solely relied on self-reported responses; thus, the number of adverse events reported might have been overestimated due to the likelihood of responding by their parents or guardians. Fourth, as text messages were sent to adolescents aged 12 to 17 years during a particular period of time, the findings cannot be generalized to the entire adolescent population in the ROK; therefore, caution needs to be exercised in interpreting the results. Nevertheless, to the best of our knowledge, this is the first study on COVID-19 vaccine safety in adolescents aged 12 to 17 years in real-world settings in the ROK using national vaccine safety surveillance data managed by the Korean government. This study found consistent safety information on Pfizer-BioNTech COVID-19 vaccination with the US and a controlled trial; serious adverse events following vaccination were extremely rare among adolescents aged 12 to 17 years. No deaths associated with the vaccine were demonstrated as a result of the causality assessment conducted by the VIIC. We will continue to closely monitor any adverse events, including anaphylaxis and myocarditis and/or pericarditis cases, after COVID-19 vaccination for adolescents and share up-to-date information on vaccine safety with policymakers and committees to support the development of evidence-based guidelines.

## Notes

### Ethics Approval

The passive surveillance activity was conducted and authorized by the public health authority; the study was not subject to institutional review board approval under government regulations. The study with the text message-based surveillance was exempted from review by the Public Institutional Review Board designated by the Korea Ministry of Health and Welfare (No. P01-202203-01-035).

### Conflicts of Interest

The authors have no conflicts of interest to declare.

### Funding

None.

### Availability of Data

The data used in this study are protected under the Personal Information Protection Act.

### Authors' Contributions

Conceptualization: YK, YKL; Data curation: SK, IH, MK; Formal analysis: SK, IH; Investigation: SK, MK; Methodology: all authors; Validation:

YK, YKL; Writing-original draft: SK, YKL; Writing-review & editing: all authors.

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