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COVID-19 Vaccine Safety First Year Findings in Adolescents

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Abstract

Background/Objectives: The Food and Drug Administration (FDA) expanded Emergency Use Authorization (EUA) for use of Pfizer-BioNTech (BNT-162b2) COVID-19 vaccine to include people ages 12 years and older on May 10, 2021. Early post-authorization safety data were limited, especially for rare outcomes of concern. We describe adverse events observed during the first full year of the U.S. COVID-19 vaccination program for adolescents ages 12–17 years.

Methods: We conducted descriptive analyses using data from 2 complementary U.S. vaccine safety monitoring systems: v-safe, a voluntary smartphone-based system that monitors reactions and health impacts, and the Vaccine Adverse Event Reporting System (VAERS), the national spontaneous reporting system. We reviewed reports and calculated adverse event reporting rates using vaccine administration data.

Results: Among 172,032 adolescents ages 12–17 years enrolled in v-safe, most reported reactions following BNT-162b2 were mild to moderate, most frequently reported on the day after vaccination, and more common after dose 2. VAERS received 20,240 adverse event reports; 91.5% were nonserious. Among adverse events of interest, we verified 39 cases of MIS-C (1.2 cases per million vaccinations), 33 (84.6%) of which had evidence of prior SARS-CoV-2 infection; and

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Contributors' Statement Page

Drs Hesse, Hause, Myers, and Shay conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. Dr. Myers designed the data collection instruments and collected data as well.

Dr. Su assisted in data acquisition and analysis and reviewed and revised the manuscript.

Ms. Marquez and Mr. Zhang performed data analysis and reviewed and revised the manuscript

Drs Cortese, Allen, Curtis, and Maloney procured and cleaned data, adjudicated potential MIS-C cases, and reviewed and revised the manuscript

Drs Thompson, Nair, Alimchandani, and Niu provided FDA insight into the study and reviewed and revised the manuscript

Ms. Gee assisted with the planning, reviewing, and revision of the manuscript

Dr. Shimabukuro conceptualized the study, coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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570 cases of myocarditis (17.7 cases per million vaccinations), most of whom (77%) reported symptom resolution at the time of report.

Conclusions: During the first year BNT-162b2 was administered to adolescents ages 12–17 years, most adverse events reported to v-safe and VAERS were mild and appeared self-limited. Rates of myocarditis were lower than earlier reports. No new serious safety concerns were identified.

Article Summary:

We evaluated the safety of Pfizer-BioNTech (BNT-162b2) COVID-19 vaccination among U.S. adolescents ages 12–17 years during the first year of vaccine administration.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech (BNT-162b2) COVID-19 vaccine for use in people ages 16 years and older on December 11, 2020;[1] vaccine administration started on December 14. On May 10, 2021, FDA expanded the EUA to include adolescents ages 12–15 years[2] based on results from a Phase 3 clinical trial.[3] The trial found that vaccinees in this age group commonly reported transient mild-to-moderate reactogenicity, primarily injection site pain, fatigue, and headache; no vaccine-related serious adverse events were observed.[3] Findings from post-authorization safety monitoring of BNT-162b2 primary series vaccination during the first 3 months of use among adolescents ages 12–17 years were generally consistent with safety data observed in pre-authorization trials; however, myocarditis was reported more commonly than expected, at 61-122 cases per million adolescent boys vaccinated.[4–6] Early v-safe participants in this age group reported local and systemic reactions; fewer than 25% of respondents reported that these reactions interfered with their ability to perform normal daily activities.[4] Although reassuring, early reports were limited in their ability to detect adverse events following dose 2, as the risk interval for some adverse events (e.g., Guillain-Barre at 42 days or MIS-C at 90 days) extended beyond the study period of even those earliest vaccine administrations in this age group.

As of May 10, 2022, one year after FDA expanded BNT-162b2 vaccine authorization to include adolescents ages 12–17 years, 32,268,525 primary series vaccine doses had been administered to adolescents and 15,493,807 were fully vaccinated with a 2-dose primary series.[7] Our objective is to provide a comprehensive safety assessment after one year of the BNT-162b2 vaccination program for U.S. adolescents using surveillance data from two complementary vaccine safety systems, v-safe and the Vaccine Adverse Event Reporting System (VAERS).

Methods

We analyzed data reported to v-safe and VAERS prior to May 23, 2022, for U.S. adolescents ages 12–17 years who received a primary series BNT-162b2 vaccine dose during December 14, 2020–May 10, 2022. We did not include v-safe and VAERS reports for adolescents ages 12–15 years if their recorded vaccination occurred before the EUA expansion on May 10, 2021, when the vaccine was authorized for this age group. CDC established v-safe (https://vsafe.cdc.gov) to monitor reactogenicity and health impacts after COVID-19 vaccination. We described daily health surveys completed by v-safe participants in the week

after vaccination as previously described (Supplemental Information)[8]. CDC's v-safe call center contacts vaccine recipients or a parent/guardian when a health survey indicates a vaccine recipient received medical care after vaccination and encourages completion of a VAERS report if indicated. VAERS is a U.S. passive surveillance system co-managed by CDC and FDA that accepts reports of adverse events after vaccination from any source, including healthcare providers, vaccine manufacturers, and members of the public.[9] The COVID-19 vaccine EUAs and CDC Provider Agreements for the COVID-19 Vaccination Program outline mandatory reporting elements.[10] Symptoms, signs, and diagnostic findings in the VAERS reports are assigned Medical Dictionary for Regulatory Activities (MedDRA) preferred terms (PTs) by trained staff.[11] More than one MedDRA PT may be assigned to a report; these terms include symptoms and diagnostic evaluations and do not necessarily correspond to medical diagnoses. VAERS reports are further classified as serious if hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death are noted by the reporter.[12] VAERS staff follow-up on serious reports and reports of selected adverse events to request additional information, including medical records, death certificates, and autopsy reports are obtained death, if available. We identified, reviewed, and adjudicated reports to VAERS of potential MIS-C and myocarditis after receipt of BNT-162b2 using methods previously described (Supplemental Information).[6,13,14] Other VAERS reports were not clinically reviewed. We calculated crude reporting rates for pre-specified adverse events of special interest (AESIs) using doses administered through May 10, 2022 as the denominator (Supplemental Materials).[7]

These surveillance activities were reviewed by CDC and conducted consistent with applicable federal law and CDC policy (45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.).

Results

v-safe data

In the first year of use under EUA, 15,493,807 adolescents ages 12–17 years received at least 1 primary-dose BNT-162b2 vaccine; 172,032 (1.1%) enrolled in v-safe, completing a total of 1,199,763 day 0–7 surveys. The median age of participants was 16 years, 54.6% were girls, 62.7% were White, and 73.4% were non-Hispanic/Latino ethnicity (Table 1). Surveys for adolescents ages 12–15 were completed by guardians; for those ages 16–17, over 97% were completed by the vaccinee. When queried, most registrants reported BNT-162b2 was administered alone, without other concurrent vaccinations (97.0% and 99.0% for dose 1 and 2, respectively). Influenza was the most common vaccine reported to be administered concurrently with BNT-162b2 (Table 2). Approximately one-third (35.7%) of total surveys were completed during May 2021, when the EUA was expanded to include 12–15-year-olds.

Participants commonly reported local injection site reactions after both doses, with most respondents reporting reactions on the day after vaccination (Table 3). During the first week, these reports of vaccine reactions decreased each subsequent day. Injection site pain was the most reported local reaction after both doses. Systemic reactions were more frequently

reported after dose 2 than dose 1 (52.5% of respondents after dose 1 vs 65.8% after dose 2; p<0.0001). Most systemic reactions were reported on the day after vaccination; reporting of systemic reactions decreased over time since vaccination. Fatigue, headache, and myalgia were the most common systemic reactions after each dose. Approximately 4% of respondents reported that they were unable to work or attend school in the week after receiving dose 2, compared to 1.3% who missed work or school due to symptoms after dose 1 (p<0.0001). Fewer than 1% of respondents received medical care for symptoms reported in the week following vaccination, regardless of dose received.

Respondents rated the severity of their local and systemic reactions following each vaccine dose based on how the reactions impacted their ability to complete activities of daily living (Table 4). While the total proportion of respondents reporting local injection site pain was similar after each dose (~61% after dose 1 or dose 2), the proportion of participants who reported their pain as moderate or severe was higher after dose 2 compared with dose 1 (28.5% vs 21.2%; p<0.0001). Similarly, systemic reactions such as fatigue (47.3% vs 30.7%; p<0.0001), headache (46.1% vs 27.5%; p<0.0001), myalgia (35.0% vs 23.2%; p<0.0001), and fever (22.2% vs 7.5%; p<0.0001) were more commonly reported generally and more commonly reported as more severe after dose 2 compared with dose 1.

VAERS data

During December 14, 2020–May 10, 2022, 32,268,525 primary series BNT-162b2 vaccine doses were administered to adolescents ages 12–17 years. In that period, VAERS received and processed 20,240 reports of adverse events among adolescents; the median age was 15 years and over half (51.9%) of the reports were for adolescent girls (Table 5). The month with the most reports filed was June 2021 (3,690). Most reports indicated BNT-162b2 was administered alone (20,038; 99%); seasonal inactivated influenza vaccine was the most frequently simultaneously administered vaccine (74; 36.6% of reported co-administered vaccines), followed by other routine adolescent vaccinations, including quadrivalent meningococcal, 9-valent HPV, and Tdap (Table 6).

Most VAERS reports were classified as nonserious (18,514; 91.5%) (Table 7). Dizziness (3,063; 15.1%) was the most commonly reported adverse event. Systemic reactions known to be associated with the vaccine (headache [2,104; 10.4%], pyrexia (fever) [1,967; 9.7%], nausea [1,912; 9.5%], fatigue [1,580; 7.8%], and pain [1,163; 5.8%]) were also frequently reported. There were 6,089 (30.1%) reports of vaccination errors, including product storage errors (1,885; 9.3%), underdoses (934; 4.6%), and product administered to a patient of an inappropriate age (865; 4.3%). Among reports listing a vaccination error, 321/6089 (5.3%) also reported an adverse health event; 27 (8.4%) were classified as serious. VAERS received 56 reports of anaphylaxis occurring on the day of or day after vaccination; 63 anaphylaxis cases were reported in the week after vaccination (Table 8). These cases were not reviewed or adjudicated; however, if all 63 reports met the Brighton Collaboration case definition,[15] the reporting rate would be 1.95 cases per million vaccine doses administered. There were 501 reports of seizures occurring in the first week following vaccination among adolescents aged 12-17 years. Sixty-nine of these reports were classified as serious, and pre-existing seizures were noted in 31/69 (44.9%).

From December 14, 2020, through May 10, 2022, 84 potential cases of MIS-C were reported to VAERS among 12-17-years-olds within 90 days after receipt of a BNT-162b2 dose (Figure 1) (Supplemental Information). Forty (47.6%) met the 2020 CDC MIS-C case definition; of these, 34 (85.0%) had evidence of past or recent SARS-CoV-2 infection, 4 (10.0%) did not have evidence of past or recent SARS-CoV-2 infection, and infection status could not be determined for 2 (5.0%). Thirty-nine of the 40 were discharged home from the hospital; 1 case with evidence of past or recent SARS-CoV-2 infection was transferred to a rehabilitation facility.

During the surveillance period, 681 VAERS reports met the search criteria for myocarditis; in 642 we obtained sufficient information from healthcare provider interviews or medical record reviews to apply the CDC case definition. Seventy-two were misclassified or did not meet the case definition for myocarditis; 570 cases were confirmed (17.7 cases per million second doses administered). Most cases (514/570; 90.2%) occurred in boys. When stratified by age, sex, and vaccine dose received, adolescent boys ages 16–17 years after dose 2 had the highest reporting rate (84.0 cases per million second doses administered) (Table 9). At the time of reporting, 77.0% indicated that they had fully recovered from symptoms of myocarditis. CDC has requested additional follow-up information for cases who reported any continuing symptoms.

We reviewed all available information for the 36 deaths reported to VAERS after vaccination; medical records, death certificates, or autopsy reports were available for 34. Causes of death included complications of malignancy or neoplasm (5); cardiomyopathy associated with genetic, ischemic, or non-COVID-19 infections (5); intracranial bleeding from a ruptured aneurysm or thrombus (without documented thrombocytopenia) (4); pulmonary emboli (4: 1 with chronic lung disease, 1 with bilateral air emboli, 2 with concomitant oral contraceptive use); COVID-19 disease (3); muscular dystrophy (2); myocarditis with an identified infectious agent (2: 1 parvovirus-B19 and 1 SARS-CoV-2); suicide (2); acute hyperglycemic crisis (1); epilepsy (1); metabolic syndrome (1); neuromuscular disorder (1); respiratory illness in a tracheotomy-dependent patient (1); and *Clostridium* sepsis (1). There was insufficient information to determine a presumptive cause of death for 4 reports. One-third (12/36) of the decedents had documentation of complex medical histories, with multiple diagnoses pre-dating COVID-19 vaccination. We observed no apparent pattern or clustering of causes of death. We found no evidence to suggest that vaccination contributed to any reported death.

Discussion

Using data from two complementary surveillance systems, v-safe and VAERS, we review safety surveillance during the first year of BNT-162b2 vaccination among U.S. adolescents ages 12–17 years. In that year, over 32 million doses were administered for primary series vaccination and over 15 million adolescents were fully vaccinated.[7] Overall, our findings are consistent with earlier reports of adverse events reported by vaccinated U.S. residents in this age group.[4,6,13]

The expansion of the BNT-162b2 EUA to include people ages 12–15 years coincided with greater U.S. vaccine availability; the greatest number of vaccinations in this age group occurred during May 2021.[7] Safety data corresponded with vaccination administration, as v-safe received the most survey responses during May 2021 and VAERS received the most reports during June.

As expected from clinical trial[3] and early safety data,[4] adolescents experienced both local and systemic reactions following vaccination, with more substantial reactions after dose 2 than dose 1. Most adolescents reported reactions to v-safe on the day following vaccination; reporting steadily decreased during the first week after vaccination, which is consistent with previous reports to v-safe for all age groups.[16] Inability to attend work or school in the week following dose 2 (4.1%) was lower than reports among adults (12.3%)[16] or children ages 5–11 years (10.9%)[8] and lower than previously described.[4] These differences may be related to changes in policies regarding school attendance, the widespread return to in-person school for the 2021–2022 school year, or the effects of circulating virus variants. Reports of receipt of healthcare after vaccination have been low among all age groups.[4,8,16]

VAERS accepts all reports of adverse events occurring after vaccination, regardless of biological or clinical plausibility that a reported outcome could be associated with vaccination. Therefore, VAERS reports alone are not used to establish a causal association with vaccination.[12] VAERS received reports of 37 deaths after BNT-162b2 vaccination; among 34 reports that included medical or autopsy data, we found no evidence to suggest an association between vaccination and death. During the surveillance period, which included periods of SARS-CoV-2 Delta and Omicron circulation, we identified 40 reports of MIS-C (1.2 cases per million vaccine doses administered). This rate is similar to the rate reported previously among persons ages 12-20 years who received at least 1 BNT-162b2 vaccination through August 31, 2021 (1.0 cases per million people who received at least 1 dose).[13] For reports of MIS-C occurring after vaccination, most cases (34 of 38 with complete information) had evidence of prior SARS-CoV-2 infection. Some MIS-C cases in this report were described in the previous report[13] and are included here to present a fuller assessment of MIS-C in this age group. The potential contribution of vaccination to these illnesses is unknown.[13] Available data do not suggest an association between BNT-162b2 vaccination and either death or MIS-C and demonstrate that vaccination is the most effective way to prevent MIS-C and other severe consequences of COVID-19.[17]

Myocarditis is a rare adverse event known to be associated with mRNA COVID-19 vaccination; risk is greater among male vaccinees and after dose 2.[4,6,18–24] Vaccination at present is the most effective approach for preventing cardiac complications related to SARS-CoV-2 infection itself, as the risk of cardiac disease after infection may be 2- to 6-fold higher than after vaccination.[25] The myocarditis reporting rate was lower for boys ages 12–15 years (48.3 cases per million second doses administered) than boys ages 16–17 years (84.0 cases per million second doses). These observations are consistent with previous findings that the peak risk group is boys ages 16–17 years although our myocarditis reporting rates are lower than those in early reports.[6] The Vaccine Safety Datalink, a network of 9 U.S. healthcare organizations conducting vaccine safety monitoring, reported a myocarditis incidence rate of 137 cases per million doses administered to boys ages

16–17.[26] Similar to earlier reports, we found that most myocarditis cases reported to VAERS experienced resolution of symptoms by the time the report was submitted.[6] A population-based cohort study found the reporting rate of myocarditis after COVID-19 mRNA vaccination was significantly higher among those who received dose 2 within 30 days of dose 1 compared to those whose doses were separated by 56 days or greater.[27] Extending the interval between dose 1 and dose 2 to 8 weeks may reduce the risk of myocarditis in groups at highest risk.[25,27]

Simultaneous vaccination with BNT-162b2 and other vaccines among adolescents ages 12–17 years was not common; only 1–3% of participants in VAERS or v-safe reported that they received a concurrent vaccination. This finding was not unexpected, as the adolescent vaccine schedule includes fewer routine vaccinations than the schedule for younger children. CDC clinical guidance states that COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration of COVID-19 vaccine and other vaccines.[28]

The findings in this report are subject to several limitations. Data from these two surveillance systems may not be representative of the BNT-162b2 vaccinated U.S. population. V-safe is a voluntary program and participants may be more likely to report an adverse event than the general vaccinated population. Some v-safe participants completed surveys for only 1 primary vaccine dose; participants who did not report a second dose may not have received it or may have been lost to follow-up. VAERS data are subject to reporting biases, including underreporting of nonserious events.[9] Because VAERS is a passive, numerator-only surveillance system, rates of adverse events generally cannot be calculated directly. However, using COVID-19 doses administered in the U.S. population, reporting rates for adverse events can be estimated, and reporting ratios for adverse events can be used to evaluate disproportional reporting of adverse events for specific vaccines. A vaccinated person could report adverse reactions to both v-safe and VAERS. V-safe collects information on common, expected, and specific reactions. VAERS collects additional data and is designed to serve as a signal detection system for new or rare serious adverse events. For both surveillance systems, disparities in access to smartphone and computer technology may impact reporting. Data collection, including review of myocarditis, MIS-C, and death reports, is ongoing in each system.

The Advisory Committee on Immunization Practices and the American Academy of Pediatrics currently recommend that adolescents ages 12–17 years receive a 2-dose primary series of an mRNA COVID-19 vaccine and a bivalent booster >2 months after completed primary series or previously received monovalent booster.[29–31] After one year of EUA administration, ~60% of adolescents have received a primary COVID-19 vaccine series.[7] Our safety findings, collected during the administration of ~32 million primary series doses of BNT-162b2 vaccine to adolescents ages 12–17 years, are consistent with previously reported data. Local and systemic reactions are relatively common; they are usually mild and resolve quickly. Post-vaccination myocarditis is a rare complication most commonly reported in boys following dose 2 of an mRNA-based vaccine. We found no new serious safety concerns in the U.S. adolescent population vaccinated with BNT-162b2. Our

findings provide additional evidence to support the U.S. COVID-19 vaccination program in adolescents to prevent COVID-19 and its serious complications.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Disclaimer:

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Abbreviations:

BNT-162b2	Pfizer-BioNTech mRNA COVID-19 vaccine
CDC	Centers for Disease Control and Prevention
CISA	Clinical Immunization Safety Assessment
COVID-19	coronavirus disease 2019
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
MedDRA	Medical Dictionary for Regulatory Activities
MIS-C	multisystem inflammatory syndrome in children
mRNA	messenger ribonucleic acid
PT	preferred terms
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
VAERS	Vaccine Adverse Events Reporting System

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What's Known on This Subject:

Findings from pre-authorization clinical trials and early U.S. monitoring among BNT-162b2 vaccinated adolescents did not identify new or serious safety concerns.

What This Study Adds:

Analyses of BNT-162b2 administration from two safety monitoring systems confirm early findings and provide additional information about rare adverse events. Reporting rates of post-vaccination myocarditis were lower than those in early reports but remained highest among boys ages 16-17 years.

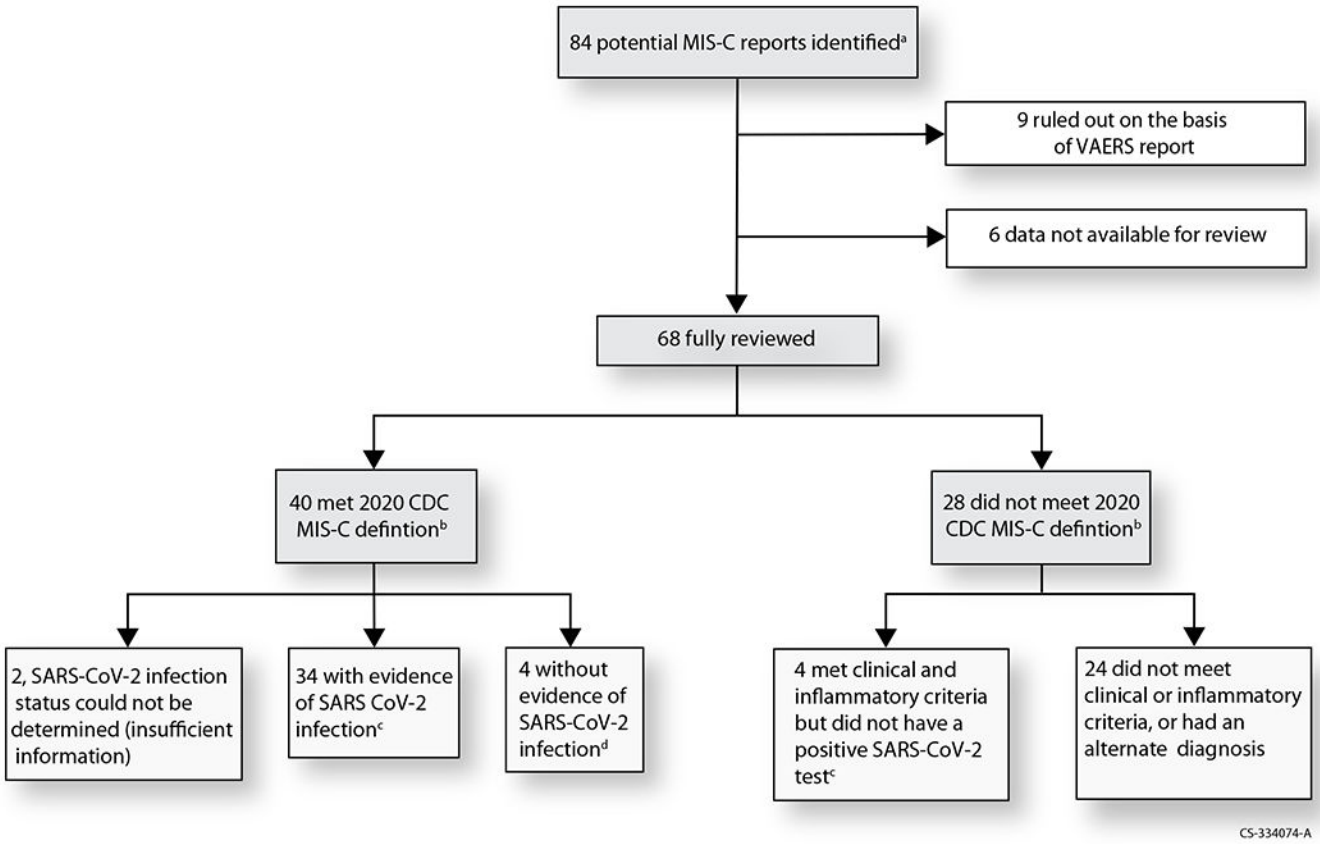

FIGURE 1:

Reports of Multisystem Inflammatory Syndrome in Children (MIS-C) made to the Vaccine Adverse Event Reporting System (VAERS), December 14, 2020–May 10, 2022.

a Potential reports were those identified by the VAERS search (Supplemental information) and in which the individual's onset of illness was <90 days after receipt of their last BNT-162b2 COVID-19 vaccine dose.

b See Supplemental Information for CDC MIS-C case definition. For this investigation, only SARS-CoV-2 serology results from serum obtained before IVIG administration were used to the meet the serology component; we allowed any prior history of a positive SARS-CoV-2 NAAT or antigen test to meet the NAAT/antigen component (i.e., without a time cut-off); the exposure criterion was not used.

c Defined as past or recent positive SARS-CoV-2 NAAT/antigen test, history of past positive NAAT/antigen test, or positive anti-nucleocapsid antibody test on serum obtained before IVIG administration.

d Four individuals with an illness after vaccination meeting the CDC MIS-C clinical and inflammatory criteria, a negative anti-nucleocapsid antibody test and negative NAAT test during MIS-C evaluation, and anti-spike antibody test not obtained

TABLE 1.

Selected demographic characteristics for adolescents ages 12–17 years who completed at least one v-safe health check-in survey on days 0–7 after receiving BNT-162b2 vaccination (N = 172,032) — United States, December 14, 2020–May 10, 2022

Characteristic	Total (%)
Sex	
Female	93,939 (54.6)
Male	75,579 (43.9)
Unknown	1649 (1.0)
Other/Prefer not to say	865 (0.5)
Median age, years (range)	16 (12–17)
12-15	85,792 (49.9%)
16-17	86,240 (51.1%)
Ethnicity	
Hispanic or Latino	35,670 (20.7)
Not Hispanic or Latino	126,242 (73.4)
Unknown	10,120 (5.9)
Race	
American Indian or Alaska Native	1,755 (1.0)
Asian	15,962 (9.3)
Black	15,838 (9.2)
Native Hawaiian or Other Pacific Islander	752 (0.4)
White	107,808 (62.7)
Multiracial	11,569 (6.7)
Other	11,173 (6.5)
Unknown	7,175 (4.2)

TABLE 2.

Vaccine coadministration for adolescents ages 12–17 years registered in v-safe who received another vaccine at the time of BNT-162b2 vaccination[a] (N = 172,032) — United States, December 14, 2020–May 10, 2022

Vaccination practice	**Dose 1 (23,565)[d] N (%)**	**Dose 2 (24,062)[e] N (%)**
COVID-19 vaccine administered alone	22,850 (97.0)	23,813 (99.0)
COVID-19 vaccine coadministered with other vaccines	715 (3.0)	249 (1.0)
Coadministered vaccine type (out of coadministration events)[b,c]		
Influenza	217 (30.3)	69 (27.7)
Human papillomavirus	53 (7.4)	15 (6.0)
Meningitis	44 (6.2)	8 (3.2)
Tetanus	17 (2.4)	10 (4.0)
Hepatitis B	8 (1.1)	1 (0.4)
Hepatitis A	4 (0.6)	2 (0.8)
MMR	4 (0.6)	2 (0.8)
Polio	2 (0.3)	--
Chickenpox	2 (0.3)	1 (0.4)
Other	18 (2.5)	7 (2.8)
Unknown	14 (2.0)	9 (3.6)
Missing[f]	399 (55.8)	141 (56.6)

[a] Registrants completed at least 1 v-safe health check-in survey on days 0–7 after BNT-162b2 vaccination

[b] These categories are not mutually exclusive. More than 1 vaccine type can be selected. Percentages for these rows are out of the coadministration events above.

[c] The vaccine types were simplified in the v-safe platform for a lay audience.

[d] Of the 148,433 participants who completed at least 1 health check-in on days 0–7 following dose 1, 23,565 answered the question regarding vaccine coadministration

[e] Of the 94,409 participants who completed at least 1 health check-in on days 0–7 following dose 2, 24,062 answered the question regarding vaccine coadministration

[f] From 12/13/2020 to 11/21/2021, health check-in surveys asked the participant if the COVID-19 vaccine was co-administered with another vaccine but did not ask the participant to specify. Starting 11/22/2021, checkboxes were provided to select vaccines administered concurrently with the COVID-19 vaccine. From 10/28/2021 through 11/28/2021, we retrospectively added vaccine types when provided by the participant; however, that information was not shared from all participants who stated that another vaccine had been co-administered with the COVID-19 vaccine.

TABLE 3.

Reactions reported for adolescents ages 12–17 years (N = 172,032) who completed at least one v-safe health check-in survey on days 0–7 after receiving Pfizer-BioNTech vaccination — United States, December 14, 2020–May 10, 2022

	% of v-safe enrollees reporting reaction or health impact [a]																	
	Dose 1 (148,433)									Dose 2 (94,409)								
Event	Days 0–7[b]	Day 0[c]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Days 0–7[b]	Day 0[c]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Any injection site reaction	**63.3**	**36.8**	**66.2**	**29.0**	**12.0**	**5.5**	**3.1**	**2.0**	**1.6**	**63.2**	**41.4**	**71.7**	**43.4**	**19.9**	**8.7**	**4.2**	**2.6**	**2.2**
Itching	5.7	1.8	2.7	2.3	1.9	1.3	0.9	0.7	0.5	5.8	1.7	2.7	2.8	2.3	1.6	1.1	0.7	0.5
Injection site pain	60.7	35.1	64.2	26.4	9.8	3.9	2.0	1.2	1.0	60.8	39.9	69.7	40.4	17.1	6.7	2.8	1.7	1.6
Redness	3.9	1.1	2.6	1.9	1.1	0.6	0.3	0.2	0.2	5.3	1.5	3.8	3.3	1.9	0.9	0.4	0.3	0.2
Swelling	7.9	2.4	7.1	3.2	1.5	0.8	0.4	0.3	0.2	9.7	3.0	8.9	5.8	3.0	1.5	0.7	0.4	0.3
Any systemic reaction	**52.5**	**26.2**	**45.1**	**25.6**	**16.7**	**12.4**	**10.6**	**9.0**	**8.0**	**65.8**	**27.6**	**74.0**	**41.2**	**22.2**	**14.3**	**10.9**	**8.9**	**8.0**
Abdominal pain	4.5	0.9	2.5	1.6	1.2	0.9	0.8	0.7	0.6	7.8	1.1	7.2	2.8	1.5	1.0	0.8	0.7	0.6
Myalgia	23.2	9.4	21.1	8.2	4.0	2.5	2.0	1.7	1.5	35.0	8.4	40.3	15.6	6.0	3.2	2.0	1.6	1.6
Chills	7.8	1.9	6.0	2.4	1.2	0.9	0.7	0.5	0.5	23.0	2.6	28.1	5.9	1.5	0.8	0.6	0.5	0.5
Diarrhea	3.7	0.5	1.7	1.3	1.1	0.8	0.7	0.7	0.6	4.1	0.6	2.4	1.7	1.2	0.8	0.6	0.5	0.4
Fatigue	30.7	12.9	24.6	12.9	7.9	5.8	4.7	4.0	3.5	47.3	15.8	53.8	22.6	10.6	6.9	5.1	4.2	3.8
Fever	9.9	2.0	7.8	3.2	1.6	1.2	1.0	0.8	0.8	29.9	3.7	36.7	9.0	2.3	1.1	0.8	0.6	0.7
Headache	27.5	10.6	19.9	11.5	7.5	5.6	4.8	4.1	3.7	46.1	12.0	51.1	22.8	11.5	6.9	5.2	4.2	3.8
Joint pain	7.2	2.0	5.6	2.5	1.5	1.1	0.9	0.6	0.6	14.8	2.4	16.4	5.9	2.4	1.3	0.9	0.7	0.7
Nausea	8.9	2.6	5.6	3.0	2.0	1.6	1.3	1.1	1.0	16.8	3.1	17.9	5.5	2.6	1.6	1.2	1.0	1.0
Rash	1.2	0.2	0.4	0.4	0.4	0.4	0.3	0.3	0.3	1.2	0.2	0.5	0.5	0.4	0.4	0.4	0.3	0.3
Vomiting	1.2	0.2	0.6	0.4	0.2	0.2	0.2	0.2	0.1	2.5	0.2	2.5	0.7	0.3	0.2	0.2	0.2	0.1
Any health impact	**10.3**	**2.1**	**8.0**	**3.2**	**1.8**	**1.5**	**1.3**	**1.2**	**1.0**	**25.4**	**3.4**	**29.5**	**8.1**	**2.9**	**1.8**	**1.3**	**1.2**	**1.3**
Unable to perform normal daily activities	9.3	1.8	7.4	2.8	1.5	1.2	1.1	0.9	0.8	23.1	3.1	27.4	7.0	2.4	1.4	1.0	0.9	0.9
Unable to attend school	1.3	0.2	0.8	0.4	0.3	0.2	0.2	0.2	0.2	4.1	0.4	4.0	1.6	0.6	0.4	0.3	0.3	0.4
Needed medical care	0.6	0.1	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.8	0.1	0.3	0.2	0.2	0.2	0.2	0.1	0.1

Event	% of v-safe enrollees reporting reaction or health impact [a]																	
	Dose 1 (148,433)									Dose 2 (94,409)								
	Days 0–7[b]	Day 0[c]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Days 0–7[b]	Day 0[c]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Telehealth	0.2	0.02	0.05	0.04	0.04	0.03	0.03	0.02	0.02	0.2	0.02	0.1	0.07	0.05	0.04	0.03	0.03	0.03
Clinic	0.3	0.04	0.03	0.05	0.05	0.06	0.07	0.06	0.07	0.3	0.03	0.08	0.07	0.07	0.08	0.07	0.07	0.06
Emergency visit	0.1	0.02	0.03	0.03	0.02	0.02	0.03	0.03	0.02	0.2	0.01	0.1	0.08	0.05	0.04	0.03	0.02	0.04
Hospitalization	0.02	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.04	0.00	0.01	0.01	0.01	0.02	0.01	0.01	0.02

[a] Dose 1 and Dose 2 responses are not paired. Enrollees do not need to have survey responses for both doses to be considered in this table

[b] Percentage of enrollees who reported a reaction or health impact at least once during days 0–7 post-vaccination.

[c] Day 0 is the day of vaccination

TABLE 4.

Most frequently reported solicited reactions for adolescents ages 12–17 years who completed at least one v-safe health check-in survey on days 0–7 after receiving BNT-162b2 vaccination (N = 172,032) — United States, December 14, 2020–May 10, 2022

	% of v-safe enrollees reporting reaction[a, b]							
	Dose 1 (148,433)				Dose 2 (94,409)			
	Mild	Moderate	Severe	Total	Mild	Moderate	Severe	Total
Injection site pain	58,608 (39.5)	29,329 (19.8)	2,127 (1.4)	90,064 (60.7)	30,484 (32.3)	23,957 (25.4)	2958 (3.1)	57,399 (60.8)
Fatigue	20,303 (13.7)	20,664 (13.9)	4,578 (3.1)	45,545 (30.7)	13,519 (14.3)	23,513 (24.9)	7,657 (8.1)	44,689 (47.3)
Headache	22,681 (15.3)	15,442 (10.4)	2,724 (1.8)	40,847 (27.5)	17,513 (18.6)	20,335 (21.5)	5,624 (6.0)	43,472 (46.1)
Myalgia	18,478 (12.5)	13,913 (9.4)	2,067 (1.4)	34,458 (23.2)	11,753 (12.5)	16,939 (17.9)	4,366 (4.6)	33,058 (35.0)
Fever[c]	10,271 (6.9)	554 (0.4)	300 (0.2)	11,125 (7.5)	17,530 (18.6)	2,182 (2.3)	1,255 (1.3)	20,967 (22.2)

[a]Percentage of enrollees who reported a reaction or health impact at least once during days 0–7 post-vaccination. Vaccinees, parents, and guardians who participate in v-safe use the following definitions to describe the severity of the symptoms: mild (noticeable, but not problematic), moderate (limit normal daily activities), or severe (make daily activities difficult or impossible). When reactions are reported on multiple days, the highest severity reported is denoted in this table.

[b]Dose 1 and Dose 2 responses are not paired. Enrollees do not need to have survey responses for both doses to be considered in this table

[c]The number of registrants who reported having a fever may differ from the total who entered information about temperature. Severity of fever was defined as: mild (no temperature entered–38.4 degrees Celsius), moderate (38.5–38.9 degrees Celsius), and severe (≥40.0 degrees Celsius). Registrants were not required to enter temperature.

TABLE 5.

Adverse event reports among adolescents ages 12–17 years who received BNT-162b2 vaccination, by selected demographic characteristics (N = 20,240)—Vaccine Adverse Event Reporting System (VAERS), United States, December 14, 2020–May 10, 2022

Characteristic	Total (%)
Sex	
Female	10,495 (51.9)
Male	9479 (46.8)
Unknown	266 (1.3)
Median age, years (range)	15 (12–17)
12–15	13,205 (65.2)
16–17	7035 (34.8)
Ethnicity	
Hispanic or Latino[a]	2637 (13.0)
Not Hispanic or Latino	8352 (41.3)
Unknown	9251 (45.7)
Race	
American Indian or Alaska Native	256 (1.3)
Asian	834 (4.1)
Black	947 (4.7)
Native Hawaiian or Other Pacific Islander	55 (0.3)
White	8625 (42.6)
Multiracial	439 (2.2)
Other	2444 (12.1)
Unknown	6599 (32.6)

[a]Includes persons reported as of Hispanic or Latino ethnicity, but of unreported or unknown race

TABLE 6:

Vaccines coadministered to adolescents ages 12–17 years at time of BNT-162b2 vaccination as reported to the Vaccine Adverse Event Reporting System (VAERS) (N = 20,240) — United States, December 14, 2020–May 10, 2022

Vaccination practice	Number (%) reporting
COVID-19 vaccine administered alone	20,038 (99.0)
COVID-19 vaccine coadministered with other vaccines[a]	202 (1.0)
Coadministered vaccines (out of 202 coadministration events)	
Influenza	74 (36.6)
Meningococcus, quadrivalent	43 (21.3)
Human papillomavirus, 9-valent	38 (18.8)
Tdap	36 (17.8)
Hepatitis A	20 (9.9)
Hepatitis B	15 (7.4)
Polio, inactivated	14 (6.9)
Meningococcus B	13 (6.4)
Measles-mumps-rubella	13 (6.4)
Varicella	13 (6.4)
Human papillomavirus, unknown	2 (1.0)
Meningococcus, unknown	1 (0.5)
Typhoid	1 (0.5)
Unknown	3 (1.5)

[a]Reported percentages of vaccines coadministered with BNT-162b2 vaccine are reported as the percentage of VAERS reports with multiple vaccines, not the percentage of total COVID-19 VAERS reports for this age group

TABLE 7.

Reports of adverse events to the Vaccine Adverse Event Reporting System (VAERS) for adolescents ages 12–17 years after receipt of BNT-162b2 vaccination (N = 20,240) — United States, December 14, 2020–May 10, 2022

Reported events	**Number (%) reporting**
Nonserious VAERS reports	18,514 (91.5)
Serious VAERS reports[a]	1726 (8.5)
Symptom, sign, diagnostic result, or condition (MedDRA PT [b])	**20,240 (100)**
Dizziness	3063 (15.1)
Headache	2104 (10.4)
Pyrexia	1967 (9.7)
Syncope	1953 (9.7)
Nausea	1912 (9.5)
Product storage error	1885 (9.3)
Chest pain	1669 (8.3)
Fatigue	1580 (7.8)
Vomiting	1433 (7.1)
Dyspnoea	1204 (6.0)
Pain	1163 (5.8)
Loss of consciousness	1111 (5.5)
No adverse event[c]	1097 (5.4)
Hyperhidrosis	1072 (5.3)
Pallor	1057 (5.2)
Underdose	934 (4.6)
Chills	905 (4.5)
Product administered to patient of inappropriate age	865 (4.3)
SARS-CoV-2 test negative	780 (3.9)
Pain in extremity	778 (3.8)

MedDRA, Medical Dictionary for Regulatory Activities; VAERS, Vaccine Adverse Event Reporting System.

[a]VAERS reports are classified as serious if any of the following are reported: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death.

[b]Signs and symptoms in VAERS reports are assigned MedDRA preferred terms (PTs) by VAERS staff members. Each VAERS report might be assigned more than one MedDRA PT, which can include normal diagnostic findings. A MedDRA PT does not indicate a medically confirmed diagnosis.

[c]Reports of no adverse event were often accompanied by vaccination error MedDRA PTs, including product preparation issue, incorrect dose administered, product storage error, underdose, or expired product administered.

TABLE 8:

Frequency and reporting rates of selected adverse events of special interest (AESI) reported within the first 21 days of vaccination to the Vaccine Adverse Event Reporting Syndrome (VAERS) for adolescents ages 12–17 years after receipt of BNT-162b2 vaccination — United States, December 14, 2020–May 10, 2022

Reports of AESI[a]	**N**	**Reports per million doses administered**[b]
Acute respiratory distress syndrome	2	0.06
Anaphylaxis (0–1 days)	56	1.74
Anaphylaxis (0–7 days)	63	1.95
Appendicitis	41	1.27
Bell's palsy	62	1.92
Cerebral venous sinus thrombosis	1	0.03
Encephalitis, myelitis, encephalomyelitis	2	0.06
Guillain-Barre syndrome (0–42 days)	23	0.71
Immune thrombocytopenia	8	0.25
Ischemic stroke	3	0.09
Kawasaki's disease	3	0.09
Myopericarditis[c]	677	21.0
MIS-C (0–7 days)[d]	48	1.49
MIS-C (0–28 days)[d]	68	2.11
Narcolepsy	2	0.06
Pulmonary embolism	10	0.31
Seizure	501	15.5
Seizure, serious[e]	*69*	*2.11*
Thrombosis with thrombocytopenia syndrome (0–7 days)	6	0.19
Thrombosis with thrombocytopenia syndrome (any time after vaccination)	17	0.53
Thrombotic thrombocytopenic purpura	4	0.12
Venous thromboembolism	27	0.84

[a] These represent all reports listing one of these outcomes; reports have not been individually reviewed nor verified by use of a specific case definition. The risk window is 0–21 days after vaccination unless otherwise indicated

[b] 32,268,525 primary series doses were administered to adolescents in this age group during the study period

[c] Reports of myocarditis or myopericarditis represent all such reports submitted to VAERS prior to clinical adjudication using the CDC case definition for COVID-19 associated myocarditis. More detailed data on myocarditis can be found in Table 9.

[d] Reports of multisystem inflammatory syndrome in children (MIS-C) represent all such reports submitted to VAERS prior to review and clinical adjudication using the CDC case definition for MIS-C. More detailed data on MIS-C can be found in Figure 1.

[e] VAERS reports are classified as serious reports if hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death are noted by the reporter

TABLE 9.

Reporting rates (per one million doses administered) of verified reports to the Vaccine Adverse Event Reporting System (VAERS) of myocarditis[a] among adolescents ages 12–17 years after BNT-162b2 vaccination by dose number — United States, December 14, 2020–May 10, 2022

	Reporting Rate (N) 12-17 years			Reporting Rate (N) 12-15 years			Reporting Rate (N) 16-17 years	
	Dose 1	Dose 2		Dose 1	Dose 2		Dose 1	Dose 2
Male	7.8 (67)	60.4 (447)	Male	6.9 (39)	48.3 (234)	Male	9.7 (28)	84.0 (213)
Female	0.9 (9)	6.1 (47)	Female	1.1 (6)	4.7 (23)	Female	0.7 (3)	8.7 (25)

MedDRA, Medical Dictionary for Regulatory Activities; VAERS, Vaccine Adverse Event Reporting System.

[a]VAERS reports of myocarditis were identified using a combination of MedDRA preferred terms, with symptom onset during day of vaccination through day 6 after vaccination and verified to meet case definition by clinician interview with a care provider, or clinician review of the medical record.