Adverse Events of BNT162b2 (Pfizer) COVID-19 Vaccine in Children Aged 12 to 17 Years in Thailand

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Background: The coronavirus disease 2019 (COVID-19) has been sabotaging the world over the last two years and vaccine is one of the key solutions. However, the concerns over its side effects can cause vaccine refusal, subsequently affecting many countries' education system recovery plans.

Objective: To actively evaluate adverse effects and their severity following COVID-19 immunization among schoolchildren aged 12 to 17 years, to support parents' decision-making.

Materials and Methods: The present study was an observational study whereby a Google-form survey on Pfizer COVID-19 vaccine adverse effects (CVAE) was responded between January and April 2022 by 537 participants. Descriptive statistics were used to analyze basic characteristics. Chi-square tests were performed for comparative analyses between junior (aged 12 to 15 years) versus senior (aged 16 to 17 years) high school students, and McNemar's test for the first dose versus second dose groups analysis with a significance level set at p-value less than 0.05.

Results: At least one CVAE was reported in 93.85% of the included participants, albeit mostly mild. The most common symptom as a local event was tenderness at the puncture site (82.50%), whereas systemic events were predominated by myalgia (74.67%). The second dose was associated with increased frequency and severity of adverse effects compared to the first dose (p<0.001). The older age group had significantly more side effects compared to the younger group (p<0.05).

Conclusion: The high incidence of CVAEs in schoolchildren was predominated by mild symptoms, with the second dose and older group associated with increased frequency of symptoms. The predominance of mild symptoms found in the present study may help reduce the concerns of parents over CVAEs, ultimately accelerating vaccine coverage in the children group, which is still a gap in vaccine administration.

Keywords: Coronavirus 2019; COVID-19 Vaccine; BNT162b2; Side effects; Adverse events; Adolescence

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The coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been sabotaging the world over the last two years and the fight against it is not yet over. Declared by the World Health Organization (WHO) as a Public Health Emergency of International Concern and a pandemic on January 30, 2020 and March 11, 2020, respectively⁽¹⁾, COVID-19 has taken too many lives and affected every sector of our society. As of July 2022, over half

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a billion confirmed cases and over 6.3 million deaths have been reported worldwide⁽²⁾. However, estimates indicate that the real number of deaths may be three times higher than reported⁽³⁾.

Thailand is a Southeast Asian, upper middleincome country originally reported as one of the countries with good COVID-19 management during the early phases of the COVID-19 pandemic. However, like other countries, Thailand has been experiencing serious waves and the number of COVID-19-related deaths is reported to be over 30,000 deaths as of June 4, 2022⁽⁴⁾.

As the pandemic affected the economic and social systems, the education system was not an exception. The closure of schools has become one of the major concerns for all parents and children. According to data released in March 2021 by UNICEF, schools with more than 168 million children globally were completely closed for almost a full year⁽⁵⁾. UNESCO has been supporting countries to address these consequences by adapting education systems⁽⁶⁾. However, as of February 28, 2022, data from UNESCO revealed that more than 669 million children globally were continuing to experience disruption to their education as a consequence of full and partial school closures⁽⁶⁾. Of those, more than 43 million are affected by full school closures⁽⁶⁾.

As it is acknowledged that prioritizing education as a public good is crucial to avoid a generational catastrophe and driving a sustainable recovery, COVID-19 vaccine administration among schoolchildren is one of the most effective strategies. Fortunately, COVID-19 vaccines validated for use by WHO are currently available. These include BNT162b2 vaccine (Pfizer), TSII/COVISHIELD, AstraZeneca/AZD1222 vaccines, Janssen/Ad26. COV 2.S developed by Johnson & Johnson, Moderna COVID-19 vaccine (mRNA 1273), Sinopharm COVID-19 vaccine, Sinovac-CoronaVac, and Bharat Biotech BBV152 COVAXIN vaccine⁽⁷⁾. Among them, Pfizer received emergency use authorization from the Food and Drug Administration (FDA) in May 2021 for 12- to 15-year-old children, and FDA Thailand approved the use of Pfizer in children aged 12 to 17 years on October 4, 2021 to follow schooling plans⁽⁷⁾.

Nevertheless, the concerns of parents over the potentially serious side effects of these vaccines on their children and teens are among the strong drivers of vaccine hesitancy or refusal⁽⁸⁾, subsequently affecting the education system's recovery plans. Therefore, more studies on the side effects of COVID-19 vaccines in children can help parents make evidence-based decisions and can help counteract social media and internet messages promoting misinformation about or mistrust of vaccines.

In Thailand, there are two systems documenting the adverse effects of COVID-19 vaccines. The first one is the Adverse Ministry of Public Health Immunization Center (MOPH-IC) system. It is a passive surveillance that provides data through an application that allows parents whose children have been vaccinated to record any effect at 30-minute, day 1, day 3, and day 7 post-vaccination. The second one is the Adverse Effects Following Immunization-Department of Disease Control (AEFI-DDC). It is also a passive surveillance system whose COVID-19 adverse effects data come from medical records of individuals visiting a hospital with vaccine-related diagnoses. However, these two databases, being passive, do not directly obtain information from children, and real-world data regarding the side effects of the Pfizer vaccine in children are still scarce, especially in Asian children. Therefore, the

aim of the present study was to actively evaluate side effects and their severity following COVID-19 immunization among children aged 12 to 17 years in Thailand.

Materials and Methods Study design and setting

The present study was a retrospective, observational study whereby a QR code containing a Google form of a survey on COVID-19 side effects was answered, between January and April 2022 by children aged 12 to 17 years, along with their parents aids, in Nakhon Ratchasima, which is known to be the largest province with the highest number of schools in Thailand⁽⁹⁾. Ethical approval for conducting the present study was obtained from the Ethics in Human Research Committee, Research and Development Institute, Nakhon Ratchasima Rajabhat University (certificate number; HE-254-2021). The side effects consisted of those that occurred within 30 days of the last dose of the Pfizer vaccine administration.

The inclusion criteria were predefined as (a) having received at least one dose of the Pfizer vaccine against COVID-19 within one month, (b) being a student in grades 7 to 12 in Nakhon Ratchasima, (c) being aged 12 to 17years, and (d) having accepted to sign the consent form.

Participants were excluded when (a) having received a vaccine other than the Pfizer one, (b) incomplete data, (c) not willing to sign the consent form, (d) not being a student in grades 7 to 12 in Nakhon Ratchasima, or (e) aged less than 12 years or more than 17 years. The survey was designed in Thai language, the native language, for a better understanding of the participants. All the questions were developed after reviewing the MOPH-IC and AEFI-DDC databases to identify the common adverse effects post-Pfizer administration. It also underwent content validity index (CVI) evaluation by four professors. After the adjustment and try-out methods of the questionnaire, a multi-stage random sampling method by draw lots was performed to avoid selection bias. Firstly, a list of middle and high schools in Nakhon Ratchasima was selected. Subsequently, simple random samplings were performed again to select classes and participants. There were only 46 participants who would receive the QR code in each grade of each school. The QR code was scanned by participants to receive the Google form of the questions after the researcher described all the important information about the present study. The questionnaire contained two sections with a Table 1. Participants' characteristics and the occurrence of vaccine adverse effects

Characteristics	Total (n=537)	Adverse reaction (n=504)	No adverse reaction (n=33)	p-value
Sex; n (%)				< 0.001
Male	311 (57.91)	281 (55.75)	30 (90.91)	
Female	226 (42.09)	223 (44.25)	3 (9.09)	
Age (years); mean±SD	15 ± 1.58	-	-	
BW (kg); mean±SD	58.62 ± 16.58	-	-	
Education; n (%)				
Junior high school	265 (49.35)	242 (48.02)	23 (69.70)	0.016
Senior high school	272 (50.65)	262 (51.98)	10 (30.30)	
Underlying disease; n (%)				
Yes	59 (10.99)	55 (10.91)	4 (12.12)	0.830
No	478 (89.01)	449 (89.09)	29 (87.88)	
Hx of drug allergy; n (%)				
Yes	27 (5.03)	27 (5.36)	0 (0.00)	0.172
No	510 (94.97)	477 (98.61)	33 (87.88)	
Previous infection with SARS CoV-2; n (%)				
Yes	8 (1.49)	7 (1.37)	1 (3.03)	0.451
No	529 (98.51)	497 (94.61)	32 (96.97)	
Stress before vaccine administration; n (%)				
Yes	376 (70.02)	357 (70.83)	19 (57.58)	0.107
No	161 (29.98)	147 (29.17)	14 (42.42)	

BW=body weight; Hx=history; SD=standard deviation

total of 14 questions. The first section was designed to collect participants' basic characteristics that might impact on vaccine outcomes. These include age, gender, body weight in kilograms, education level, underlying disease, history of allergy, previous SARS-CoV-2 infection, preparation methods, and stress level that rank from 0 to 5 score as no stress at all to the most stressful feeling, before vaccination. The second section was designed to mainly focus on participants' experiences following COVID-19 vaccination. COVID-19 vaccination history was obtained, including the date and time of administration of the first and second doses, side effects, severity (serious=unable to perform normal daily activities, unable to attend a school or visiting a physician due to side effects; mild=not reaching the serious criteria). Participants without any symptoms after vaccination could report so by checking the 'No Symptom' block. In addition, unlisted side effects occurring in participants could be reported in the 'others' space. Participants were able to contact the researcher at any time in case any problem with the survey occurred.

Sample size and statistical analysis

The sample size was calculated with a finite population proportion⁽¹⁰⁾. The calculations were based

on a 5% margin of error and a 95% confidence interval. For the whole city population of Nakhon Ratchasima, Thailand, where the survey was conducted, there was a population of 186,206 people aged 12 to 17 years⁽⁹⁾. As a result from the calculation based on a previous study, a sample size of 369 responses was determined to be sufficient for the present study. That said, the author increased this sample size by 1.5 times to 554 participants to reduce sampling bias.

Descriptive statistics were used for the analyses of basic characteristics, along with the frequency of any adverse outcome in each group as seen in Table 1. The participants were divided into two groups as junior (for 12 to 15 years old) and senior (for 16 to 17 years old) high school student groups. Chi-square tests were performed for comparative analysis between the two groups, and McNemar's test was used for the first dose versus second dose groups analysis. The association of vaccine side effects with participants' characteristics was also analyzed with a significance level set at p-value less than 0.05.

Results

Basic characteristics of participants

Of the 554 responses received in the present study, 17 participants were excluded from the analysis because of missing important data such as the onset



and duration of side effects. In addition, some of those excluded did not receive the Pfizer vaccine. Therefore, 537 participants' data were included in the analyses. All of them completely received two doses of the vaccine. Of them, 311 (57.91%) were male and 226 (42.09%) were female. The mean age was 15 (±1.58) years. Based on their level of education, they were classified into two groups as junior and senior high school with 265 (49.35%) and 272 (50.65%) participants in each group, respectively. Ten point ninety-nine percent of the participants reported having underlying diseases including G6PD deficiency, allergic rhinitis, and asthma. Only 5.03% and 1.49% of the present study participants reported having a history of drug allergy and previous infection with SARS-CoV-2, respectively.

Overall, 93.85% of the students reported at least one adverse effect regardless of the number of doses, and the incidence was higher in males and higher age group. Details are summarized in Table 1.

Adverse effects following vaccination: type, frequency, and severity

In the present study, 504 participants reported side effects following the Pfizer injection, which accounted for 93.85%. The most reported local event was tenderness at the puncture site (82.50%), while systemic events included myalgia (74.67%), drowsiness (60.34%), fatigue (60.65%), and fever (44.51%) (see Figure 1). Interestingly, a transient blurred vision was reported in six junior and two senior high school students with unclear vision for a few minutes post-injection, returning to normal afterward.

In more than 90% of participants, symptoms occurred within 24 hours post-injection for both the first and second doses. The adverse effects disappeared within two days in nearly 60% of the participants, while they lasted more than three days, with a maximum of seven days, in less than one-fifth

Table 2. Occurrence of adverse effects at the $1^{\mbox{\tiny st}}$ dose versus the $2^{\mbox{\tiny nd}}$ dose

Adverse reactions	Frequen	p-value	
	First dose (n=537)	Second dose (n=537)	
Any	431 (80.26)	480 (89.39)	< 0.001
Fever	143 (26.63)	208 (38.73)	< 0.001
Myalgia	344 (64.06)	360 (67.04)	0.121
Pain at puncture site	384 (71.51)	395 (73.56)	0.292
Joint pain	70 (13.14)	74 (13.78)	0.572
Fatigue	239 (44.51)	222 (41.34)	0.093
Drowsiness	278 (51.77)	324 (60.34)	0.127
Headache	121 (22.53)	125 (23.28)	0.677
Faint	8 (1.49)	11 (2.05)	0.491
Nausea/vomiting	15 (2.79)	19 (3.54)	0.371
Abdominal pain	3 (0.56)	9 (1.68)	0.083
Diarrhea	5 (0.93)	6 (1.12)	0.706
Rash	4 (0.74)	5 (0.93)	0.655
Petechiae	N/A	5 (0.93)	N/A
Palpitation	24 (4.47)	29 (5.40)	0.251
Chest discomfort	16 (2.98)	25 (4.66)	0.012
Dyspnea	21 (3.91)	32 (5.96)	0.027
Blurred vision	N/A	10 (1.86)	N/A
Severity	19 (3.54)	46 (8.57)	< 0.001

N/A=not applicable

of the participants.

Overall, the adverse effects were predominantly mild and acceptable, with the serious symptoms only occurring in 3.54% and 8.57% after the first dose and the second dose, respectively. Only one student with chest pain was admitted to rule out myocarditis, and her tests led to a final diagnosis of sinus tachycardia with a heart rate of 150 bpm, normal rhythm, and troponin I of less than 0.1. Participants were categorized to further analyze the association between the presence of post-vaccination adverse outcomes and the number of received doses, as shown in Table 2. Compared with the first dose, the second dose was reported to show relatively more serious adverse effects (p<0.001). Symptoms such as fever, chest discomfort, and dyspnea showed a significant difference in frequency between the first dose and the second dose.

In addition, the older age group had significantly more adverse effects such as fever, myalgia, joint pain, fatigue, drowsiness, and headache, compared to the younger group (p<0.05) (see Table 3).

Discussion

The COVID-19 pandemic has taken too many

Table 3. Comparison of adverse events' frequency between junior and senior high school students

Adverse reactions	Frequen	p-value	
	Senior high school (n=272)	Junior high school (n=265)	
Any	262 (96.32)	242 (91.32)	0.016
Fever	141(51.84)	98 (36.98)	0.001
Myalgia	220 (80.88)	181 (68.30)	0.001
Pain at puncture site	241 (88.60)	202 (76.23)	< 0.001
Joint pain	60 (22.06)	38 (14.34)	0.021
Fatigue	165 (60.66)	107 (40.38)	< 0.001
Drowsy	183 (67.28)	141 (53.21)	< 0.001
Headache	105 (38.60)	66 (24.91)	< 0.001
Faint	14 (5.15)	5 (1.89)	0.041
Nausea/vomiting	14 (5.15)	13 (4.91)	0.898
Abdominal pain	3 (1.10)	9 (3.40)	0.072
Diarrhea	5 (1.84)	3 (1.13)	0.499
Rash	3 (1.10)	4 (1.51)	0.678
Petechiae	3 (1.10)	2 (0.75)	0.674
Palpitation	22 (8.09)	13 (4.91)	0.135
Chest discomfort	13 (4.78)	11 (4.15)	0.725
Dyspnea	13 (4.78)	16 (6.04)	0.519
Blurred vision	2 (0.74)	6 (2.26)	0.144

lives and affected every sector of our society, including the education system. It is acknowledged that prioritizing education as a public good is crucial to avoid a generational catastrophe and driving a sustainable recovery. Therefore, the COVID-19 vaccine administration among schoolchildren is one of the most effective strategies.

However, since the concerns of parents over the potentially serious side effects of these vaccines on their children and teens are among the strong drivers of vaccine hesitancy or refusal⁽⁸⁾, subsequently affecting the education system's recovery plans, there is a need for more studies on the side effects of COVID-19 vaccines in children. Such studies cannot only help parents make evidence-based decisions but also counteract social media and internet messages promoting misinformation about or mistrust of vaccines.

In the present study, it was found that the students-reported outcomes were predominated by mild symptoms not necessitating hospitalization. Overall, the side effects were reported by 93.85% of the participants, the most common being tenderness at the puncture site at 82.50%, myalgia at 74.67%, drowsiness at 60.34%, fatigue at 60.65%, and fever at 44.51%, while rash and petechiae were the least reported outcomes after the vaccination. No serious

cases such as myocarditis or anaphylaxis were reported.

The overall incidence of COVID-19 vaccine side effects is very variable, ranging from 39.48% to 93.1% in some studies^(11,12). Moreover, side effects have been reported to occur more often in younger vaccine recipients than in older vaccine recipients^(13,14), most probably due to the fact that the immune response triggered by vaccines in younger individuals is typically stronger than in those of an older age. For instance, Chan et al.⁽¹⁴⁾ found that the adolescent group was at increased risk of systemic (aOR 1.427, 95% CI 1.088 to 1.874) adverse reactions after the BNT162b2 vaccine compared to the middleaged group. This is in line with the present study findings. However, in a study evaluating side effects of COVID-19 Pfizer-BioNTech mRNA vaccine in children aged 12 to 18 years in Saudi Arabia, Alamer et al.⁽¹⁵⁾ found an overall incidence of 60%, lower than that of the present study. Whether ethnicity affects the incidence of COVID-19 vaccines' adverse events in some populations is not clear. In a recently published prospective cohort study in Thailand including children aged 10 to 17 who received two doses of Sinopharm, at least one adverse reaction was reported with a frequency of 71.18% after the first dose⁽¹⁶⁾. Although this frequency is lower than the one in the present study, it is widely reported that side effects are lower in inactivated vaccines compared to mRNA vaccines. Chen and associates showed in a meta-analysis of randomized controlled trials that the incidence rates of adverse events of inactivated vaccine, mRNA vaccine, and viral vector vaccine were 23.0%, 48.0%, and 76.0%, respectively⁽¹⁷⁾.

The present study showed that more adverse outcomes were reported in males and senior high school students aged 16 to 17 years. These findings are similar to those by Mohsin et al.⁽¹¹⁾ who found that the odds of experiencing a COVID-19 vaccine side effect were 92% lower in female participants compared to male counterparts in Bangladesh. However, it is worth mentioning that the association of gender with COVID-19 vaccine side effects is controversial in the literature. Several studies have reported an increased risk of COVID-19 Pfizer vaccine side effects in female adolescents^(15,18,19), and it is indeed reported that numerous immunological, genetic, hormonal, and environmental factors that differ between males and females can contribute to gender-specific vaccine responses and outcomes⁽²⁰⁾. That said, serious adverse events have been widely reported to occur more in male adolescents at up to

70.6%, compared to female counterparts⁽²¹⁾.

The fact that side effects were more frequently reported in the older group of 16 to 17 years compared to the younger one of 12 to 15 years in the present study is in line with the findings by Berg et al.⁽²²⁾. In their study on self-reported symptoms in adolescents aged 12 to 19 years after BNT162b2 vaccine against SARS-CoV-2, they found that younger adolescents aged 12 to 14 years generally reported lower proportions of symptoms compared to the 15 to 19 years group⁽²²⁾.

Similar to the results from clinical trials and other studies on Pfizer vaccines in adolescents^(18,19,23), the present study shows that adverse events as any symptom, fever, chest discomfort, and dyspnea, were more common after the second dose of the vaccine compared to the first dose (p<0.05). The severity of symptoms was also higher after the second dose compared to the first dose.

Studies reporting adverse effects of COVID-19 in adolescent population group are still scarce and those performed mainly focused on myocarditis or pericarditis as the most concerning side effects. Most of post-vaccination myocarditis or pericarditis cases present with chest pain(24-28). In the present study, chest discomfort was reported in 4.47% of the participants, a finding that is in line the first prospective study on cardiovascular manifestations in Thailand during the national campaign of vaccination against the COVID-19 pandemic for adolescents, which showed a 4.32% occurrence of chest pain⁽²⁹⁾. In the present study, one student with chest pain was admitted to rule out myocarditis. Her test results led to a final diagnosis of sinus tachycardia. The fact that no myocarditis or pericarditis case was found in the present study does not corroborate the findings of Mansanguan et al.⁽²⁹⁾ who found one case of confirmed myopericarditis, four cases of subclinical myocarditis, and two cases of pericarditis in a relatively smaller sample size of 301 adolescents in Thailand. The authors discuss that the incidence of myocarditis/pericarditis found in their study may be higher than in other studies due to the study protocol, which required determining baseline troponin-T, CK-MB, ECG, and echocardiography before vaccination. This difference in findings may also be due to the fact that their study design only analyzed data after the second dose of the BNT162b2 mRNA COVID-19 vaccine. Indeed, it is now acknowledged that myopericarditis is predominant after the second dose. Analysis of previous reports showed that 93% of myopericarditis occurred after the second dose $^{(30)}$.

To the author's knowledge, this is the first study to actively investigate on real-world adverse effects of the Pfizer COVID-19 vaccine in adolescents aged 12 to 17 years in Thailand in English literature. The active approach is one of the strengths of the present study as data from passive surveillance systems for this new vaccine's AEFI were subject to underreporting in many countries^(21,31,32). For example, in the present study, concerning symptoms such as palpitation, chest pain, dyspnea, and blurred vision were reported but no one went through laboratory check-ups to confirm the disease diagnosis. Nevertheless, they completely recovered without taking medicine or requiring hospitalization. Transient blurred vision was reported in the present study with a frequency of 1.49% and it is worth noting it has never been reported in previous studies on COVID-19 vaccines-related side effects in adolescents^(15,18,19,21,23,33). Transient bilateral visual field loss was first reported in a Thai ophthalmologist within an hour after the second dose of Sinovac COVID-19 vaccination⁽³⁴⁾. The proposed possible mechanism could be related to an acute arterial vasospasm in the postchiasmatic visual pathway, triggered by the COVID-19 vaccine. Ocular complications after COVID-19 vaccination have been recently reported in the USA, of which 26.69% are blurred vision in adults of 18 years or older⁽³⁵⁾. The authors of the study caution the physicians to be aware of these rare but possible ocular adverse effects after COVID-19 vaccination. Large-scale studies on ocular complications of COVID-19 vaccines in adolescent subpopulation are needed for robust evidence.

Another strength is that this is a community-based survey whereby the researcher directly described the aims to students and teachers during school class via Zoom or Google Meeting applications before sending them the QR code. Therefore, if they had any misconceptions or non-understanding, they were able to instantly ask questions, which may reduce information bias. Moreover, the adverse effects were carefully listed in the survey after consulting the two biggest passive surveillance databases.

However, the present study still bears limitations to be considered. A recall bias cannot be completely ruled out as the researcher started to collect data in January 2022 while most of the participants received vaccines in December 2021. Furthermore, the samples for the present study were taken from only one province, Nakhon Ratchasima. As a result, the generalizability of the findings in different areas may not be guaranteed, thus necessitating further largescale research. Finally, the present study does neither evaluate the COVID-19 vaccine-(including other manufacturers) related medium- or long-term side effects, nor investigate on side effects after booster dose, implying the need for further research.

Conclusion

The present study showed the most common adverse events occurring after the Pfizer vaccine administration in children aged 12 to 17 years are tolerable and subside within a few days without fatal reports. While a relatively higher frequency of side effects can be expected after Pfizer vaccine administration, especially after the second dose and in older group, the predominance of mild symptoms found in the present study may help reduce the concerns of parents over COVID-19 vaccine adverse effects, ultimately accelerating vaccine coverage in the children population, which is still a gap in vaccine administration. Actively investigating AEFI of COVID-19 vaccines helps reduce underreporting and detect unreported side effects, thus cautioning the health care providers to be aware of the rare but possible adverse effects after COVID-19 vaccination.

What is already known on this topic?

The BNT162b2 Pfizer vaccine is among the approved COVID-19 vaccines for children younger than 18 years after clinical trials showing good efficacy and safety profiles. FDA Thailand approved the use of the BNT162b2 vaccine in children aged 12 to 17 years, and there were only passive surveillance systems to detect the AEFI of the vaccine.

Side effects of COVID-19 vaccines are also present in adolescent population, and the concerns of parents over the potentially serious side effects of these vaccines on their children and teens are among the strong drivers of vaccine hesitancy or refusal.

What this study adds?

This is the first study to actively investigate on AEFI of the Pfizer vaccine in children aged 12 to 17 years in Thailand. The relatively higher incidence of side effects is mainly predominated by mild symptoms subsiding within a few days without requiring hospitalization.

The findings from the present study corroborate the fact that the second dose and older group are associated with increased frequency of symptoms.

The predominance of mild symptoms found in the present study may help reduce the concerns of parents over CVAEs, ultimately accelerating vaccine coverage in the children group which is still a gap in vaccine administration.

Symptoms such as palpitation, chest discomfort, and dyspnea were reported but they mostly completely resolved without taking medicine or requiring hospitalization.

Contrary to the previous studies on COVID-19 vaccines-related side effects in adolescents, transient blurred vision was reported in the present study with a frequency of 1.49%.

Actively investigating AEFI of COVID-19 vaccines helps reduce underreporting and detect unreported side effects, thus cautioning the health care providers to be aware of the rare but possible adverse effects after COVID-19 vaccination.

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Conflicts of interest

The author declares no conflicts of interest.

References

- 1. Cucinotta D, Vanelli M. WHO declares COVID-19 a pandemic. Acta Biomed 2020;91:157-60.
- COVID Live Coronavirus statistics Worldometer [Internet]. 2022 [cited 2022 Jul 4]. Available from: https://www.worldometers.info/coronavirus/.
- 3. Estimating excess mortality due to the COVID-19 pandemic: a systematic analysis of COVID-19-related mortality, 2020-21. Lancet 2022;399:1513-36.
- Thailand COVID-19 Overview Johns Hopkins [Internet]. 2022 [cited 2022 Jul 6]. Available from: https://coronavirus.jhu.edu/region/thailand.
- Unicef. COVID-19: Schools for more than 168 million children globally have been completely closed for almost a full year, says UNICEF [Internet]. 2021 [cited 2022 Jul 6]. Available from: https://www.unicef.org/ press-releases/schools-more-168-million-childrenglobally-have-been-completely-closed.
- UNESCO. Education: From disruption to recovery [Internet]. 2022 [cited 2022 Jul 4]. Available from: https://www.unesco.org/en/covid-19/educationresponse.
- World Health Organization. WHO lists additional COVID-19 vaccine for emergency use and issues interim policy recommendations [Internet]. 2021 [cited 2022 Jul 7]. Available from: https://www.who. int/news/item/07-05-2021-who-lists-additional-covid-

19-vaccine-for-emergency-use-and-issues-interimpolicy-recommendations.

- Suran M. Why parents still hesitate to vaccinate their children against COVID-19. JAMA 2022;327:23-5.
- Ministry of Education. Schools in Thailand [Internet]. 2022 [cited 2022 Jul 4]. Available from: http://www. en.moe.go.th/enMoe2017/.
- Daniel WW, Cross CL. Biostatistics: A foundation for analysis in the health sciences. New York: Wiley & Sons; 1995.
- Mohsin M, Mahmud S, Uddin Mian A, Hasan P, Muyeed A, Taif Ali M, et al. Side effects of COVID-19 vaccines and perceptions about COVID-19 and its vaccines in Bangladesh: A Cross-sectional study. Vaccine X 2022;12:100207.
- Riad A, Pokorná A, Attia S, Klugarová J, Koščík M, Klugar M. Prevalence of COVID-19 vaccine side effects among healthcare workers in the Czech Republic. J Clin Med 2021;10:1428.
- Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med 2020;383:2603-15.
- 14. Chan EWW, Leung MTY, Lau LKW, Leung J, Lum D, Wong RS, et al. Comparing self-reported reactogenicity between adolescents and adults following the use of BNT162b2 (Pfizer-BioNTech) messenger RNA COVID-19 vaccine: a prospective cohort study. Int J Infect Dis 2022;116:47-50.
- Alamer E, Alhazmi A, Qasir NA, Alamer R, Areeshi H, Gohal G, et al. Side effects of COVID-19 Pfizer-BioNTech mRNA vaccine in children aged 12-18 years in Saudi Arabia. Vaccines (Basel) 2021;9:1297.
- Thonginnetra S, Tawinprai K, Niemsorn K, Promsena P, Tandhansakul M, Kasemlawan N, et al. Safety after BBIBP-CorV (Sinopharm) COVID-19 vaccine in adolescents aged 10-17 years in Thailand. Vaccines (Basel) 2022;10:1765.
- 17. Chen M, Yuan Y, Zhou Y, Deng Z, Zhao J, Feng F, et al. Safety of SARS-CoV-2 vaccines: a systematic review and meta-analysis of randomized controlled trials. Infect Dis Poverty 2021;10:94.
- Ogawa T, Yamada T, Matsumoto Y, Minami K, Kawanishi F, Nakano T, et al. Adverse events after administration of the first and second doses of messenger RNA-based COVID-19 vaccines in Japanese subjects aged 12-18 years. J Int Med Res 2022;50:3000605221127518.
- Alrowdhan FK, Alwably A, Altala AS, Alfaraj H, Farawaty MN, Shaheen RS, et al. Evaluation of shortterm symptoms associated with COVID-19 vaccines used among adolescents in Saudi Arabia. Cureus 2022;14:e29306.
- Flanagan KL, Fink AL, Plebanski M, Klein SL. Sex and gender differences in the outcomes of vaccination over the life course. Annu Rev Cell Dev Biol 2017;33:577-99.
- 21. Hause AM, Gee J, Baggs J, Abara WE, Marquez

P, Thompson D, et al. COVID-19 vaccine safety in adolescents aged 12-17 years - United States, December 14, 2020-July 16, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1053-8.

- 22. Berg SK, Wallach-Kildemoes H, Rasmussen LR, Nygaard U, Bundgaard H, Petersen MNS, et al. Shortand long-term self-reported symptoms in adolescents aged 12-19 years after vaccination against SARS-CoV-2 compared to adolescents not vaccinated-A Danish retrospective cohort study. Vaccines (Basel) 2022;10:1863.
- Frenck RW Jr, Klein NP, Kitchin N, Gurtman A, Absalon J, Lockhart S, et al. Safety, immunogenicity, and efficacy of the BNT162b2 Covid-19 vaccine in adolescents. N Engl J Med 2021;385:239-50.
- 24. Snapiri O, Rosenberg Danziger C, Shirman N, Weissbach A, Lowenthal A, Ayalon I, et al. Transient cardiac injury in adolescents receiving the BNT162b2 mRNA COVID-19 vaccine. Pediatr Infect Dis J 2021;40:e360-3.
- Minocha PK, Better D, Singh RK, Hoque T. Recurrence of acute myocarditis temporally associated with receipt of the mRNA coronavirus disease 2019 (COVID-19) vaccine in a male adolescent. J Pediatr 2021;238:321-3.
- McLean K, Johnson TJ. Myopericarditis in a previously healthy adolescent male following COVID-19 vaccination: A case report. Acad Emerg Med 2021;28:918-21.
- Marshall M, Ferguson ID, Lewis P, Jaggi P, Gagliardo C, Collins JS, et al. Symptomatic acute myocarditis in 7 adolescents after Pfizer-BioNTech COVID-19 vaccination. Pediatrics 2021;148:e2021052478.
- 28. Schauer J, Buddhe S, Colyer J, Sagiv E, Law Y, Mallenahalli Chikkabyrappa S, et al. Myopericarditis after the Pfizer messenger ribonucleic acid coronavirus disease vaccine in adolescents. J Pediatr 2021;238:317-20.
- Mansanguan S, Charunwatthana P, Piyaphanee W, Dechkhajorn W, Poolcharoen A, Mansanguan C. Cardiovascular manifestation of the BNT162b2 mRNA COVID-19 vaccine in adolescents. Trop Med Infect Dis 2022;7:196.
- Long SS. Important insights into myopericarditis after the Pfizer mRNA COVID-19 vaccination in adolescents. J Pediatr 2021;238:5.
- Hasan SS, Rashid A, Osama S, Mustafa ZU, Merchant HA. Covid-19 vaccine safety and adverse event analysis from Pakistan. Clin Immunol Commun 2022;2:91-7.
- Ontario Agency for Health Protection and Promotion (Public Health Ontario). Adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to November 20, 2022 [Internet]. 2021 [cited 2022 Jul 7]. Available from: https://www. publichealthontario.ca/-/media/documents/ncov/epi/ covid-19-aefi-report.pdf?sc_lang=en.
- 33. Aldali JA, Alotaibi FT, Alasiri GA, Almesned RA,

Alromih AM, Almohandes AM, et al. Evaluate the side effect associated with COVID-19 vaccine on adolescents in Riyadh, Saudi Arabia: A cross-section study. Saudi Med J 2022;43:1248-53.

 Jumroendararasame C, Panyakorn S, Othong R, Jumroendararasame A, Srimanan W, Tipparut K. Transient visual field loss after COVID-19 vaccination: Experienced by ophthalmologist, case report. Am J Ophthalmol Case Rep 2021;24:101212.

 Nyankerh CNA, Boateng AK, Appah M. Ocular complications after COVID-19 vaccination, vaccine adverse event reporting system. Vaccines (Basel) 2022;10:941.