

## COVID-19 Vaccine Safety in Children Aged 5–11 Years — United States, November 3–December 19, 2021

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On October 29, 2021, the Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 (BNT162b2) mRNA vaccine to expand its use to children aged 5–11 years, administered as 2 doses (10 µg, 0.2mL each) 3 weeks apart (1). As of December 19, 2021, only the Pfizer-BioNTech COVID-19 vaccine is authorized for administration to children aged 5–17 years (2,3). In preauthorization clinical trials, Pfizer-BioNTech COVID-19 vaccine was administered to 3,109 children aged 5–11 years; most adverse events were mild to moderate, and no serious adverse events related to vaccination were reported (4). To further characterize safety of the vaccine in children aged 5–11 years, CDC reviewed adverse events after receipt of Pfizer-BioNTech COVID-19 vaccine reported to the Vaccine Adverse Event Reporting System (VAERS), a passive vaccine safety surveillance system co-managed by CDC and FDA, and adverse events and health impact assessments reported to v-safe, a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination,\* during November 3–December 19, 2021. Approximately 8.7 million doses of Pfizer-BioNTech COVID-19 vaccine were administered to children aged 5–11 years<sup>†</sup> during this period; VAERS received 4,249 reports of adverse events after vaccination with Pfizer-BioNTech COVID-19 vaccine in this age group, 4,149 (97.6%) of which were not serious. Approximately 42,504 children aged 5–11 years were enrolled in v-safe after vaccination with Pfizer-BioNTech COVID-19 vaccine; after dose 2, a total of 17,180 (57.5%) local and 12,223 systemic (40.9%) reactions (including injection-site pain, fatigue, or headache) were reported. The preliminary safety findings are

similar to those from preauthorization clinical trials (4,5). The Advisory Committee on Immunization Practices (ACIP) recommends the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years for the prevention of COVID-19 (6). Parents and guardians of children aged 5–11 years vaccinated with Pfizer-BioNTech COVID-19 vaccine should be advised that local and systemic reactions are expected after vaccination. Vaccination is the most effective way to prevent COVID-19. CDC and FDA will

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\* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

<sup>†</sup> <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic> (Accessed December 19, 2021).



continue to monitor vaccine safety and will provide updates as needed to guide COVID-19 vaccination recommendations.

VAERS is a national passive vaccine safety surveillance system, jointly managed by CDC and FDA, that monitors adverse events after vaccination (7). VAERS accepts reports from anyone, including health care providers,<sup>§</sup> vaccine manufacturers, and members of the public. Symptoms, signs, and diagnostic findings in VAERS reports are assigned Medical Dictionary for Regulatory Activities (MedDRA) preferred terms by VAERS staff members.<sup>¶</sup> 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.<sup>\*\*</sup> Reports of serious adverse events receive follow-up by VAERS staff members to obtain additional information, including medical records. For reports of death, death certificates and autopsy reports are obtained, if available. CDC physicians reviewed all available information for each decedent to form an impression about cause of death. Reports of myocarditis and pericarditis after receipt of COVID-19 vaccine were identified by a search for

selected MedDRA preferred terms (7); CDC staff members attempted to collect information about clinical course and recovery related to myocarditis and pericarditis from patients and health care providers.

CDC established v-safe,<sup>††</sup> a voluntary smartphone-based active safety surveillance system, specifically to monitor adverse events after COVID-19 vaccination. Parents and guardians can enroll children in v-safe after either the first or second vaccine dose. Text message reminders for online health surveys are sent to parents or guardians to complete for a child.<sup>§§</sup> Health surveys sent in the first week after vaccination included questions about local injection site and systemic reactions (mild, moderate, or severe)<sup>¶¶</sup> and health impacts (i.e., whether the child was unable to perform normal daily activities, missed school, or received care from a medical professional because of new symptoms or conditions). CDC's v-safe call center contacted a parent or guardian when a report indicated that a

<sup>††</sup> <https://vsafe.cdc.gov>

<sup>§§</sup> Children and adolescents aged ≤15 years must be enrolled by a parent or guardian and cannot self-enroll. Children aged 5–11 years might be enrolled in v-safe if they were vaccinated on or after November 3, 2021. Health check-ins are sent via text messages that link to web-based surveys on days 0–7 after vaccination; then weekly through 6 weeks after vaccination; and then 3, 6, and 12 months after vaccination.

<sup>¶¶</sup> Parents and guardians who participate in v-safe use the following definitions to describe the severity of a child's symptoms: mild (noticeable, but not problematic), moderate (limit normal daily activities), or severe (make daily activities difficult or impossible).

<sup>§</sup> Under COVID-19 vaccine EUA requirements, health care providers are required to report certain adverse events after vaccination to VAERS, including death. <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html>

<sup>¶</sup> Each VAERS report might be assigned more than one MedDRA preferred term. A MedDRA-coded event does not indicate a medically confirmed diagnosis. <https://www.meddra.org/how-to-use/basics/hierarchy>

<sup>\*\*</sup> Based on the Code of Federal Regulations Title 21. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32>

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child received medical care for new or worsening symptoms; completion of a VAERS report, if indicated, was encouraged.

VAERS and v-safe data collected during November 3–December 19, 2021 among children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine were analyzed and described overall and by sex, age group, and race/ethnicity. Among 5,277 VAERS reports received for children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, 1,028 (19.5%) were excluded from this analysis because vaccination occurred before authorization for use in this age group or date of vaccination was unknown. SAS software (version 9.4; SAS Institute) was used to conduct all analyses. These activities were reviewed by CDC and conducted consistent with applicable federal law and CDC policy.<sup>\*\*\*</sup>

## Review of VAERS Data

During November 3–December 19, 2021, VAERS received and processed 4,249 reports of adverse events (Table 1) for children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine<sup>†††</sup>; the median age was 8 years, and 1,896

<sup>\*\*\*</sup> 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

<sup>†††</sup> Processed VAERS reports are those that have been coded using MedDRA, have been deduplicated, and have undergone standard quality assurance and quality control review.

**TABLE 1. Adverse event reports among children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, by selected demographic characteristics and reported symptoms (N = 4,249) — Vaccine Adverse Event Reporting System, United States, November 3–December 19, 2021**

Characteristic	Total, % (N = 4,249)	Nonserious, % (n = 4,149)	Serious, %* (n = 100)
<b>Sex</b>			
Female	45.0	45.1	39.0
Male	44.6	44.2	61.0
Unknown	10.4	10.7	0
<b>Age range, yrs (median)</b>	<b>5–11 (8)</b>	<b>5–11 (8)</b>	<b>5–11 (9)</b>
<b>Ethnicity</b>			
Hispanic or Latino	11.0	10.9	16.0
Non-Hispanic or Latino	40.0	39.7	56.0
Unknown ethnicity	48.9	49.4	28.0
<b>Race</b>			
American Indian or Alaska Native	0.6	0.6	0
Asian	4.0	4.0	7.0
Black	4.1	4.2	2.0
Native Hawaiian or Other Pacific Islander	0.2	0.2	0
White	39.5	39.2	52.0
Multiracial	2.2	2.1	9.0
Other	7.1	7.1	4.0
Unknown race	42.3	42.7	26.0

**Abbreviation:** VAERS = Vaccine Adverse Event Reporting System.

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

(44.6%) reports were for males. Most children (4,143; 97.5%) received Pfizer-BioNTech COVID-19 vaccine alone; seasonal influenza vaccine was the most frequently simultaneously administered vaccine (91 [2.1%] children).

Overall, 4,149 (97.6%) VAERS reports were for nonserious events, and 100 (2.4%) were for serious events. The median age of children with reports of nonserious events was 8 years, and 1,835 (44.2%) of these reports were for males. The most commonly reported nonserious events were related to vaccine administration (some without any adverse event), including no adverse event (1,157; 27.9%), product preparation issue (925; 22.3%), and incorrect dose administered (675; 16.3%), (Table 2). The median age of children with reports of serious events was 9 years, and 61 (61.0%) reports were among males. The most commonly reported conditions and diagnostic findings among the 100 reports of serious events were fever (29; 29.0%), vomiting (21; 21.0%), and increased troponin<sup>§§§</sup> (15; 15.0%). Among 12 serious reports of seizure, one child experienced syncope (not seizure) and another child potentially experienced syncope, two children experienced febrile seizure, one child had a history of seizures, two children had a potentially evolving seizure disorder, and five children experienced new-onset seizures. Among 15 preliminary reports of myocarditis identified during the analytic period, 11 were verified (by provider interview or medical record review) and met the case definition for myocarditis<sup>¶¶¶</sup>; of these 11 children, seven recovered, and four were recovering at time of the report. VAERS received two reports of death during the analytic period; both are under review. These deaths occurred in two females, aged 5 and 6 years, both of whom had complicated medical histories and were in fragile health before vaccination. None of the data suggested a causal association between death and vaccination.

## Review of v-safe Data

During November 3–December 19, 2021, v-safe enrolled 42,504 children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine (Table 3); second dose information was available for 29,899 (70.3%) of these children. During the week after receipt of dose 1, local (23,290; 54.8%) and systemic (14,734; 34.7%) reactions were frequently reported; systemic

<sup>§§§</sup> Troponins are proteins found in myocytes (heart muscle cells). Troponin levels typically are measured as part of the evaluation of chest pain or other symptoms of possible myocardial damage.

<sup>¶¶¶</sup> Acute myocarditis was defined as presence of signs and symptoms (one or more new or worsening of the following: chest pain/pressure/discomfort, dyspnea/shortness of breath/pain with breathing, palpitations, or syncope; or two or more of the following in children aged ≤11 years: irritability, vomiting, poor feeding, tachypnea, or lethargy); and one or more new finding of elevated troponin, electrocardiogram findings consistent with myocarditis, abnormal cardiac function or wall motion on echocardiogram, cardiac magnetic resonance imaging findings consistent with myocarditis, or histopathologic findings consistent with myocarditis; and no other identifiable cause for these findings.

reactions were more frequently reported during the week after dose 2 (12,223; 40.9%) than dose 1. Reactions were reported most frequently on the day after vaccination for both doses. The most frequently reported reactions after either dose were injection site pain, fatigue, and headache. Fever was more frequently reported after dose 2 (4,001; 13.4%) than dose 1 (3,350; 7.9%).

**TABLE 2. Most frequent symptoms, signs, diagnostic results, and conditions by MedDRA preferred term\* reported to the Vaccine Adverse Event Reporting System among children aged 5–11 years after receipt of Pfizer-BioNTech COVID-19 vaccine (N = 4,249) — United States, November 3–December 19, 2021**

Symptom, sign, diagnostic result, or condition (MedDRA PT)	No. reporting	% Reporting
<b>Nonserious reports (n = 4,149)</b>		
No adverse event†	1,157	27.9
Product preparation issue	925	22.3
Incorrect dose administered	675	16.3
Underdose	324	7.8
Vomiting	316	7.6
Fever	291	7.0
Headache	255	6.2
Syncope	255	6.2
Dizziness	244	5.9
Fatigue	201	4.8
Nausea	192	4.6
Urticaria	186	4.5
Rash	166	4.0
Pallor	151	3.6
Product storage error	146	3.5
<b>Serious reports‡ (n = 100)</b>		
Fever	29	29.0
Vomiting	21	21.0
Troponin increased	15	15.0
Chest pain	12	12.0
Echocardiogram normal	12	12.0
Blood test	11	11.0
C-reactive protein increased	11	11.0
SARS-CoV-2 test negative	11	11.0
Appendicitis	10	10.0
Electrocardiogram normal	10	10.0
Headache	10	10.0
Rash	10	10.0
Seizure	10	10.0
Intensive care	9	9.0
Full blood count normal	8	8.0

**Abbreviations:** MedDRA PT = Medical Dictionary for Regulatory Activities preferred term; VAERS = Vaccine Adverse Event Reporting System.

\* Signs and symptoms in VAERS reports are assigned MedDRA 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. Reports of myocarditis and seizure were identified using a combination of MedDRA PTs; in some cases, reports of myocarditis (identified by fulfilling criteria of the CDC working case definition of myocarditis) and seizure did not have the MedDRA PT “myocarditis” or “seizure” assigned to them. <https://www.meddra.org/how-to-use/basics/hierarchy>

† Reports of no adverse event were accompanied by product preparation issue, incorrect dose administered, or underdose.

‡ 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; MedDRA PTs are included with serious reports when they occur in association with the criteria for serious classification (i.e., radiologic or laboratory tests that occur during a hospitalization).

Approximately 5.1% of parents reported that their child was unable to perform normal daily activities on the day after receipt of dose 1, and 7.4% after receipt of dose 2. Approximately 1% of parents reported seeking medical care in the week after vaccination; most medical care was received via a clinic appointment (441; 0.6%). Fourteen (0.02%) children reportedly received care at a hospital; information regarding reason for hospitalization was available for five children and included appendicitis (two), vomiting and dehydration (one), respiratory infection (one), and retropharyngeal cellulitis (one). Parents and guardians of all hospitalized children were contacted; two parents completed VAERS reports, and one revealed hospitalization was reported in error.

## Discussion

This report provides preliminary safety findings from VAERS and v-safe data collected during the administration of approximately 8 million doses of Pfizer-BioNTech COVID-19 vaccine to children aged 5–11 years. The findings summarized in this report are similar to the safety data from preauthorization trials for Pfizer-BioNTech COVID-19 vaccine administered to

**TABLE 3. Reactions reported for children aged 5–11 years (N = 42,504) who completed at least one v-safe health check-in survey on days 0–7 after receiving Pfizer-BioNTech COVID-19 vaccine — United States, November 3–December 19, 2021**

Event	% of v-safe enrollees reporting reaction or health impact*	
	Dose 1 (N = 42,504)	Dose 2 (n = 29,899)
<b>Any injection site reaction</b>	54.8	57.5
Itching	3.8	3.7
Pain	52.7	55.8
Redness	3.7	4.4
Swelling	3.9	4.9
<b>Any systemic reaction</b>	34.7	40.9
Abdominal pain	5.1	6.4
Myalgia	7.1	10.2
Chills	3.9	6.8
Diarrhea	2.6	2.2
Fatigue	20.1	25.9
Fever	7.9	13.4
Headache	13.9	19.8
Joint pain	2.1	2.9
Nausea	5.0	6.9
Rash	1.2	1.0
Vomiting	2.3	2.7
<b>Any health impact</b>	10.9	15.1
Unable to perform normal daily activities	5.1	7.4
Unable to attend school	7.9	10.9
Needed medical care	1.2	1.1
Telehealth	0.3	0.2
Clinic	0.6	0.6
Emergency visit	0.1	0.1
Hospitalization	0.02	0.02

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



children aged 5–11 years (4,5). Trial participants who received Pfizer-BioNTech COVID-19 vaccine frequently reported local (86.2%) and systemic (66.6%) reactions that were mostly mild (i.e., did not interfere with normal daily activities) or moderate (some interference with normal daily activities); no serious adverse events judged to be related to vaccination were reported (3).

Among VAERS reports for children aged 5–11 years who received Pfizer-BioNTech COVID-19 vaccine, approximately 97% were nonserious. The most common adverse events reported to VAERS in the age group were related to administration error. This age group is the first to receive a smaller dosage of mRNA (10 µg) than that recommended for persons aged ≥12 years (30 µg), and administration errors are not unexpected. Most reports of administration errors often mentioned that no adverse event was associated with receipt of an incorrect dose.

Myocarditis is a rare and serious adverse event that has been associated with mRNA-based COVID-19 vaccines; reporting rates for vaccine-associated myocarditis appears highest among males aged 12–29 years (8). To date, myocarditis among children aged 5–11 years appears rare; 11 verified VAERS reports have been received after administration of approximately eight million vaccine doses, and, in an active vaccine safety surveillance system, no chart-confirmed reports of myocarditis were observed during the 1–21 days or 1–42 days after 333,000 vaccine doses were administered to children of the same age (6). These cases appear consistent with other reports of myocarditis after mRNA COVID-19 vaccination regarding time to symptom onset and a mild clinical course (9). Two deaths after Pfizer-BioNTech COVID-19 vaccine were reported for children with multiple chronic medical conditions; on initial review, no data were found that would suggest a causal association between death and vaccination.

Local (57.5%) and systemic (40.9%) reactions after receipt of dose 2 of Pfizer-BioNTech COVID-19 vaccination among v-safe registrants aged 5–11 years were less frequently reported than reactions reported among children and adolescents aged 12–15 years (local 62.4%; systemic, 63.4%) (9). Fourteen v-safe registrants aged 5–11 years were reported to have been hospitalized after vaccination. V-safe does not directly record diagnoses associated with hospitalization; however, parents and guardians can include supplemental text for each health check-in. Whether hospitalization was the result of vaccination could not be determined; however, all parents and guardians who reported a child's hospitalization were contacted and encouraged to complete a VAERS report. Two parents completed a VAERS report on behalf of a child who was reported to v-safe to have been hospitalized.

## Summary

### What is already known about this topic?

In preauthorization trials for Pfizer-BioNTech (BNT162b2) COVID-19 vaccine, vaccinated children aged 5–11 years reported mild to moderately severe local and systemic reactions; no serious vaccination-related events were noted.

### What is added by this report?

After authorization of Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years during October 2021, and administration of approximately 8 million doses, local and systemic reactions after vaccination were commonly reported to VAERS and v-safe for vaccinated children aged 5–11 years. Serious adverse events were rarely reported.

### What are the implications for public health practice??

Parents and guardians of children aged 5–11 years should be advised that local and systemic reactions are expected after vaccination with Pfizer-BioNTech COVID-19 vaccine and are more common after the second dose.

The findings in this report are subject to at least four limitations. First, VAERS is a passive surveillance reporting system and is subject to reporting biases and underreporting, especially of nonserious events (8). Second, data on race/ethnicity were not provided in >40% of VAERS reports. Third, v-safe is a voluntary program; as a result, v-safe data might not be representative of the vaccinated population. Finally, these data are limited by the short surveillance period and might change as safety monitoring continues and more doses are administered to children aged 5–11 years.

Vaccination is the most effective way to prevent COVID-19 infection. ACIP recommends the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years for the prevention of COVID-19 (10). Preliminary safety findings are similar to those described in the clinical trials. Parents and guardians of children aged 5–11 years vaccinated with Pfizer-BioNTech COVID-19 vaccine should be advised that local and systemic reactions are expected after vaccination. CDC and FDA will continue to monitor vaccine safety and will provide updates as needed to guide COVID-19 vaccination recommendations.

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## Interim Estimate of Vaccine Effectiveness of BNT162b2 (Pfizer-BioNTech) Vaccine in Preventing SARS-CoV-2 Infection Among Adolescents Aged 12–17 Years — Arizona, July–December 2021

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The BNT162b2 (Pfizer-BioNTech) mRNA COVID-19 vaccine has demonstrated high efficacy in preventing infection with SARS-CoV-2 (the virus that causes COVID-19) in randomized placebo-controlled Phase III trials in persons aged 12–17 years (referred to as adolescents in this report) (1); however, data on real-world vaccine effectiveness (VE) among adolescents are limited (1–3). As of December 2021, the Pfizer-BioNTech vaccine is approved by the Food and Drug Administration (FDA) for adolescents aged 16–17 years and under FDA emergency use authorization for those aged 12–15 years. In a prospective cohort in Arizona, 243 adolescents aged 12–17 years were tested for SARS-CoV-2 by reverse transcription–polymerase chain reaction (RT-PCR) each week, irrespective of symptoms, and upon onset of COVID-19–like illness during July 25–December 4, 2021; the SARS-CoV-2 B.1.617.2 (Delta) variant was the predominant strain during this study period. During the study, 190 adolescents contributed fully vaccinated person-time ( $\geq 14$  days after receiving 2 doses of Pfizer-BioNTech vaccine), 30 contributed partially vaccinated person-time (receipt of 1 dose or receipt of 2 doses but with the second dose completed  $< 14$  days earlier), and 66 contributed unvaccinated person-time. Using the Cox proportional-hazards model, the estimated VE of full Pfizer-BioNTech vaccination for preventing SARS-CoV-2 infection was 92% (95% CI = 79%–97%), adjusted for sociodemographic characteristics, health information, frequency of social contact, mask use, location, and local virus circulation. These findings from a real-world setting indicate that 2 doses of Pfizer-BioNTech vaccine are highly effective in preventing SARS-CoV-2 infection among Arizona adolescents. CDC recommends COVID-19 vaccination for all eligible persons in the United States, including persons aged 12–17 years.\*

The PROTECT<sup>†</sup> study is a prospective cohort of persons aged 4 months–17 years initiated in Arizona in July 2021. The study seeks to understand the risk for COVID-19 and how

well COVID-19 vaccines protect children and adolescents from SARS-CoV-2 infection and illness. PROTECT expanded to Florida, Texas, and Utah in late September 2021, and those sites will be included in future analyses. PROTECT is an ancillary study of the HEROES-RECOVER cohorts,<sup>§</sup> which previously reported VE of COVID-19 vaccines among working adults aged 18–85 years using similar methods (4). PROTECT participants in Arizona were recruited from families of adults participating in the HEROES study and the general public. Upon enrollment, participants responded to electronic surveys collecting demographic, health and vaccination history, and prior SARS-CoV-2 infection information. Participants submitted self-collected (or parent-/guardian-collected) mid-turbinate nasal swabs weekly, irrespective of COVID-19–like illness symptoms, and collected an additional swab at the onset of any COVID-19–like illness. Self-reported signs and symptoms of COVID-19–like illness (fever, chills, cough, shortness of breath, sore throat, diarrhea, muscle or body aches, change in smell or taste, or loss of appetite or poor feeding) that occurred in the preceding 7 days were self-reported on the weekly nasal swab envelopes. Specimens were shipped on cold packs and tested by RT-PCR assay for SARS-CoV-2 at Marshfield Clinic Laboratory (Marshfield, Wisconsin). Receipt of COVID-19 vaccines was documented by self-report in electronic surveys and direct upload of vaccine card images by participants' parents or guardians. The number of hours and percentage of time participants wore masks in school and in the community were also collected via self-reported electronic surveys upon enrollment and each subsequent month.

The primary outcome measure was time to RT-PCR–confirmed SARS-CoV-2 infection in vaccinated participants compared with that in unvaccinated participants. VE was calculated using the Anderson-Gill extension of the Cox proportional-hazards models, in which unvaccinated person-time included days before receiving the first dose of a COVID-19

\* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html>

<sup>†</sup> Pediatric Research Observing Trends and Exposures in COVID-19 Timelines (PROTECT).

<sup>§</sup> Arizona Healthcare, Emergency Response and Other Essential Workers Surveillance Study (HEROES) and Research on the Epidemiology of SARS-CoV-2 in Essential Response Personnel (RECOVER) cohorts.

vaccine, and fully vaccinated person-time included number of days following 14 days after receipt of the second of 2 Pfizer-BioNTech vaccine doses. For participants infected with SARS-CoV-2, the event date for this analysis was the earlier of the collection date of the first specimen to test positive or the symptom onset date. Unadjusted VE was calculated as  $100\% \times (1 - \text{hazard ratio for SARS-CoV-2 infection in vaccinated versus unvaccinated participants})$ . An adjusted model used an inverse probability of treatment weighting approach (5) with individual propensities to be vaccinated during each week based on sociodemographic characteristics (age, sex, race/ethnicity, and household size); health information (chronic conditions and daily medication use); frequency of close social contact (school and community); percentage of time wearing masks (school and community); and local virus circulation (daily percentage of all SARS-CoV-2 tests performed in the local county returning a positive result). These predicted propensities were used to calculate stabilized weights, which were incorporated into a Cox proportional-hazards model. Robust SEs were used to account for the clustering of participants within the same household and correlation by stabilized weights. All analyses were conducted using SAS software (version 9.4; SAS Institute) or R software (version 4.1.2; R Foundation for Statistical Computing). This activity was approved by University of Arizona Institutional Review Board on which CDC relied. The study was conducted consistent with applicable federal law and CDC policy.<sup>¶</sup>

Among 1,478 participants aged 4 months–17 years in the full Arizona PROTECT cohort, 280 (18.9%) were aged 12–17 years; 32 (11.4%) of these participants were excluded based on a documented RT-PCR–positive SARS-CoV-2 test result before enrollment, three were excluded because of failure to complete weekly nasal swabs, one was excluded because vaccination information was incomplete, and one was excluded because the participant had received the mRNA-1273 (Moderna) COVID-19 vaccine, leaving 243 participants (86.8% of participants aged 12–17 years) in the analytic sample.

Approximately one half (51.4%) were male, 65.8% were from Tucson, most were aged 12–15 years (74.5%), White (87.7%), non-Hispanic (74.5%), and had private insurance (85.2%) (Table 1). Participants reported attending in-person school a mean of 28.2 (SE = 1.0) hours per week. They reported wearing a mask in school 73.3% (SE = 2.4) of the time; the SE, in part, reflects the variability in mask mandates across the state (6). Participants who received a positive SARS-CoV-2 test result during the study reported a lower percentage of time masked in school (48.6%, SE = 10.0) compared with those

who did not receive a positive test result (75.7%, SE = 2.3) ( $p = 0.031$ ). Participants also reported using masks in the community a mean of 58.5% (SE = 2.6) of the time overall, with participants who received positive SARS-CoV-2 test results reporting a lower mean percentage of community masked time (29.3%; SE = 9.0) compared with those who received negative test results (61.3%; SE = 2.7) ( $p = 0.003$ ).

During the study period, 66 participants contributed 4,288 unvaccinated person-days, 30 contributed 909 partially vaccinated person-days, and 190 contributed 21,693 fully vaccinated person-days (Table 2). Most ( $n = 171$ , 70.3%) vaccinated participants entered the study fully vaccinated. The median number of fully vaccinated person-days during the analysis period was 119 (IQR = 105–133 days).

Twenty-one persons (8.6%) received positive RT-PCR SARS-CoV-2 test results (Table 1). RT-PCR–confirmed infection was more prevalent among residents of areas other than Tucson or Phoenix ( $p = 0.003$ ). The majority ( $n = 18$ , 85.7%) of participants with RT-PCR–confirmed infection reported COVID-19–like illness. The remaining three participants reported being asymptomatic. Two participants with RT-PCR–confirmed infections, both unvaccinated and from the same household, sought outpatient medical care for their illness.

During the 4,288 unvaccinated person-days, 16 RT-PCR–confirmed infections were identified (incidence rate = 3.73 per 1,000 person-days) (Table 2). During the 909 person-days <14 days after receipt of the second vaccine dose, when persons were considered partially vaccinated, no RT-PCR–confirmed infections were identified. Five RT-PCR–confirmed infections occurred during 21,693 fully vaccinated person-days (incidence rate = 0.23 per 1,000 person-days). Estimated unadjusted VE of full vaccination for preventing SARS-CoV-2 infection was 94% (95% CI = 83%–98%). Estimated adjusted VE of full vaccination for preventing SARS-CoV-2 infection was 92% (95% CI = 79%–97%).

## Discussion

Analysis of a prospective Arizona cohort of adolescents found adjusted VE for full vaccination with 2 doses of Pfizer-BioNTech vaccine to be 92% against RT-PCR–confirmed SARS-CoV-2 infection, indicating that the Pfizer-BioNTech COVID-19 vaccine is highly effective in real-world conditions among adolescents aged 12–17 years.

These findings are consistent with those from previous Phase III trials (1,7) and recent observational studies of mRNA VE against severe COVID-19 in adolescents and young adults (3,8). The scientific rigor of these findings is enhanced by the study's prospective design and the participants' weekly specimen collections. The observation period for this analysis coincided with the period of Delta variant predominance in the

<sup>¶</sup>45 C.F.R. part 46; 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d), 5 U.S.C. Sect. 552a, 44 U.S.C. Sect. 3501 et seq.



United States and with return to in-person K–12 instruction in Arizona schools, with potentially higher rates of exposure.

The findings in this report are subject to at least five limitations. First, VE point estimates should be interpreted with caution given the moderately wide CIs, attributable in part to the limited number of unvaccinated person-days relative to fully vaccinated person-days, and a small overall sample size. Second, although several potential confounders were controlled for, including differences in mask use between vaccinated and unvaccinated participants, residual and unmeasured confounding might have occurred. Third, self-collection of

specimens and use of nasal rather than nasopharyngeal swabs could reduce sensitivity of virus detection by RT-PCR but might have increased participation, because studies indicate that nasal swabs are more acceptable to participants (9); if the difference in sensitivity of virus detection between the two methods disproportionately affected those who received the vaccine, VE would be overestimated. Fourth, if vaccination attenuates viral RNA shedding among children, as has been noted in some studies of adults (4), this effect would also result in overestimation of VE by reducing RT-PCR detection among infected but vaccinated participants. Finally, the study

**TABLE 1. Demographic and epidemiologic characteristics of adolescents aged 12–17 years in the Arizona PROTECT Pfizer-BioNTech COVID-19 vaccine effectiveness cohort (N = 243) — Arizona, July–December 2021**

Characteristic	Participants	SARS-CoV-2 infection	No SARS-CoV-2 infection	p-value*	Unvaccinated	Vaccinated 1 dose	p-value*
	No. (col. %)	No. (row %)	No. (row %)		No. (row %)	No. (row %)	
<b>Total</b>	<b>243 (100.0)</b>	<b>21 (8.6)</b>	<b>222 (91.4)</b>	—	<b>49 (20.2)</b>	<b>194 (79.8)</b>	—
<b>Gender</b>							
Male	125 (51.4)	12 (9.6)	113 (90.4)	0.191	25 (20.0)	100 (80.0)	>0.999
Female	106 (43.6)	7 (6.6)	99 (93.4)		22 (20.8)	84 (79.2)	
Transgender	2 (0.8)	1 (50.0)	1 (50.0)		0 (0.0)	2 (100.0)	
None of these or did not respond	10 (4.1)	1 (10.0)	9 (90.0)		2 (20.0)	8 (80.0)	
<b>Site</b>							
Phoenix	49 (20.2)	5 (10.2)	44 (89.2)	0.003	10 (20.4)	39 (79.6)	0.594
Tucson	160 (65.8)	8 (5.0)	152 (95.0)		30 (18.8)	130 (81.2)	
Other	34 (14.0)	8 (23.5)	26 (76.5)		9 (26.5)	25 (73.5)	
<b>Age group, yrs</b>							
12–15	181 (74.5)	15 (8.3)	166 (91.7)	0.941	38 (21.0)	143 (79.0)	0.713
16–17	62 (25.5)	6 (9.7)	56 (90.3)		11 (17.7)	51 (82.3)	
<b>Ethnicity (all races)</b>							
Hispanic	64 (25.5)	3 (4.8)	59 (95.2)	0.298	10 (16.1)	54 (83.9)	0.383
Non-Hispanic	179 (74.5)	18 (9.9)	163 (90.1)		39 (22.7)	140 (77.2)	
<b>Race (all ethnicities)</b>							
White	216 (87.7)	20 (9.4)	196 (90.6)	0.484	40 (18.8)	175 (81.2)	0.041
Other races <sup>†</sup>	27 (12.3)	1 (3.3)	26 (96.7)		9 (36.7)	19 (63.3)	
<b>Household composition</b>							
1 child per household	58 (23.9)	3 (5.2)	55 (94.8)	0.422	10 (17.2)	48 (82.8)	0.654
≥2 children per household	185 (76.1)	18 (9.7)	167 (90.3)		39 (21.1)	146 (78.9)	
<b>Swab adherence<sup>§</sup></b>							
>80%	194 (79.8)	19 (9.8)	175 (90.2)	0.264	35 (18.0)	159 (82.0)	0.149
<b>Chronic conditions<sup>¶</sup></b>							
≥1	25 (10.3)	4 (16.0)	21 (84.0)	0.247	7 (28.0)	18 (72.0)	0.443
None	218 (89.7)	17 (7.8)	201 (92.2)		42 (19.3)	176 (80.7)	
<b>Insurance</b>							
Private	207 (85.2)	17 (8.2)	190 (91.8)	0.387	39 (18.8)	168 (81.2)	0.409
None or did not respond	18 (7.4)	3 (16.7)	15 (83.3)		5 (27.8)	13 (72.2)	
Public	18 (7.4)	1 (5.6)	17 (94.4)		5 (27.8)	13 (72.2)	
<b>Potential virus exposure and mask use (hours weekly), no. (col. %)</b>							
Hours attending school, mean (SE)	28.2 (1.0)	22.2 (3.8)	28.8 (1.0)	0.178	25.2 (2.4)	29.0 (1.0)	0.308
% time masked, school, mean (SE)	73.3 (2.4)	48.6 (10.0)	75.7 (2.3)	0.031	61.6 (6.1)	76.2 (2.5)	0.216
Hours in community, mean (SE)	10.4 (0.8)	11.9 (2.1)	10.3 (0.9)	0.174	11.6 (1.7)	10.1 (1.0)	0.228
% time masked, community, mean (SE)	58.5 (2.6)	29.3 (9.0)	61.3 (2.7)	0.003	39.5 (6.2)	63.2 (2.8)	0.002

**Abbreviations:** Col = column; PROTECT = Pediatric Research Observing Trends and Exposures in COVID-19 Timelines.

\* P-values comparing the percentage of persons with SARS-CoV-2 infections to those not infected by sociodemographic and health categories and comparing the percentage of vaccinated persons to those not vaccinated by these categories, calculated using Pearson's chi-square test (cells with ≥5 observations) or Fisher's exact test (cells with <5 observations). P-values for continuous variables calculated using the Mann-Whitney test.

<sup>†</sup> All participants in the "Other races" category were collapsed into a single group because of small numbers.

<sup>§</sup> Number and percentage of participants who completed weekly nasal swab throughout the analysis period.

<sup>¶</sup> Chronic conditions included asthma or chronic lung disease, cancer, diabetes, heart disease, hypertension, immunosuppression or autoimmune disorder, kidney disease, liver disease, neurologic or neuromuscular disorder, or other chronic conditions.

might not be generalizable to other populations. The study was restricted to adolescents in Arizona and might not be representative of the racial or ethnic distribution in Arizona nor the United States. In addition, participants reported very few chronic conditions and low rates of obesity; previous studies have indicated that VE has not varied by chronic conditions except for among immunocompromised adults (10). The study was also restricted to persons aged 12–17 years; it is not known whether these findings can be generalized to children aged 5–11 years, who are now eligible to receive the Pfizer-BioNTech vaccine under an emergency use authorization.

The VE estimates described in this report for the Pfizer-BioNTech vaccine in real-world conditions during the period of Delta variant predominance corroborate and expand upon the VE estimates from other recent studies in adolescents (1,7) and reinforce previous findings that current vaccination efforts are resulting in substantial preventive benefits among adolescents aged 12–17 years. CDC recommends COVID-19 vaccination for all eligible persons in the United States, including adolescents aged 12–17 years.

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### Summary

#### What is already known about this topic?

The Pfizer-BioNTech COVID-19 vaccine has been shown to be effective in preventing SARS-CoV-2 infection in adolescents in randomized placebo-controlled Phase III trials.

#### What is added by this report?

A prospective cohort of 243 adolescents aged 12–17 years in Arizona completed weekly SARS-CoV-2 testing by nasal swab for 19 consecutive weeks. Under real-world conditions, vaccine effectiveness of full immunization (completion of the second in a 2-dose series  $\geq 14$  days earlier) was 92% against SARS-CoV-2 infections irrespective of symptom status.

#### What are the implications for public health practice?

In real-world conditions among adolescents aged 12–17 years, the Pfizer-BioNTech vaccine was highly effective in preventing SARS-CoV-2 infection.

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**TABLE 2. Contributing participants, total person-days, number of RT-PCR–confirmed SARS-CoV-2 infections by vaccination status, and estimated Pfizer-BioNTech COVID-19 vaccine effectiveness for full vaccination in preventing infection among vaccine-eligible adolescents aged 12–17 years (N = 243) — Arizona, July–December 2021**

Pfizer COVID-19 vaccination status	No. of contributing participants*	Total person-days	No. of days, median (IQR)	No. of SARS-CoV-2 infections	VE, % (95% CI)	
					Unadjusted	Adjusted <sup>†,§</sup>
Unvaccinated	66	4,288	62 (23–98)	16	—	—
Partially vaccinated ( $\geq 14$ days after dose 1 to day 13 after dose 2)	30	909	21 (20–28)	0	—	—
Fully vaccinated ( $\geq 14$ days after dose 2)	190	21,693	119 (105–133)	5	94 (83–98)	92 (79–97)

**Abbreviations:** RT-PCR = reverse transcription–polymerase chain reaction; SMD = standardized mean difference; VE = vaccine effectiveness.

\* Contributing participants in vaccination categories did not equal the number of participants in the study because participants could contribute to more than one vaccination category since vaccination status varies by time.

<sup>†</sup> Adjusted VE is inversely weighted for propensity to be vaccinated; all covariates met balance criteria of SMD  $< 0.2$  after weighting except community mask use and local virus circulation (SMD = 0.228 and 0.288, respectively), but community mask use was only found to change VE estimate by  $\geq 5\%$  when added to the model and was therefore included as a covariate in the Cox regression model for VE.

<sup>§</sup> Five participants missing community mask use were excluded from analysis; this exclusion did not affect the VE estimate.

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## Characteristics and Clinical Outcomes of Children and Adolescents Aged <18 Years Hospitalized with COVID-19 — Six Hospitals, United States, July–August 2021

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During June 2021, the highly transmissible<sup>†</sup> B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, became the predominant circulating strain in the United States. U.S. pediatric COVID-19–related hospitalizations increased during July–August 2021 following emergence of the Delta variant and peaked in September 2021.<sup>§</sup> As of May 12, 2021, CDC recommended COVID-19 vaccinations for persons aged ≥12 years,<sup>¶</sup> and on November 2, 2021, COVID-19 vaccinations were recommended for persons aged 5–11 years.<sup>\*\*</sup> To date, clinical signs and symptoms, illness course, and factors contributing to hospitalizations during the period of Delta predominance have not been well described in pediatric patients. CDC partnered with six children’s hospitals to review medical record data for patients aged <18 years with COVID-19–related hospitalizations during July–August 2021.<sup>††</sup> Among 915 patients identified, 713 (77.9%) were hospitalized for COVID-19 (acute COVID-19 as the primary or contributing reason for hospitalization), 177 (19.3%) had incidental positive SARS-CoV-2 test results (asymptomatic or mild infection unrelated to the reason for hospitalization), and 25 (2.7%) had multisystem inflammatory syndrome in children (MIS-C), a rare but serious inflammatory condition associated with COVID-19.<sup>§§</sup> Among the 713 patients

hospitalized for COVID-19, 24.7% were aged <1 year, 17.1% were aged 1–4 years, 20.1% were aged 5–11 years, and 38.1% were aged 12–17 years. Approximately two thirds of patients (67.5%) had one or more underlying medical conditions, with obesity being the most common (32.4%); among patients aged 12–17 years, 61.4% had obesity. Among patients hospitalized for COVID-19, 15.8% had a viral coinfection<sup>¶¶</sup> (66.4% of whom had respiratory syncytial virus [RSV] infection). Approximately one third (33.9%) of patients aged <5 years hospitalized for COVID-19 had a viral coinfection. Among 272 vaccine-eligible (aged 12–17 years) patients hospitalized for COVID-19, one (0.4%) was fully vaccinated.<sup>\*\*\*</sup> Approximately one half (54.0%) of patients hospitalized for COVID-19 received oxygen support, 29.5% were admitted to the intensive care unit (ICU), and 1.5% died; of those requiring respiratory support, 14.5% required invasive mechanical ventilation (IMV). Among pediatric patients with COVID-19–related hospitalizations, many had severe illness and viral coinfections, and few vaccine-eligible patients hospitalized for COVID-19 were vaccinated, highlighting the importance of vaccination for those aged ≥5 years and other prevention strategies to protect children and adolescents from COVID-19, particularly those with underlying medical conditions.

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† <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>; <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (Accessed September 15, 2021).

§ <https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions>

¶ [https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s\\_cid=mm7020e1\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w)

\*\* [https://www.cdc.gov/mmwr/volumes/70/wr/mm7045e1.htm?s\\_cid=mm7045e1\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7045e1.htm?s_cid=mm7045e1_w)

†† COVID-19 was confirmed with laboratory detection of SARS-CoV-2 by reverse transcription–polymerase chain reaction or antigen test.

§§ Patients with MIS-C as the reason for hospitalization included patients who met the clinical case definition for MIS-C (clinically severe illness requiring hospitalization in a person aged <21 years with fever, laboratory evidence of inflammation, multisystem [≥2] organ involvement and no alternative plausible diagnosis, and evidence of current or recent SARS-CoV-2 infection by reverse transcription polymerase chain reaction, serology or antigen test, or COVID-19 exposure within the 4 weeks preceding symptom onset [<https://emergency.cdc.gov/han/2020/han00432.asp>]) and were hospitalized for diagnosis and management of MIS-C, based on chart review.

¶¶ Patients were considered to have a viral coinfection if they had ≥1 of the following infections: type A influenza, type B influenza, unspecified influenza, coronavirus 229e, coronavirus hku1, coronavirus nl63, coronavirus 0c43, respiratory syncytial virus, adenovirus, parainfluenza type 1, parainfluenza type 2, parainfluenza type 3, parainfluenza type 4, human metapneumovirus, rhinovirus, enterovirus, or other viral coinfection.

\*\*\* Fully vaccinated was defined as having received 2 doses of an mRNA-based COVID-19 vaccine ≥14 days before hospital admission date. Partially vaccinated was defined as having received only 1 dose of an mRNA-based COVID-19 vaccine ≥14 days before hospitalization. All vaccinated patients in this study received the Pfizer-BioNTech (BNT162b2) vaccine.



Data were collected from six U.S. children's hospitals located in areas with high COVID-19 incidence during July–August 2021 (Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas).<sup>†††</sup> Data from hospitalized patients aged <18 years with COVID-19 or SARS-CoV-2 infection<sup>§§§</sup> were abstracted from electronic medical records using REDCap software (version 11.1.8; Vanderbilt University). Patients were categorized<sup>¶¶¶</sup> by reason for hospitalization: 1) acute COVID-19, 2) incidental positive SARS-CoV-2 test result, or

3) MIS-C. Patient demographic characteristics, medical history, coinfections, and disease severity, including need for and duration of respiratory support, ICU admission, IMV, extracorporeal membrane oxygenation (ECMO),<sup>\*\*\*\*</sup> and deaths were abstracted from the medical record. Among patients hospitalized for COVID-19, presence of underlying medical conditions (including obesity),<sup>††††</sup> viral coinfection, and illness course were described by age group. Pearson's chi-square and Kruskal-Wallis tests were used to compare categorical and continuous variables, respectively; p-values <0.05 were

<sup>†††</sup> A convenience sample of six hospitals was selected among members of the Children's Hospital Association. All hospitals were in jurisdictions with a high level of COVID-19 community transmission during July–August 2021; these jurisdictions were not represented by the COVID-NET surveillance system. <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html>

<sup>§§§</sup> COVID-19 diagnosis indicated in medical record or based on positive SARS-CoV-2 test result (antigen or polymerase chain reaction/nucleic acid amplification test, or antibody test among patients with a diagnosis of MIS-C).

<sup>¶¶¶</sup> Abstractors selected the category that best fit the overall reason for hospitalization, with adjudication by project leaders, and through audits of 5% of all charts.

<sup>\*\*\*\*</sup> ECMO is a form of advanced life support used in patients with medically refractory respiratory or cardiac failure.

<sup>††††</sup> For children aged ≥2 years, height and weight were used to calculate body mass index (BMI) (kg/m<sup>2</sup>). BMI percentiles were calculated using BMI, age, and sex. Children with BMI percentiles ≥95% were considered to have obesity (<https://www.cdc.gov/obesity/childhood/defining.html>) and those with BMI ≥120% of the 95th percentile were considered to have severe obesity. BMI data extracted from charts was used if height or weight was missing. If BMI was missing or unable to be calculated, a diagnosis of obesity recorded in charts was used and severity of obesity was unable to be assessed. Obesity was not assessed for children aged <2 years.

**TABLE 1. Demographic characteristics and COVID-19 vaccination status of hospitalized patients aged <18 years with a positive SARS-CoV-2 test result or diagnosis of COVID-19, by reason for hospitalization — six hospitals,\* United States, July–August 2021**

Characteristic	Reason for hospitalization, no. (%)			
	Overall N = 915 (100)	COVID-19 <sup>†</sup> n = 713 (77.9)	Incidental positive SARS-CoV-2 test result n = 177 (19.3)	MIS-C <sup>§</sup> n = 25 (2.7)
Age, yrs, median (IQR)	8.0 (1.3–14.0)	8.0 (1.0–14.0)	9.0 (2.0–14.0)	8.0 (4.0–13.0)
Age group, yrs				
<1	206 (22.5)	176 (24.7)	29 (16.4)	1 (4.0)
1–4	167 (18.3)	122 (17.1)	36 (20.3)	9 (36.0)
5–11	197 (21.5)	143 (20.1)	47 (26.6)	7 (28.0)
12–17	345 (37.7)	272 (38.1)	65 (36.7)	8 (32.0)
Sex				
Female	437 (47.8)	340 (47.7)	87 (49.2)	10 (40.0)
Male	478 (52.2)	373 (52.3)	90 (50.8)	15 (60.0)
Race/Ethnicity				
White, non-Hispanic	277 (30.3)	210 (29.5)	59 (33.3)	8 (32.0)
Black or African American, non-Hispanic	260 (28.4)	202 (28.3)	48 (27.1)	10 (40.0)
Hispanic	267 (29.2)	211 (29.6)	52 (29.4)	4 (16.0)
Other, Non-Hispanic <sup>¶</sup>	42 (4.6)	35 (4.9)	6 (3.4)	1 (4.0)
Unknown	69 (7.5)	55 (7.7)	12 (6.8)	2 (8.0)
COVID-19 vaccination status				
Eligible for vaccination (aged 12–17 yrs)**	345 (37.7)	272 (38.1)	65 (36.7)	8 (32.0)
Fully vaccinated	3 (0.9)	1 (0.4)	2 (3.1)	0 (—)
Partially vaccinated	18 (5.2)	12 (4.4)	4 (6.2)	2 (25.0)
Not vaccinated	224 (64.9)	196 (72.1)	22 (33.8)	6 (75.0)
Unknown vaccination status	100 (29.0)	63 (23.2)	37 (56.9)	0 (—)
Ineligible for vaccination (aged <12 yrs)	570 (62.3)	441 (61.9)	112 (63.3)	17 (68.0)

**Abbreviation:** MIS-C = multisystem inflammatory syndrome in children.

\* The six children's hospitals were in Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas.

<sup>†</sup> Patients hospitalized for COVID-19 included patients with acute COVID-19 as the primary reason for hospitalization or with acute COVID-19 as a secondary or contributing reason for hospitalization, based on chart review.

<sup>§</sup> Patients with MIS-C as the reason for hospitalization included patients who met the clinical case definition for MIS-C (clinically severe illness requiring hospitalization in a person aged <21 years with fever, laboratory evidence of inflammation, multisystem [≥2] organ involvement and no alternative plausible diagnosis, and evidence of current or recent SARS-CoV-2 infection by reverse transcription polymerase chain reaction, serology or antigen test, or COVID-19 exposure within the 4 weeks preceding symptom onset [<https://emergency.cdc.gov/han/2020/han00432.asp>]) and were hospitalized for diagnosis and management of MIS-C, based on chart review.

<sup>¶</sup> Other race/ethnicity includes Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, and Other (not specified).

\*\* Fully vaccinated was defined as having received 2 doses of an mRNA-based COVID-19 vaccine ≥14 days before the hospital admission date. Partially vaccinated was defined as having received only 1 dose of an mRNA-based COVID-19 vaccine ≥14 days before hospitalization. All vaccinated patients in this study received the Pfizer-BioNTech (BNT162b2) vaccine.

considered statistically significant. All analyses were conducted using SAS (version 9.4; SAS Institute) and R (Version 4.0.3; R Foundation for Statistical Computing). This activity was reviewed by CDC and the other participating institutions and was conducted consistent with applicable federal law and CDC policy.<sup>§§§§</sup>

<sup>§§§§</sup> 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

Among 915 patients aged <18 years, 713 (77.9%) were hospitalized for COVID-19, 177 (19.3%) had incidental SARS-CoV-2 infections, and 25 (2.7%) had MIS-C (Table 1). Among all 915 patients, 22.5% were aged <1 year, 18.3% were aged 1–4 years, 21.5% were aged 5–11 years, and 37.7% were aged 12–17 years. Among the 713 patients hospitalized for COVID-19, approximately one half (373; 52.3%) were male, 210 (29.5%) were non-Hispanic White persons, 202 (28.3%)

**TABLE 2. Hospitalization and illness course among children and adolescents aged <18 years hospitalized for COVID-19,\* by age group — six hospitals,† United States, July–August 2021**

Characteristic	Age group, yrs, no. (%)					p-value <sup>§</sup>
	Overall (N = 713)	<1 (n = 176)	1–4 (n = 122)	5–11 (n = 143)	12–17 (n = 272)	
<b>No. of underlying medical conditions</b>						
None	232 (32.5)	124 (70.5)	51 (41.8)	25 (17.5)	32 (11.8)	<0.001
1–2	366 (51.3)	47 (26.7)	46 (37.7)	89 (62.2)	184 (67.6)	
≥3	115 (16.1)	5 (2.8)	25 (20.5)	29 (20.3)	56 (20.6)	
<b>Five most prevalent conditions by system</b>						
Metabolic or endocrine <sup>¶</sup>	258 (36.2)	2 (1.1)	17 (13.9)	59 (41.3)	180 (66.2)	<0.001
Obesity**	231 (32.4)	—	16 (13.1)	48 (33.6)	167 (61.4)	
Obesity	90 (39.0)	—	14 (87.5)	17 (35.4)	59 (35.3)	<0.001
Severe obesity	131 (56.7)	—	1 (6.3)	29 (60.4)	101 (60.5)	
Obesity, unknown severity	10 (4.3)	—	1 (6.3)	2 (4.2)	7 (4.2)	
Neurologic or developmental <sup>††</sup>	144 (20.2)	41 (23.3)	33 (27.0)	28 (19.6)	42 (15.4)	0.038
Seizure disorder	57 (8.0)	6 (3.4)	15 (12.3)	14 (9.8)	22 (8.1)	0.033
Respiratory <sup>§§</sup>	142 (19.9)	7 (4.0)	18 (14.8)	34 (23.8)	83 (30.5)	<0.001
Asthma or RAD	114 (16.0)	2 (1.1)	12 (9.8)	26 (18.2)	74 (27.2)	<0.001
Gastrointestinal or hepatic <sup>¶¶</sup>	85 (11.9)	12 (6.8)	28 (23.0)	16 (11.2)	29 (10.7)	<0.001
Feeding tube dependent	59 (8.3)	7 (4.0)	23 (18.9)	13 (9.1)	16 (5.9)	<0.001
Psychiatric <sup>***</sup>	58 (8.1)	0 (—)	0 (—)	13 (9.1)	45 (16.5)	<0.001
Depression	23 (3.2)	0 (—)	0 (—)	1 (0.7)	22 (8.1)	<0.001
<b>Multiple admissions</b>						
Yes	28 (3.9)	4 (2.3)	5 (4.1)	6 (4.2)	13 (4.8)	0.607
No	685 (96.1)	172 (97.7)	117 (95.9)	137 (95.8)	259 (95.2)	
Unknown	14 (2.4)	3 (1.9)	2 (2.0)	2 (1.9)	6 (2.7)	
Hospital length of stay, median days (IQR)	3.0 (1.0–7.0)	3.0 (1.0–6.8)	3.0 (2.0–4.5)	3.0 (1.0–7.0)	4.0 (2.0–8.0)	0.187
<b>Admitted to ICU</b>						
Yes	210 (29.5)	34 (19.3)	31 (25.4)	37 (25.9)	108 (39.7)	<0.001
No	503 (70.5)	142 (80.7)	91 (74.6)	106 (74.1)	164 (60.3)	
Total length of stay in ICU, median days (IQR)	3.0 (1.0–7.0)	3.0 (1.0–6.8)	3.0 (2.0–4.5)	3.0 (1.0–7.0)	4.0 (2.0–8.0)	0.187
<b>Highest level of respiratory support required</b>						
No oxygen support	328 (46.0)	94 (53.4)	57 (46.7)	82 (57.3)	95 (34.9)	<0.001
Oxygen support	385 (54.0)	82 (46.6)	65 (53.3)	61 (42.7)	177 (65.1)	
Nasal cannula	111 (28.8)	22 (26.8)	14 (21.5)	24 (39.3)	51 (28.8)	
Mask	7 (1.8)	0 (—)	2 (3.1)	1 (1.6)	4 (2.3)	
CPAP or BiPAP	69 (17.9)	5 (6.1)	10 (15.4)	11 (18.0)	43 (24.3)	
High-flow nasal cannula	142 (36.9)	43 (52.4)	32 (49.2)	14 (23.0)	53 (29.9)	
IMV	56 (14.5)	12 (14.6)	7 (10.8)	11 (18.0)	26 (14.7)	
Duration on IMV, median days (IQR)	7.0 (4.0–14.0)	6.0 (4.8–12.3)	6.0 (2.0–11.5)	5.5 (1.8–10.3)	9.5 (5.0–21.3)	0.596
<b>ECMO required</b>						
Yes	8 (1.1)	1 (0.6)	1 (0.8)	1 (0.7)	5 (1.8)	0.567
No	705 (98.9)	175 (99.4)	121 (99.2)	142 (99.3)	267 (98.2)	
Duration on ECMO, median days (IQR)	12.0 (5.5–17.8)	1.0 (1.0–1.0)	13.0 (13.0–13.0)	—	15.0 (11.0–26.0)	0.247
<b>Viral coinfection<sup>†††</sup></b>						
RSV	113 (15.8)	57 (32.4)	44 (36.1)	6 (4.2)	6 (2.2)	<0.001
	75 (66.4)	42 (73.7)	26 (59.1)	4 (66.7)	3 (50.0)	<0.001
<b>Discharge status</b>						
Discharged alive	702 (98.5)	174 (98.9)	122 (100.0)	142 (99.3)	264 (97.1)	0.231
Deceased	11 (1.5)	2 (1.1)	0 (—)	1 (0.7)	8 (2.9)	

See table footnotes on the next page.

**TABLE 2. (Continued) Hospitalization and illness course among children and adolescents aged <18 years hospitalized for COVID-19,\* by age group — six hospitals,† United States, July–August 2021**

**Abbreviations:** BiPAP = bilevel positive airway pressure; BMI = body mass index; CPAP = continuous positive airway pressure; ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IMV = invasive mechanical ventilation; RAD = reactive airway disease; RSV = respiratory syncytial virus.

\* Patients hospitalized for COVID-19 included patients with acute COVID-19 as the primary reason for hospitalization or with acute COVID-19 as a secondary or contributing reason for hospitalization, based on chart review.

† The six children's hospitals were in Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas.

§ Clinical characteristics and outcomes were compared among groups using Pearson's chi-square test for categorical variables and a Kruskal-Wallis test for nonnormally distributed variables.

¶ Metabolic and endocrine conditions included dyslipidemia, obesity, thyroid disorder, type 1 diabetes, type 2 diabetes, and other endocrine disorders.

\*\* For children aged  $\geq 2$  years, height and weight were used to calculate BMI ( $\text{kg}/\text{m}^2$ ). BMI percentiles were calculated using BMI, age, and sex. Those children with BMI percentiles  $\geq 95$ th percentile were considered to have obesity and those with BMI  $\geq 120\%$  of the 95th percentile were considered to have severe obesity. BMI data extracted from charts were used if height or weight was missing. If BMI was missing or unable to be calculated, a diagnosis of obesity recorded in charts was used and severity of obesity was unable to be assessed. Obesity was not assessed for children aged <2 years.

†† Neurologic and developmental conditions included attention deficit hyperactivity disorder, autism spectrum disorder, cerebral palsy, cognitive dysfunction, muscular dystrophy, neural tube defect or spina bifida, neurologic or neurodevelopmental disorder, neuropathy, plegias or paralysis, preterm birth (for children aged <2 years only), seizure disorder, and wheelchair/walker-dependence or bed-bound status.

§§ Respiratory conditions included active tuberculosis, asthma or reactive airway disease, chronic hypoxemic respiratory failure with oxygen or ventilator dependence, cystic fibrosis, current smoking or e-cigarette use, tracheostomy dependence, and other chronic lung diseases.

¶¶ Gastrointestinal or hepatic conditions included Crohn's disease, feeding tube dependence, liver disease, malnutrition, ulcerative colitis, and other gastrointestinal disorders.

\*\*\* Psychiatric conditions included anxiety, borderline personality disorder, depression, substance use disorder, and other psychiatric diagnoses.

††† Patients were considered to have a viral coinfection if they had at least one of the following infections: type A influenza, type B influenza, unspecified influenza, coronavirus 229e, coronavirus hku1, coronavirus n63, coronavirus 0c43, respiratory syncytial virus, adenovirus, parainfluenza type 1, parainfluenza type 2, parainfluenza type 3, parainfluenza type 4, human metapneumovirus, rhinovirus enterovirus, or other viral coinfection.

were non-Hispanic Black persons or African American persons (Black), and 211 (29.6%) were Hispanic persons.

Among the 713 patients hospitalized for COVID-19, 32.5%, 51.3%, and 16.1% had zero, one or two, and three or more underlying medical conditions, respectively (Table 2). The most common conditions were obesity (32.4%), asthma or reactive airway disease (16.0%), and feeding tube dependence (8.3%). Among patients aged 12–17 years, 61.4% had obesity (60.5% of whom had severe obesity). Among patients aged 5–11 years, 33.6% had obesity (60.4% of whom had severe obesity). Among patients hospitalized for COVID-19, 210 (29.5%) had ICU admissions, eight (1.1%) received ECMO, and 11 (1.5%) died. Of the 385 (54.0%) patients hospitalized for COVID-19 who received oxygen support, high-flow nasal cannula was the most common highest level of support (142; 36.9%); 56 (14.5%) patients received IMV. Across all age groups, the median hospital stay was 3 days, and the median IMV duration was 7 days. Patients aged 12–17 years had the longest median hospitalizations (4 days) and IMV requirement (9.5 days). Viral coinfection was common among patients aged <1 year (32.4%) and 1–4 years (36.1%); overall, approximately two thirds of viral coinfections were with RSV (Table 2).

Among 272 vaccine-eligible patients hospitalized for COVID-19, one (0.4%) was fully vaccinated and 12 (4.4%) were partially vaccinated with an mRNA COVID-19 vaccine at the time of hospitalization (Table 1).

A higher percentage of patients hospitalized for COVID-19 with any underlying condition were admitted to the ICU (34.7%) compared with those without an underlying condition (18.5%) ( $p < 0.001$ ) (Table 3). The duration of hospitalization was longer for patients with obesity (median = 4 days

[IQR = 2.0–7.5 days]) than that for those without obesity (median = 2 days [IQR = 1.0–5.0 days]) ( $p < 0.001$ ). A higher proportion of patients with obesity were admitted to the ICU (41.1%) than were those without obesity (23.9%) ( $p < 0.001$ ). A higher proportion of patients with viral coinfection required oxygen support (69.0%) compared with those without viral coinfection (51.2%) ( $p < 0.001$ ).

## Discussion

In this study of six U.S. hospitals during July–August, 2021, approximately three quarters of pediatric patients with COVID-19–related hospitalizations were hospitalized for COVID-19. The majority of those hospitalized for COVID-19 were Black or Hispanic and were aged <5 or 12–17 years. Approximately one third of patients aged <1 and 1–4 years had a viral coinfection, approximately one third of patients aged 5–11 years and approximately two thirds of patients aged 12–17 years had obesity. Less than 1% of vaccine-eligible patients were fully vaccinated against COVID-19.

Five of the six hospitals had policies to test all pediatric patients for SARS-CoV-2 upon admission during the study period, allowing for detection of incidental positive SARS-CoV-2 test results. However, the proportion of such patients was smaller in this study compared with that in a previous report (1). Patients aged 0–4 and 12–17 years accounted for 79% of COVID-19–related hospitalizations in this study, which is consistent with data from other hospitals and communities (2). Among hospitalized children aged <5 years, most were aged <1 year, which might reflect clinical practice differences, because infants might be more likely to be hospitalized with milder disease than older children (3). Most patients were

**TABLE 3. Hospitalization and illness course among children and adolescents aged <18 years hospitalized for COVID-19\* by presence of underlying medical conditions, obesity, and viral coinfection — six hospitals,† United States, July–August 2021**

Characteristic	No. (%)								
	Underlying medical condition			Obesity <sup>§</sup>			Viral coinfection		
	Yes (n = 481)	No (n = 232)	p-value <sup>¶</sup>	Yes (n = 231)	No (n = 482)	p-value <sup>¶</sup>	Yes (n = 113)	No (n = 600)	p-value <sup>¶</sup>
<b>Multiple admissions</b>									
Yes	23 (4.8)	5 (2.2)	0.137	12 (5.2)	16 (3.3)	0.317	3 (2.7)	25 (4.2)	0.621
No	458 (95.2)	227 (97.8)		219 (94.8)	466 (96.7)		110 (97.3)	575 (95.8)	
Hospital length of stay, median days (IQR)	3.0 (2.0–7.0)	2.0 (1.0–4.0)	<0.001	4.0 (2.0–7.5)	2.0 (1.0–5.0)	<0.001	3.0 (2.0–6.0)	3.0 (1.0–6.0)	0.085
<b>Admitted to ICU</b>									
Yes	167 (34.7)	43 (18.5)	<0.001	95 (41.1)	115 (23.9)	<0.001	36 (31.9)	174 (29.0)	0.618
No	314 (65.3)	189 (81.5)		136 (58.9)	367 (76.1)		77 (68.1)	426 (71.0)	
ICU length of stay, median days (IQR)	4.0 (1.0–8.0)	2.0 (1.0–4.0)	0.023	4.0 (2.0–8.0)	3.0 (1.0–6.5)	0.014	4.0 (1.8–10.3)	3.0 (1.0–7.0)	0.37
<b>Highest level of respiratory support required</b>									
None	199 (41.4)	129 (55.6)	<0.001	61 (26.4)	267 (55.4)	<0.001	35 (31.0)	293 (48.8)	<0.001
Oxygen support	282 (58.6)	103 (44.4)		170 (73.6)	215 (44.6)		78 (69.0)	307 (51.2)	
Nasal cannula	77 (27.3)	34 (33.0)		47 (27.6)	64 (29.8)		10 (12.8)	101 (32.9)	
Mask	6 (2.1)	1 (1.0)		2 (1.2)	5 (2.3)		1 (1.3)	6 (2.0)	
CPAP or BIPAP	62 (22.0)	7 (6.8)		43 (25.3)	26 (12.1)		8 (10.3)	61 (20.0)	
High-flow nasal cannula	91 (32.3)	51 (49.5)		55 (32.4)	87 (40.5)		46 (59.0)	96 (31.3)	
IMV	46 (16.3)	10 (9.7)		23 (13.5)	33 (15.3)		13 (16.7)	43 (14.0)	
IMV duration, median days (IQR)	8.0 (4.0–15.0)	5.5 (1.0–6.8)	0.161	8.0 (5.0–14.5)	6.0 (3.8–13.5)	0.472	6.0 (5.0–13.0)	7.0 (3.0–14.5)	0.804
<b>ECMO required</b>									
Yes	5 (1.0)	3 (1.3)	1.000	5 (2.2)	3 (0.6)	0.147	2 (1.8)	6 (1.0)	0.821
No	476 (99.0)	229 (98.7)		226 (97.8)	479 (99.4)		111 (98.2)	594 (99.0)	
ECMO duration, median days (IQR)	15.0 (11.0–26.0)	1.0 (0.5–7.0)	0.101	15.0 (11.0–26.0)	1.0 (0.5–7.0)	0.101	7.0 (4.0–10.0)	13.0 (8.0–23.3)	0.505
<b>Viral coinfection**</b>	<b>49 (10.2)</b>	<b>64 (27.6)</b>	<b>&lt;0.001</b>	<b>7 (3.0)</b>	<b>106 (22.0)</b>	<b>&lt;0.001</b>	<b>113 (100.0)</b>	<b>0 (—)</b>	<b>&lt;0.001</b>
RSV	31 (63.3)	44 (68.8)	<0.001	2 (28.6)	73 (68.9)	<0.001	75 (66.4)	0 (—)	<0.001
<b>Discharge status</b>									
Discharged alive	472 (98.1)	230 (99.1)	0.517	227 (98.3)	475 (98.5)	0.595	111 (98.2)	591 (98.5)	0.81
Deceased	9 (1.9)	2 (0.9)		4 (1.7)	7 (1.5)		2 (1.8)	9 (1.5)	

**Abbreviations:** BIPAP = bilevel positive airway pressure; BMI = body mass index; CPAP = continuous positive airway pressure; ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IMV = invasive mechanical ventilation; RSV = respiratory syncytial virus.

\* Patients hospitalized for COVID-19 included patients with acute COVID-19 as the primary reason for hospitalization or with acute COVID-19 as a secondary or contributing reason for hospitalization, based on chart review.

† The six children's hospitals were in Arkansas, District of Columbia, Florida, Illinois, Louisiana, and Texas.

§ For children aged ≥2 years, height and weight were used to calculate BMI (kg/m<sup>2</sup>). BMI percentiles were calculated using BMI, age, and sex. Those children with BMI percentiles ≥95th percentile were considered to have obesity, and those with BMI ≥120% of the 95th percentile were considered to have severe obesity. BMI data extracted from charts were used if height or weight was missing. If BMI was missing or unable to be calculated, a diagnosis of obesity recorded in charts was used and severity of obesity was unable to be assessed. Obesity was not assessed for children aged <2 years.

¶ Clinical characteristics and outcomes were compared among groups using Pearson's chi-square test for categorical variables and a Kruskal-Wallis test for nonnormally distributed variables.

\*\* Patients were considered to have a viral coinfection if they had ≥1 of the following infections: type A influenza, type B influenza, unspecified influenza, coronavirus 229e, coronavirus hku1, coronavirus nl63, coronavirus 0c43, respiratory syncytial virus, adenovirus, parainfluenza type 1, parainfluenza type 2, parainfluenza type 3, parainfluenza type 4, human metapneumovirus, rhinovirus, enterovirus, or other viral coinfection.

Black or Hispanic in this study; an earlier study demonstrated higher hospitalization rates among Black or Hispanic children compared with White children (1).

Approximately two thirds of patients hospitalized for COVID-19, including 83% and 88% of patients aged 5–11 and 12–17 years, respectively, had one or more underlying medical conditions. Approximately two thirds of patients hospitalized for COVID-19 aged 12–17 years had obesity. Compared with patients without obesity, those with obesity required higher levels and longer duration of care. These findings are consistent with previous reports (4) and highlight the

importance of obesity and other medical conditions as risk factors for severe COVID-19 in children and adolescents.

The proportions of patients admitted to ICU and who required IMV are similar to those in prior reports, which predominantly included hospitalized pediatric COVID-19 patients before Delta variant predominance (2,5). Adolescents were more likely to require ICU admission and oxygen support compared with other age groups and required the longest median duration of IMV. The median duration of IMV overall (7 days) is consistent with previous reports (6,7). Approximately one half of patients aged 1–4 years required



**Summary****What is already known about this topic?**

Pediatric COVID-19–related hospitalization rates increased when the highly transmissible SARS-CoV-2 B.1.617.2 (Delta) variant became the predominant circulating strain.

**What is added by this report?**

Among children and adolescents with SARS-CoV-2 infection admitted to six hospitals during July–August 2021, 77.9% were hospitalized for acute COVID-19. Among these patients, approximately one third aged <5 years had a viral coinfection (approximately two thirds of which were respiratory syncytial virus) and approximately two thirds of those aged 12–17 years had obesity; only 0.4% of age-eligible patients were fully vaccinated.

**What are the implications for public health practice?**

COVID-19 vaccination and other prevention strategies are important to protect children from COVID-19, particularly children with obesity and other underlying health conditions.

oxygen support, which might be related to the high proportion with viral coinfection. This study occurred during July–August 2021, the first period during the COVID-19 pandemic with high circulation of RSV<sup>1,2,3,4</sup> and other respiratory viruses. Compared with prior studies (2,5), this study found a high proportion of patients had high-flow nasal cannula as the highest level of respiratory support (37%), which might reflect a change in practice to avoid intubation or the high proportion of viral coinfections, including RSV.

On November 2, 2021, CDC recommended COVID-19 vaccinations for children aged 5–11 years (8). As of July 31, 2021, 29% of U.S. persons aged 12–17 years were fully vaccinated against COVID-19.<sup>5,6,7,8,9,10</sup> In this study, only 0.4% of vaccine-eligible adolescents hospitalized for COVID-19 were fully vaccinated. Hospitalization rates have been shown to be 10 times higher among unvaccinated adolescents compared with fully vaccinated adolescents (2). Similarly, this study demonstrates that unvaccinated children hospitalized for COVID-19 could experience severe disease and reinforces the importance of vaccination of all eligible children to provide individual protection and to protect those who are not yet eligible to be vaccinated.

The findings in this report are subject to at least five limitations. First, the data came from only six hospitals, five of which are in the southern U.S. region. The proportion of adolescents with obesity in the southern United States is higher than in other regions,<sup>11,12,13,14</sup> which might explain the high rates

of obesity described in this report. Therefore, findings might not be generalizable to other areas. Second, findings might reflect differences in practices by hospitals or changes in practice over time and might not reflect differences in severity of COVID-19 related to the Delta variant. Third, incomplete or missing data in medical records might lead to underreporting and underestimation of details such as COVID-19 vaccination frequencies. Fourth, at the time of hospitalization, persons aged 12–15 years had only been vaccine-eligible for 2–3 months (9), possibly contributing to the low vaccination rates observed. Finally, hospitals identified patients for review based on positive polymerase chain reaction and antigen SARS-CoV-2 test results and hospitalization during the study period. Therefore, proportions of patients with MIS-C are likely underestimated.

Among pediatric patients with COVID-19–related hospitalizations, many had severe illness and viral coinfections, and few vaccine-eligible patients hospitalized for COVID-19 were vaccinated. These data highlight the importance of COVID-19 vaccination for those aged ≥5 years and other prevention strategies to protect children and adolescents from COVID-19, particularly those with obesity and other underlying health conditions. Further research and surveillance for viral coinfections with SARS-CoV-2 in pediatric patients can inform public health and capacity planning (10).

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<sup>1,2,3,4</sup> <https://emergency.cdc.gov/han/2021/han00443.asp>; <https://www.cdc.gov/surveillance/nrevss/rsv/natl-trend.html>

<sup>5,6,7,8,9,10</sup> <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends>

<sup>11,12,13,14</sup> [https://nccd.cdc.gov/dnpao\\_dtm/rdPage.aspx?rdReport=DNPAO\\_DTM.ExploreByTopic&cisClass=OWS&cisTopic=&go=GO](https://nccd.cdc.gov/dnpao_dtm/rdPage.aspx?rdReport=DNPAO_DTM.ExploreByTopic&cisClass=OWS&cisTopic=&go=GO)

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## Evaluation of a Test to Stay Strategy in Transitional Kindergarten Through Grade 12 Schools — Los Angeles County, California, August 16–October 31, 2021

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On July 12, 2021, the California Department of Public Health updated COVID-19 school guidance, allowing a Test to Stay (TTS) strategy to increase access to in-person learning\* (1). The TTS strategy enabled unvaccinated students, exposed in school to a person infected with SARS-CoV-2 (the virus that causes COVID-19), to remain in school while under quarantine, if both the infected person and the exposed person wore masks correctly and consistently throughout the exposure. To stay in school during the quarantine period, the exposed student must remain asymptomatic, wear a mask at school, and undergo twice weekly testing for SARS-CoV-2. To date, few studies have evaluated the impact of TTS on transmission (2–4). This study evaluated a TTS strategy implemented by Los Angeles County Department of Public Health (LAC DPH). During September 20–October 31, 2021, among 78 school districts, one half permitted TTS; in total, 432 (21%) of 2,067 schools adopted TTS. TTS schools did not experience increases in COVID-19 incidence among students after TTS implementation, and in 20 identified outbreaks in TTS schools,<sup>†</sup> no tertiary transmission was identified. The ratio of student COVID-19 incidence in TTS districts to that in non-TTS districts was similar before and after TTS adoption (rate ratio = 0.5). Non-TTS schools lost an estimated 92,455 in-person school days during September 20–October 31 while students were in quarantine, compared with no lost days among quarantined students in TTS schools. Non-TTS schools cited resource-related reasons for not adopting TTS; 75% of these schools were in LAC's most disadvantaged neighborhoods. Preliminary data from LAC suggest that a school-based TTS strategy does not increase school transmission of SARS-CoV-2, and might greatly reduce loss of in-person school days; however, TTS might have barriers to

implementation and require resources that are not available for some schools. Continued efforts to simplify school quarantine strategies might help to ensure that all students have access to safe in-person education. Although vaccination remains the leading public health recommendation to protect against COVID-19 for persons aged ≥5 years, schools might consider TTS as an option for allowing students with a school exposure who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

LAC has 78 public school districts with 2,067 schools for students in transitional kindergarten through grade 12.<sup>§</sup> Schools require indoor masking, physical distancing where feasible, vaccination, isolation of persons with confirmed cases, contact tracing, quarantining of close contacts, and SARS-CoV-2 testing (5). School SARS-CoV-2 testing strategies include weekly testing of asymptomatic, unexposed persons and response testing of persons with symptoms or exposures using SARS-CoV-2 nucleic acid amplification tests or antigen tests. LAC DPH is notified of school COVID-19 cases and close contacts of persons who received positive test results via a secure line list or online survey using REDCap (version 10.3.3; Vanderbilt University).

LAC DPH allowed schools to adopt a TTS strategy starting on September 20, 2021. For asymptomatic, unvaccinated students under quarantine orders,<sup>¶</sup> TTS was permitted during the quarantine period if the exposure occurred in school and the exposed student and infected person both wore masks correctly and consistently during the exposure. During TTS, contacts could continue in-person academic activities during regular school hours if they remained asymptomatic, wore a mask while at school (indoors, outdoors, and on school buses), received testing twice weekly by a certified testing program or health care provider,\*\* and agreed to quarantine at home

\* California Department of Public Health's Test to Stay strategy in k–12 schools is described in section 8 of the COVID-19 Public Health Guidance for K–12 Schools in California, 2021–22 School Year. <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/K-12-Guidance-2021-22-School-Year.aspx>

<sup>†</sup> A school outbreak was defined as three or more epidemiologically linked COVID-19 school-associated cases within 14 days. Outbreaks that occurred after September 20, 2021, were reviewed. Because students participating in TTS were permitted to continue in-person academic activities in school only while under quarantine, outbreak data review was limited to outbreaks that occurred in an academic setting at school (e.g., classroom outbreak). Outbreaks in youth sports settings were excluded.

<sup>§</sup> Los Angeles County Public School Districts do not include independent, independent charter, regional occupational programs, or Los Angeles County Special Education. Transitional kindergarten is a public school program serving to bridge preschool and kindergarten.

<sup>¶</sup> Fully vaccinated persons with school exposures are exempt from quarantine but are recommended to test 5–7 days after their last exposure date. A person is considered fully vaccinated 2 weeks after receiving 1) the Janssen (Johnson & Johnson) COVID-19 vaccine; 2) the second dose of a Pfizer or Moderna mRNA COVID-19 vaccine; or 3) completing the series of a COVID-19 vaccine that is listed for emergency use by the World Health Organization.

\*\* For school-based TTS, the California Department of Public Health recommends the same testing cadence as in standard quarantine: testing immediately after notification of the exposure and subsequent testing on or after day 5 following the date of last exposure.

when not at school. Contacts could not participate in extracurricular activities or before- or after-school care during the quarantine period.

School COVID-19 cases were defined as a laboratory-confirmed SARS-CoV-2 infection in a person who was at school anytime during the 14 days before their episode date (symptom onset date or the positive SARS-CoV-2 test result date, whichever was earlier). School cases were verified with test results reported by laboratories or health care providers to the LAC DPH Integrated Reporting and Investigation Surveillance System (IRIS). Cases among students with episode dates during August 16–October 31 and school exposures of student close contacts during August 17–October 31 were used to calculate secondary infection risk (number of quarantined contacts with a COVID-19 diagnosis 1–14 days after exposure divided by the total number of quarantined contacts).<sup>††</sup> COVID-19 student case rates were calculated as the average daily number of student cases during a 7-day period divided by the number of enrolled students.<sup>§§</sup> COVID-19 student rates are presented with 95% CIs; rates with non-overlapping CIs were considered to be significantly different. COVID-19 student rate ratios were calculated by dividing COVID-19 student case rates in TTS schools by those in non-TTS schools.

School district administrators were interviewed during November 3–16, 2021, to determine whether the district adopted TTS and to assess implementation challenges and reasons for not implementing TTS. TTS districts might have permitted TTS only for certain school levels; therefore, schools were subsequently categorized as having adopted versus not adopted TTS. School outbreak data were reviewed for evidence of tertiary transmission within TTS schools. Tertiary transmission was defined as likely SARS-CoV-2 transmission to a student, from a student participating in TTS who received a positive SARS-CoV-2 test result during the TTS period (i.e., a student with a secondary case). Schools were grouped into quartiles of disadvantage based on the California Healthy Places Index (HPI)<sup>¶¶</sup> (6). Zip codes falling within the lowest HPI quartile represented the most disadvantaged neighborhoods. Among non-TTS schools, estimation of lost in-person school days assumed 5 missed school days for each 7-day

student quarantine.<sup>\*\*\*</sup> This analysis was restricted to public school districts; Pasadena Unified School District (USD), Long Beach USD, and non-residents of LAC were excluded.<sup>†††</sup> SAS statistical software (version 9.4; SAS Institute) was used for all analyses. This public health surveillance activity was reviewed and approved by LAC DPH.

An estimated 1,292,067 LAC public school students returned to school for the 2021–22 academic year, which commenced on August 16, 2021, for most LAC public schools. During August 16–October 31, an average of 462,189 student and staff member SARS-CoV-2 tests were conducted each week in all schools. During the week of August 16, 0.6% of test results were positive, but this percentage declined to 0.2% by October 31 (Figure 1). Among all schools, 12,919 student COVID-19 cases (1% of the student population) and 57,513 student contacts (4% of the student population) were reported during the 10-week observation period; case numbers peaked at 2,270 during the week of August 16, and the number of contacts peaked at 8,589 during the week of August 23.

During September 20–October 31, among 78 school districts, 39 (50%) permitted TTS; within these districts, 94% of schools (432 of 452) adopted TTS (Table). These TTS schools constitute 21% of LAC public schools. LAC's largest school district, which accounts for one third of public school students, did not adopt TTS. Overall, within the 1,635 non-TTS schools, 4,322 COVID-19 cases occurred among 967,188 enrolled students (4.7 cases per 1,000 students); among 18,729 student close contacts, the secondary infection risk was 1.3%. Non-TTS districts lost an estimated 92,455 in-person school days during September 20–October 31 while students were in quarantine. Within the 432 TTS schools, among 324,879 enrolled students, 812 COVID-19 cases occurred (2.5 cases per 1,000 students); among 7,511 student close contacts, the secondary infection risk was 0.7%. As a result of the TTS protocol, no in-person school days were lost among quarantined students participating in TTS. Among 20 school outbreaks that occurred in TTS schools after TTS implementation, three outbreaks included four TTS students who were secondarily infected; contact tracing confirmed seven contacts of these patients and identified no tertiary transmission.

<sup>††</sup> Contacts who had a positive SARS-CoV-2 test result 1–14 days after exposure reported in IRIS but not identified by schools were also classified as having secondary infections. In order to correct surveillance data reporting ambiguities, contacts with a positive SARS-CoV-2 test result date the same as the quarantine start date were not considered to have secondary infections.

<sup>§§</sup> School district student enrollment was reported by the California Department of Education for the 2020–21 school year.

<sup>¶¶</sup> California HPI classifies California zip codes into quartiles based on a composite score of disadvantages. Indicators that determine the HPI score include economic, education, transportation, social, neighborhood, housing, clean environment, and health care access. Zip codes falling within the lowest HPI quartile in LAC represent the most disadvantaged neighborhoods.

<sup>\*\*\*</sup> Number of lost school days assumed that the quarantined students were under a 7-day quarantine period, and the student might be released from quarantine after day 7 from the last date of exposure, if the student remained without symptoms and had a negative SARS-CoV-2 viral diagnostic test result from a specimen collected on or after day 5 from the last date of exposure. It is assumed that every 7-day student quarantine resulted in 5 days of missed in-person school days. This represents the lower bound of missed in-person school days because quarantined persons without symptoms and a SARS-CoV-2 viral diagnostic test during quarantine were subject to a 10-day quarantine period.

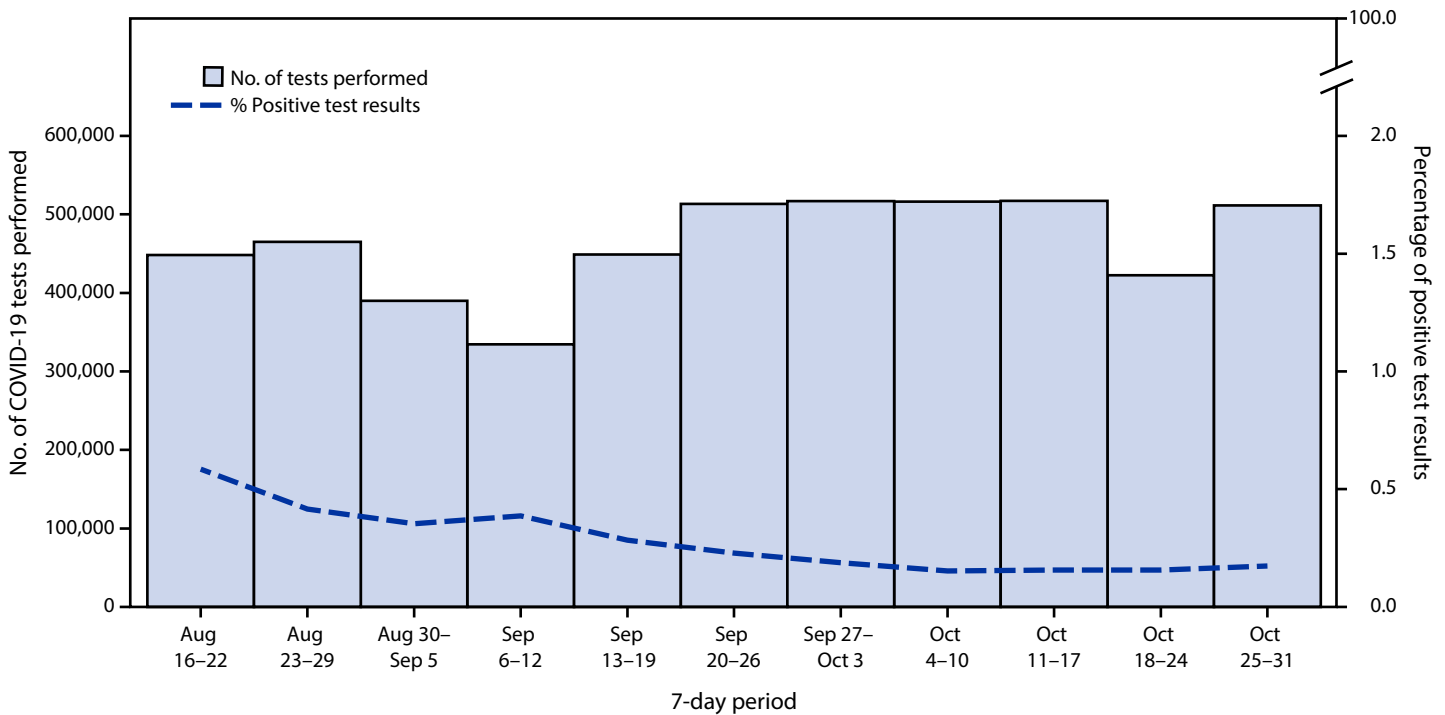
<sup>†††</sup> The cities of Long Beach and Pasadena have their own health departments, separate from LAC DPH, and were therefore not included in the analysis.



Before TTS adoption (August 16–September 19, 2021), average daily student COVID-19 incidence was lower in TTS districts (10 per 100,000 students; 95% CI = 7–13) than in non-TTS districts (20 per 100,000 students; 95% CI = 18–23) (Figure 2). After TTS adoption, average student daily case rates declined in all districts but remained lower on average

in TTS districts (6 per 100,000 students; 95% CI = 3–9) compared with non-TTS districts (11 per 100,000 students; 95% CI = 9–13). The ratio of student COVID-19 incidence in TTS districts to that in non-TTS districts was similar before and after TTS adoption (rate ratio = 0.5). (Figure 2).

**FIGURE 1. Number of SARS-CoV-2 tests performed and percentage of positive test results\* in transitional kindergarten through grade 12 public school districts — Los Angeles County, California, August 16–October 31, 2021**



\* Weekly data might have included repeat tests for an individual person.

**TABLE. Characteristics of transitional kindergarten through grade 12 public schools, by school Test to Stay status — Los Angeles County, California, September 20–October 31, 2021**

Characteristic	Did not implement TTS (n = 1,635)	Implemented TTS (n = 432)
<b>Schools</b>		
No. of enrolled students*	967,188 <sup>†</sup>	324,879
<b>Student COVID-19 cases, total</b>	<b>4,322</b>	<b>812</b>
Elementary school, no. (% of total)	2,403 (56)	341 (42)
Middle school, no. (% of total)	956 (22)	159 (20)
High school, no. (% of total)	963 (22)	312 (38)
<b>Student close contacts of COVID-19 cases,<sup>§</sup> total</b>	<b>18,729</b>	<b>7,511</b>
Elementary school, no. (% of total)	9,177 (49)	2,253 (30)
Middle school, no. (% of total)	4,870 (26)	1,878 (25)
High school, no. (% of total)	4,682 (25)	3,380 (45)
Student secondary infection risk <sup>¶</sup>	1.3	0.7
Percentage of schools in the most disadvantaged neighborhoods**	74	26

**Abbreviations:** HPI = Healthy Places Index; LAC = Los Angeles County; TTS = Test to Stay.

\* District student enrollment reported by the California Department of Education as of the 2020–21 school year.

<sup>†</sup> LAC's largest school district, which accounts for one third of public-school students, did not adopt TTS.

<sup>§</sup> Student contacts with unknown school level and age were excluded.

<sup>¶</sup> Secondary infection risk was defined as the number of quarantined contacts who received a positive SARS-CoV-2 test result 1–14 days after exposure divided by the total number of quarantined contacts. Limited to student school contacts.

\*\* Based on the California HPI, which classifies California zip codes into quartiles based on a composite score of disadvantages. Indicators that determine the HPI score include economic, education, transportation, social, neighborhood, housing, clean environment, and healthcare access. Zip codes falling within the lowest HPI quartile in LAC represent the most disadvantaged neighborhoods. HPI data were missing for 16 non-TTS schools and 22 TTS schools.

Among the schools that implemented TTS, 107 of 410 (26%) were categorized as most disadvantaged compared with 1,192 of 1,619 (74%) non-TTS schools.<sup>§§§</sup> Challenges cited to TTS implementation were limited staffing and systems to monitor mask use, testing, and lack of family support (Supplementary Table, <https://stacks.cdc.gov/view/cdc/112641>). Non-TTS districts reported similar resource barriers.

**Discussion**

Among LAC schools that implemented TTS during September 20–October 31, 2021, COVID-19 incidence did not increase, and tertiary transmission was not identified in school outbreaks after TTS implementation. Non-TTS districts lost substantial in-person school days. Taken together, these findings reinforce the usefulness of TTS for helping to maintain in-person learning in schools.

Only one in five public schools in LAC adopted TTS, and non-TTS schools cited resource-related reasons for opting out of TTS. Inability to implement TTS might exacerbate health and educational disparities between TTS and non-TTS schools. Operationalizing TTS requires staffing resources and systems for monitoring eligibility for and compliance to TTS that might not currently be available in schools in disadvantaged communities,

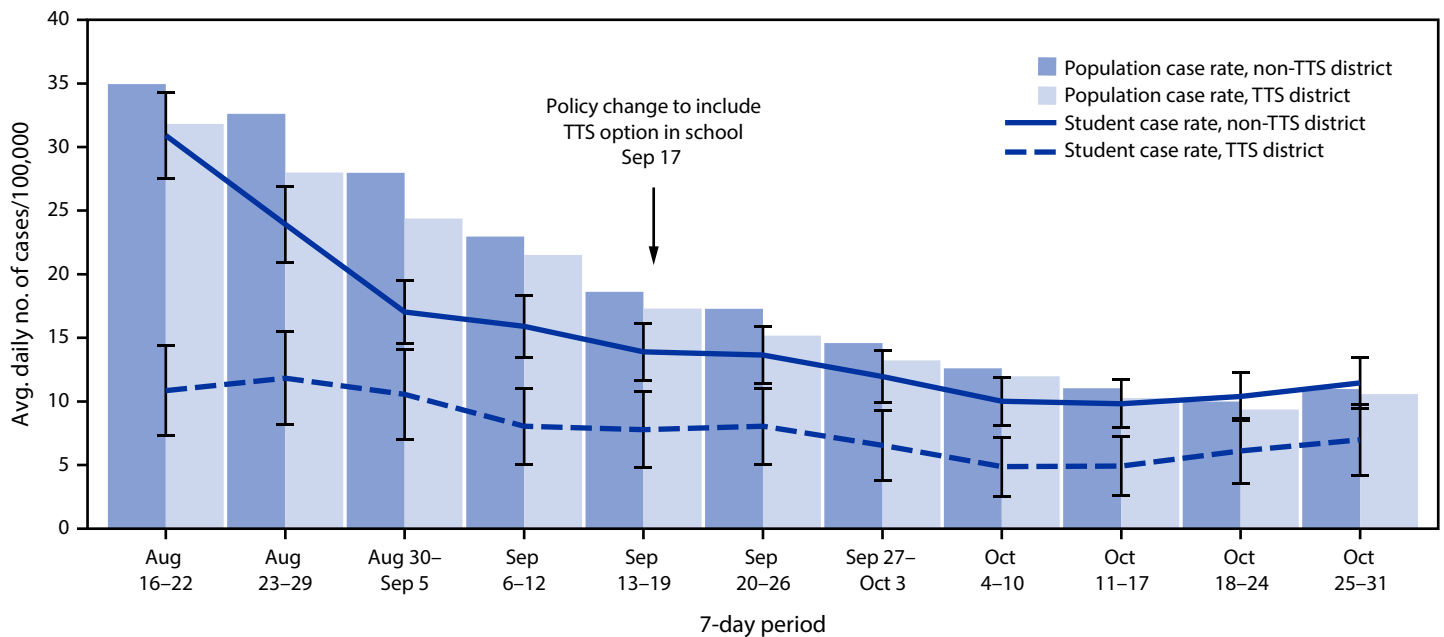
<sup>§§§</sup> HPI data were missing for 16 (1%) of 1,635 non-TTS schools and 22 (5%) of 432 TTS schools.

including most LAC non-TTS schools. Moreover, because TTS is currently permitted for quarantined students only during regular school hours, families who rely on before- and after-school programs might opt for home quarantine.

The findings in this report are subject to at least three limitations. First, monitoring systems were not established to assess compliance with TTS requirements or designed to evaluate school transmission before and after TTS adoption. Second, this analysis relied on the existing school case reporting system to characterize school transmission after TTS adoption. Because TTS schools were not required to inform LAC DPH about which students participated in TTS, tertiary transmission from a student participating in TTS could not be determined in non-outbreak settings. Finally, rates were unadjusted and did not control for confounders. However, non-TTS schools were disproportionately located in the most disadvantaged neighborhoods, where population case rates tend to be highest (7); this might explain the difference in student case rates in TTS and non-TTS schools.

Preliminary data from LAC suggest that a school-based TTS strategy in a large and diverse county did not increase school transmission risk and might greatly reduce loss of in-person school days. Thus, schools might consider TTS as an option for keeping quarantined students in school to continue in-person learning. However, the resources and operational complexities required to implement school-based TTS might present

**FIGURE 2. Student and population COVID-19 case rates,\* by school district Test to Stay status — Los Angeles County, California, August 16–October 31, 2021**



**Abbreviation:** TTS = Test to Stay.

\* SARS-CoV-2 student case rates were calculated as the average daily number of student cases reported to Los Angeles County Department of Public Health during a 7-day period divided by the number of enrolled students at the school district level. SARS-CoV-2 population case rates were calculated as the average daily number of community cases reported to Los Angeles County Department of Public Health during a 7-day period divided by the population of county residents at the school district level. Standard error bars shown for student case rates.

**Summary****What is already known about this topic?**

Los Angeles County Department of Public Health permits Test to Stay (TTS) as a COVID-19 quarantine strategy that allows students with school exposures to remain in school if both infected and exposed persons wore masks.

**What is added by this report?**

One in five LAC public schools adopted TTS. In TTS schools, student case rates did not increase, and tertiary transmission was not identified. A higher percentage of disadvantaged schools did not implement TTS.

**What are the implications for public health practice?**

TTS does not appear to increase transmission risk in public schools and might greatly reduce loss of in-person school days. Implementation requires resources that might be currently unavailable for some schools. Vaccination remains the leading recommendation to protect against COVID-19; TTS allows students with a school exposure to remain in the classroom as an alternative to home quarantine.

barriers, particularly for disadvantaged schools. Efforts to better understand barriers and simplify school quarantine strategies might help ensure that all students have access to safe in-person education. Although vaccination remains the leading public health recommendation to protect against COVID-19 for those aged  $\geq 5$  years, schools might consider TTS as an option for allowing close contacts who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

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## Evaluation of Test to Stay Strategy on Secondary and Tertiary Transmission of SARS-CoV-2 in K–12 Schools — Lake County, Illinois, August 9–October 29, 2021

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The COVID-19 pandemic has resulted in school closures and reduction of in-person learning (1). In August 2021, the Lake County Health Department (LCHD) in Illinois introduced a Test to Stay (TTS) strategy, whereby unvaccinated students, teachers, and staff members with certain school-related COVID-19 exposures could remain in school and participate in school-related extracurricular activities. Eligibility to participate in TTS required the following conditions to be met: 1) the exposure occurred while both the person with COVID-19 (index patient) and the close contact were masked; 2) the close contact remained asymptomatic, practiced consistent mask wearing, and maintained physical distancing; and 3) the close contact underwent testing for SARS-CoV-2 (the virus that causes COVID-19) on days 1, 3, 5, and 7 after exposure to the index patient. LCHD permitted kindergarten through grade 12 (K–12) schools in Lake County to implement TTS; 90 schools, representing 31 school districts in Lake County, implemented TTS during August 9–October 29, 2021. During the implementation period, 258 COVID-19 cases were reported. Among 1,035 students and staff members enrolled in TTS, the secondary attack risk (number of close contacts who received a positive SARS-CoV-2 test result within 14 days after exposure to an index patient, divided by total number of close contacts) was 1.5% (16 of 1,035). Among the 16 secondary cases identified, all were in students, and none appeared to transmit SARS-CoV-2 to other school-based contacts. However, nine tertiary cases were identified among household contacts of the 16 secondary cases, and four of the nine were fully vaccinated. Assuming a maximum of 8 missed school days for every 10-day quarantine period, up to 8,152 in-person learning days were saved among TTS participants. Implementation of TTS with other concurrent prevention strategies, including masking and physical distancing, limited further spread of SARS-CoV-2 within K–12 schools and allowed students to safely sustain in-person learning. Although vaccination remains the leading public health recommendation to protect against COVID-19 for those aged ≥5 years, schools might consider TTS as an option for allowing close contacts who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

In fall 2021, LCHD encouraged eligible schools in Lake County, Illinois, to implement TTS. School eligibility criteria included 1) ability to report test results, including index patients and school-based close contacts, to Illinois Department of Public Health (IDPH) and LCHD within 24 hours and 2) school staff members' availability for interviews to provide details regarding school-related exposures. School-based close contacts of persons with COVID-19 were eligible to participate in TTS if both the person with COVID-19 (i.e., index patient) and the contact were masked during the exposure, and the exposure occurred at school or while participating in school-related extracurricular activities. Contacts who met eligibility criteria could participate in TTS if they remained asymptomatic, practiced consistent mask wearing, maintained physical distancing, obtained parental consent, and underwent SARS-CoV-2 testing at school or off campus\* on days 1, 3, 5, and 7 after exposure. Asymptomatic TTS participants who received negative SARS-CoV-2 test results and adhered to TTS requirements, including mandatory masking, could ride the school bus and attend in-person learning and school-based extracurricular activities, including sports. TTS participants were required to quarantine at home for 14 days while not attending school or participating in school-based activities. Close contacts were defined as persons who were within 3 feet (0.9 meters) of a COVID-19 patient for ≥15 cumulative minutes over a 24-hour period.† Close contacts who had unmasked exposures within 6 feet (1.8 meters) of a COVID-19 patient were not eligible for TTS and quarantined at home. Persons who were fully vaccinated or who received

\* Schools were provided flexibility to recommend that close contacts get off-campus nucleic acid amplification testing or antigen testing through pharmacies, clinics, or community-based testing sites during extended holidays when an interruption in the testing cadence was anticipated or if the school experienced a shortage of testing resources. In addition, some schools might have contracted private laboratories to assist in their testing program.

† Contacts with exposure to COVID-19 outside of school in the 14 days before the school-based exposure were not eligible to participate in TTS. Staff member close contacts were defined as those within 6 ft of a patient with COVID-19 for ≥15 cumulative minutes over a 24-hour period. Before October 18, 2021, a close contact on school transportation was defined by IDPH as being within 6 ft for ≥15 minutes over a 24-hour period. After October 18, 2021, the definition changed to <3 ft for ≥15 minutes over a 24-hour period and those within 3–6 ft were no longer considered close contacts if both the confirmed patient and the close contact were masked and windows were opened or HEPA air filter was used.



a COVID-19 diagnosis in the 90 days before exposure were not required to quarantine and were not eligible to participate in TTS.

Schools reported COVID-19 case and close contact information to LCHD via REDCap (version 11.2.6; Vanderbilt University). LCHD staff members called parents of close contacts to identify additional exposures outside of school. Data were supplemented with information from the Salesforce case investigation and contact tracing management system, Illinois' National Electronic Disease Surveillance System (I-NEDSS), and the Illinois state vaccination registry. Among TTS participants, secondary cases were defined as contacts who received a positive SARS-CoV-2 test result by a contact within 14 days after exposure to an index patient. Secondary attack risk of TTS participants was defined as number of close contacts who received a positive SARS-CoV-2 test result within 14 days after exposure divided by total number of close contacts. Estimated in-person learning days saved from TTS was calculated assuming a maximum of 8 missed school days for every 10-day quarantine. All analyses were performed using SAS software (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.<sup>§</sup>

During August 9–October 29, 2021, 90 Lake County schools implemented TTS, representing 53.7% (6,267) of staff members and 53.4% (65,384) of public school students in Lake County (2). During this period, 258 index COVID-19 patients and 1,664 close contacts were reported. Among 1,068 close contacts eligible for TTS, 1,035 (96.9%) participated (Figure). Among TTS participants, 16 secondary cases were identified, all of whom were in students (Table 1); no secondary cases were identified among staff members. Eleven of the 16 secondary cases occurred among males, and nearly all cases were in non-Hispanic White students. The overall secondary attack risk was 1.5% (16 of 1,035).

The 16 students with secondary cases received their positive test results on days 1 (three students), 2 (two), 3 (two), 4 (two), 5 (four), 6 (one), and 10 (two). Testing after day 7 occurred for those who missed the last day of TTS testing because of school holidays or weekends. Seven of the 16 students with secondary cases were symptomatic on the date of their positive test result, three developed symptoms after receiving a positive test result, and six remained asymptomatic. Based on investigation interviews, the most common likely locations<sup>¶</sup> of COVID-19 exposure among TTS participants were school buses (56.3%), classrooms (32.4%), and school-sanctioned sports (7.4%); among these locations, the secondary attack risks were 1.5%, 0.6%, and 6.5%, respectively (Table 2).

<sup>§</sup> 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

<sup>¶</sup> Exposure locations are mutually exclusive. School nurses reported one exposure site per close contact.

**TABLE 1. Demographic characteristics of Test to Stay participants by SARS-CoV-2 test results — Lake County, Illinois, August 9–October 29, 2021**

Characteristic	Test results of close contacts		
	Positive* (n = 16)	Negative (n = 1,019)	Total (N = 1,035)
<b>Student age, yrs, median (range)</b>	11 (5–16)	10 (3–18)	<b>10 (3–18)</b>
<b>Gender, no. (column %)</b>			
Female	5 (31.3)	467 (45.8)	<b>472 (45.6)</b>
Male	11 (68.8)	493 (48.4)	<b>504 (48.7)</b>
Unknown	0 (—)	59 (5.8)	<b>59 (5.7)</b>
<b>Race, no. (column %)</b>			
Black	2 (12.5)	35 (3.4)	<b>37 (3.6)</b>
White	14 (87.5)	662 (64.9)	<b>676 (65.3)</b>
Asian	0 (—)	71 (7.0)	<b>71 (6.9)</b>
American Indian or Alaska Native	0 (—)	7 (0.7)	<b>7 (0.7)</b>
Other	0 (—)	136 (13.4)	<b>136 (13.1)</b>
Unknown	0 (—)	108 (10.6)	<b>108 (10.4)</b>
<b>Ethnicity, no. (column %)</b>			
Hispanic/Latino	1 (6.3)	104 (10.2)	<b>105 (10.1)</b>
Not Hispanic/Latino	15 (93.8)	611 (60.0)	<b>626 (60.5)</b>
Other	0 (—)	117 (11.5)	<b>117 (11.3)</b>
Unknown	0 (—)	187 (18.3)	<b>187 (18.1)</b>

\* This group represents secondary cases.

Secondary transmission was lowest in elementary schools (1.1%), followed by middle schools (1.3%) and high schools (4.9%).

Assuming a maximum of 8 missed school days for every 10-day quarantine, TTS preserved up to 8,152 in-person learning days for TTS close contacts. None of the 16 secondary cases appeared to transmit SARS-CoV-2 to other school-based contacts. However, nine tertiary cases in five households were identified among household contacts of the 16 secondary cases; four of the nine were fully vaccinated (Figure).

## Discussion

Implementation of a TTS strategy with multiple prevention components, including masking and physical distancing, resulted in low secondary transmission of SARS-CoV-2 in K–12 schools in Lake County, Illinois. These findings highlight the usefulness of TTS to limit school-based transmission and sustain in-person learning (1,3,4). Previous research suggests that limited in-person instruction during the pandemic might have had a negative effect on learning and well-being among children (5).

Secondary transmission risk to students exposed during school-sanctioned sports was higher than that associated with classroom or school bus exposures. This is consistent with studies showing high transmission among sports participants (6,7). Also consistent with previous research (8), this study found that household contacts of persons exposed at school continue to be at risk for infection; among household contacts of the 16 secondary patients, nine tertiary cases were identified, four in fully vaccinated persons. Schools can help inform parents

**TABLE 2. Grade level and exposure site characteristics of Test to Stay participants by SARS-CoV-2 test results — Lake County, Illinois, August 9–October 29, 2021**

Characteristic	Test results of close contacts		
	Positive (n = 16)	Negative (n = 1,019)	Total (N = 1,035)
<b>Grade level/Staff members, no. (row %)</b>			
Teachers/Staff members	0 (—)	2 (100)	2
Elementary school students (grades K–5)	7 (1.1)	620 (98.9)	627
Middle school students (grades 6–8)	4 (1.3)	299 (98.7)	303
High school students (grades 9–12)	5 (4.9)	98 (95.1)	103
<b>Location of exposure,* no. (row %)</b>			
Classroom†	2 (0.6)	333 (99.4)	335
School bus	9 (1.5)	574 (98.5)	583
School-sanctioned sport	5 (6.5)	72 (93.5)	77
Extracurricular activity‡	0 (—)	6 (100)	6
Unknown	0 (—)	34 (100)	34

\* Exposure locations are mutually exclusive. School nurses reported one exposure site per close contact.

† Classroom exposures include academic classes, indoor recess, physical education class, and staff meetings.

‡ Extracurricular activities include drama club and band.

### Summary

#### What is already known about this topic?

COVID-19 transmission within K–12 schools can remain low with implementation of multiple, concurrent prevention strategies.

#### What is added by this report?

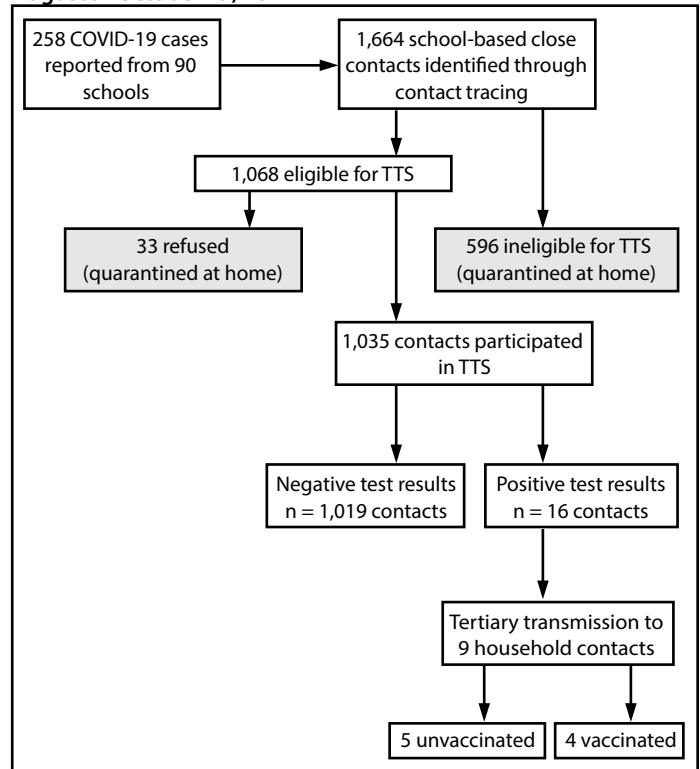
During fall 2021, 90 Lake County, Illinois, schools implemented Test to Stay (TTS), permitting eligible close contacts with masked COVID-19 exposures to remain in school. Secondary transmission among TTS participants was 1.5%; no tertiary transmission was observed among school-based contacts; however, tertiary cases were identified among household contacts. Implementation of TTS preserved up to 8,152 in-person learning days.

#### What are the implications for public health practice?

Although vaccination remains the leading recommendation to protect against COVID-19, TTS allows close contacts to remain in the classroom as an alternative to home quarantine.

and guardians about the benefits of COVID-19 prevention strategies, including vaccination.

Although TTS can help limit in-school transmission of SARS-CoV-2, it is a resource-intensive strategy that might be difficult to implement because of increased administrative demands on staff members, requirements for robust contact identification and tracing, and testing availability. Low-resource schools might lack space for physical distancing during lunch, resulting in unmasked exposures within 6 feet, which would disqualify students from TTS eligibility, necessitating home quarantine. Among the 90 TTS schools in this study, 25.6% participated in a subsidized lunch program, compared with 38.1% of schools that did not implement TTS (9). Some

**FIGURE. Identification of students and staff members who received a positive SARS-CoV-2 test result, school-based close contacts,\* and SARS-CoV-2 test results among close contacts — Lake County, Illinois, August 9–October 29, 2021**

**Abbreviation:** TTS = Test to Stay program.

\* Ineligibility for TTS includes unmasked exposures within 6 feet of a person with a case of COVID-19 and exposure to a person with a case of COVID-19 outside of school or school-related activities.

schools reported a shortage of testing supplies, requiring TTS participants to access off-site testing, which might have presented a barrier in low-resource school settings. State and local public health and education agencies should strive to ensure that schools in low-resource areas have equitable access to staffing and testing supplies to implement TTS.

The findings in this report are subject to at least seven limitations. First, inequity in school districts' staffing and testing resources might have introduced selection bias because only schools with sufficient resources offered TTS. High-resource schools might have more staffing capacity and physical spacing to apply prevention strategies (e.g., distancing students), which might have resulted in low transmission levels that are not generalizable to low-resource schools. Second, data might not be generalizable to areas with higher COVID-19 incidences and lower vaccination rates; COVID-19 incidence (7-day rolling average number of cases per 100,000 persons) in Lake County ranged from 59.7 to 217.1 over the evaluation period, with 53.5% of the total population vaccinated (10). Third, 33% of parents did not respond to LCHD calls or might have chosen not to disclose exposures occurring outside school, resulting in students at high risk being incorrectly enrolled

in TTS. This would likely have resulted in an overestimation of secondary transmission among TTS participants. Fourth, testing days often deviated from testing cadence because school testing was not conducted on weekends. This deviation might have resulted in a delay of case and close contact identification. Fifth, teachers and staff members had much lower participation rates than did students in this evaluation because of high vaccination rates, low number of exposures meeting close contact definition, and lack of awareness in some schools that adults could participate in TTS. Sixth, households representing three secondary cases were unresponsive to attempted interviews to ascertain tertiary transmission, resulting in incomplete investigations. Finally, this analysis assumes that secondary attack risk represents direct transmission from contacts to cases. Given the unknown exposures and overlapping incubation and infectious periods that occur, distinct generations of transmission might be difficult to ascertain.

Implementation of TTS in coordination with other concurrent prevention strategies, including masking and physical distancing, allowed transmission of SARS-CoV-2 to remain low among K–12 schools in Lake County, Illinois, and saved up to 8,152 in-person learning days. Although vaccination remains the leading public health recommendation to protect against COVID-19 for those aged  $\geq 5$  years, schools might consider TTS as an option for allowing close contacts who are not fully vaccinated to remain in the classroom as an alternative to home quarantine.

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## Investigation of a SARS-CoV-2 B.1.1.529 (Omicron) Variant Cluster — Nebraska, November–December 2021

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The B.1.1.529 (Omicron) variant of SARS-CoV-2 (the virus that causes COVID-19) was first detected in specimens collected on November 11, 2021, in Botswana and on November 14 in South Africa;\* the first confirmed case of Omicron in the United States was identified in California on December 1, 2021 (1). On November 29, the Nebraska Department of Health and Human Services was notified of six probable cases<sup>†</sup> of COVID-19 in one household, including one case in a man aged 48 years (the index patient) who had recently returned from Nigeria. Given the patient's travel history, Omicron infection was suspected. Specimens from all six persons in the household tested positive for SARS-CoV-2 by reverse transcription–polymerase chain reaction (RT-PCR) testing on December 1, and the following day genomic sequencing by the Nebraska Public Health Laboratory identified an identical Omicron genotype from each specimen (Figure). Phylogenetic analysis was conducted to determine if this cluster represented an independent introduction of Omicron into the United States, and a detailed epidemiologic investigation was conducted. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.<sup>§</sup>

The index patient, who was unvaccinated, had a history of domestically acquired symptomatic SARS-CoV-2 infection confirmed by RT-PCR a year prior in November 2020. He reported unmasked close contact<sup>¶</sup> with a masked, coughing person on November 20, 2021, during an international conference in Nigeria, which included attendees from multiple African countries. Before his return trip to the United States, he completed required pretravel testing with receipt of a negative antigen test result on November 21. Upon his return on November 23, while still asymptomatic, he had unmasked close contact with five household contacts. One household contact was fully vaccinated\*\*

(second Pfizer-BioNTech vaccine dose received in August 2021) and had previous symptomatic COVID-19 (RT-PCR confirmed in November 2020), three were unvaccinated and had previous symptomatic COVID-19 (RT-PCR confirmed in November 2020), and one was unvaccinated and had mild upper respiratory symptoms in November 2020, just before illness onset in the other household members, but received a negative SARS-CoV-2 RT-PCR test result at that time. No household members reported underlying medical conditions or immunocompromising conditions known to increase the risk for severe COVID-19 or diminish response to vaccination.<sup>††</sup>

On November 24, 2021, the index patient experienced symptoms consistent with COVID-19<sup>§§</sup> and initially received a positive SARS-CoV-2 antigen test result from a local medical center on November 26. All six household members (median age = 18.5 years; range = 11–48 years) experienced symptom onset during November 24–26; median interval between earliest possible exposure to the index patient and symptom onset was 73 hours (range = 33–75 hours). The index patient and the four household contacts with previous confirmed infections described the symptoms and severity of their recent COVID-19 infection as being similar to or milder than those during their first infection. The five reinfected patients experienced fewer current symptoms, including loss of taste (none), loss of smell (none), and subjective fever (two), compared with symptoms reported during their first infections (four, four, and four, respectively). The unvaccinated patient without a previous COVID-19 diagnosis experienced cough, joint pain, congestion, fever, and chills. None required hospitalization for either their first or second infections. Twelve close community contacts of the family were identified. Four consented to testing for SARS-CoV-2 (median of 10.5 days postexposure; range = 10–11 days); specimens from these four close contacts tested negative.

Epidemiologic and clinical features of Omicron infection are still being described. Observations from this investigation, which included one patient who experienced reinfection<sup>¶¶</sup> after having been fully vaccinated, four patients who experienced reinfection,

\* <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html>

† <https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/>

§ 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

¶ <https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html#closecontact>

\*\* <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#:~:text=A%20person%20is%20considered%20fully,for%20fully%20vaccinated%20people>

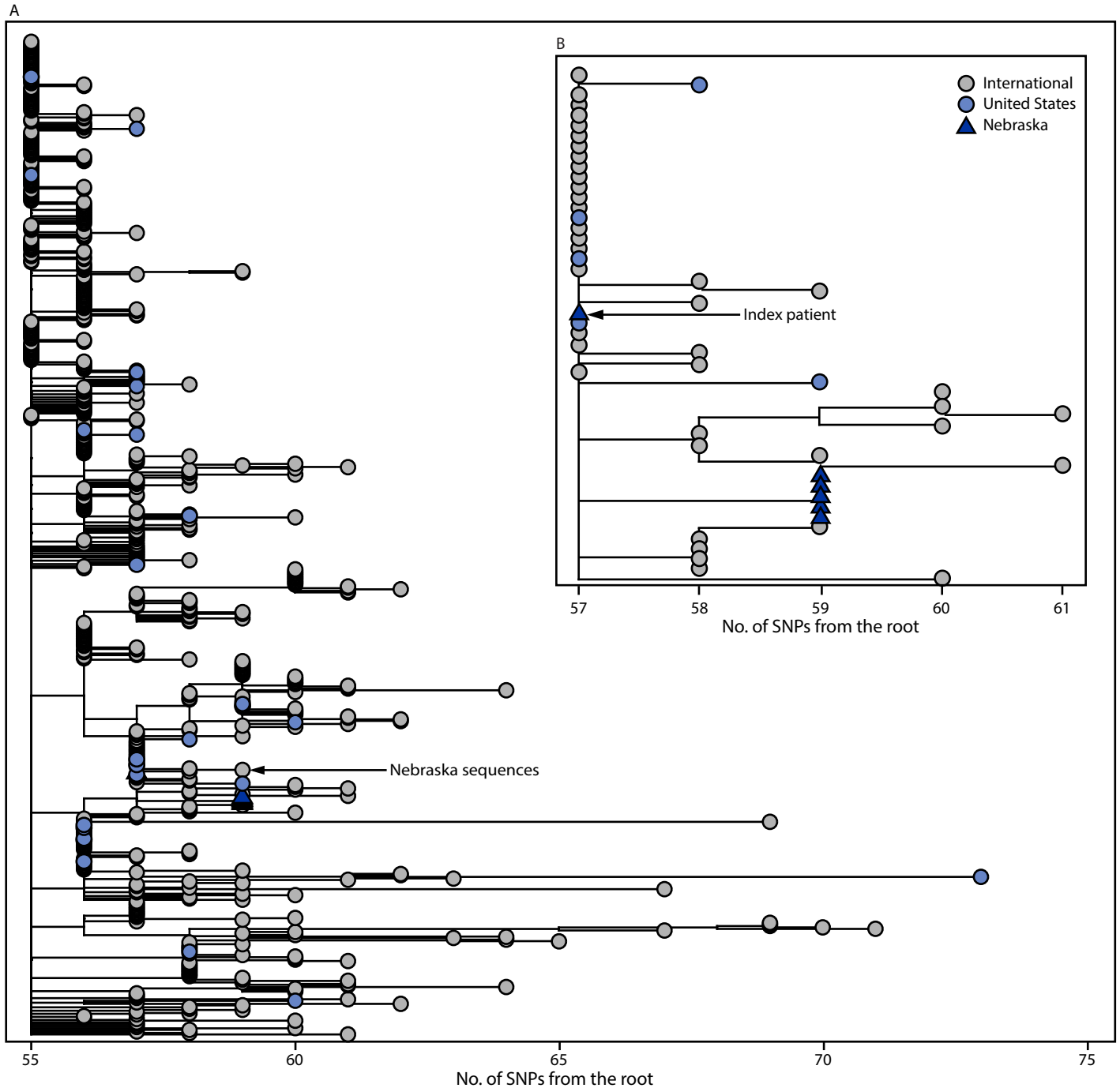
†† <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

§§ Abdominal pain, diarrhea, fatigue, headache, muscle aches, chest pressure, chills, subjective fever, cough, runny nose, sore throat, and dizziness.

¶¶ <https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/#:~:text=The%20following%20should%20be%20enumerated%20as%20a%20new%20case>



FIGURE. Global phylogeny of B.1.1.529 (Omicron) samples available on Global Initiative on Sharing All Influenza Data\* as of December 6, 2021 (650 total genomes) (A) and expanded view of Omicron sequences† (B) — Nebraska, November–December 2021§,¶,\*\*,††,§§



**Abbreviation:** SNP = single nucleotide polymorphism.

\* <https://www.gisaid.org>

† Branch lengths are shown in number of mutations from the root. The maximum-likelihood phylogenetic trees are rooted with the original SARS-CoV-2 genome Wuhan/Hu-1/2019.

§ Each of the six SARS-CoV-2 genomes generated from this cluster is >94% complete and shares 100% nucleotide identity across the length of the genome, consistent with household transmission.

¶ Genomes from the five secondary cases have SNPs at nucleotide positions T1552C and C23709T that are not yet found in other Omicron genomes sampled.

\*\* The genome from the index patient, NCOV21-42615, has the ambiguous nucleotide “N” at positions 1552 and 23709 and further inspection of the read-level data showed nucleotide variability at both sites. The SNP allele frequency at these sites in the NCOV21-42615 genome is >50%, consistent with epidemiologic findings of household transmission from the index patient to all secondary cases.

†† <https://academic.oup.com/bioinformatics/article/34/23/4121/5001388>

§§ <https://onlinelibrary.wiley.com/doi/full/10.1111/2041-210X.12628>

and one who experienced their first infection, suggest a shorter incubation period and a clinical syndrome similar to or milder than that associated with previously described variants in persons who have been vaccinated or previously infected, and add to existing evidence suggesting an increased potential for reinfection.<sup>\*\*\*</sup> Whereas the median SARS-CoV-2 incubation period has been described as  $\geq 5$  days (2,3), and closer to 4 days for the SARS-CoV-2 B.1.617.2 (Delta) variant,<sup>†††</sup> the median incubation period<sup>§§§</sup> observed in this cluster was approximately 3 days. Although few clinical descriptions of Omicron infections are available, mild illness among vaccinated patients has been reported (4). It is unknown whether the mild clinical syndromes or differing symptom descriptions are a result of existing immunity or altered clinical features associated with Omicron infection. The five reinfections, including one after full vaccination, might be explained by waning immunity, the potential for partial immune evasion by Omicron, or both. Conclusions drawn from these observations are limited by small sample size. More data will be needed to fully understand the epidemiology of the Omicron variant.

Travel history of the index patient and phylogenetic analysis of the secondary cases indicate an international introduction of the Omicron variant, consistent with other early cases identified in the United States (1). The recent emergence of Omicron, which is now projected to be the dominant variant in the United States,<sup>¶¶¶</sup> reinforces the importance of vaccination, in coordination with other prevention strategies (e.g., masking and physical distancing), to protect people from COVID-19, slow transmission, and reduce the likelihood of new variants emerging. In addition, the rapid identification and epidemiologic characterization of this cluster underscore the importance of robust and timely genomic surveillance to detect and respond to emerging SARS-CoV-2 variants of concern.

<sup>\*\*\*</sup> <https://www.medrxiv.org/content/10.1101/2021.11.11.21266068v2>

<sup>†††</sup> <https://www.medrxiv.org/content/10.1101/2021.07.07.21260122v2>

<sup>§§§</sup> Incubation period is defined as the interval from earliest possible exposure of household contacts to the index patient until symptom onset.

<sup>¶¶¶</sup> <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>

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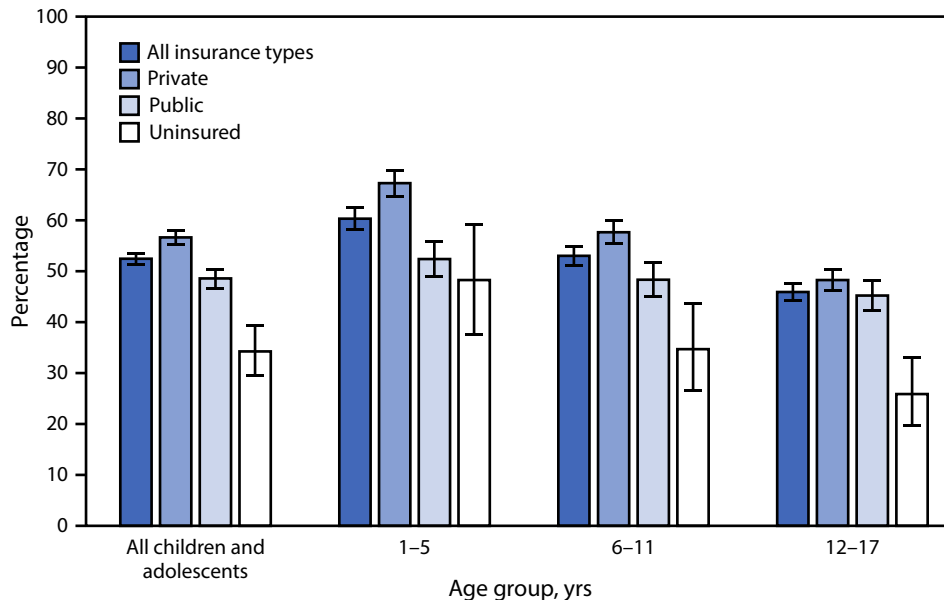
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## QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

## Percentage\* of Children and Adolescents Aged 1–17 Years Who Received an Influenza Vaccine Within the Past 12 Months,<sup>†</sup> by Health Insurance Coverage<sup>§</sup> and Age Group — National Health Interview Survey, United States, 2019–2020<sup>¶</sup>



\* With 95% CIs indicated with error bars.

<sup>†</sup> Based on an affirmative response to the question, “There are two types of flu vaccinations. One is a shot and the other is a spray, mist, or drop in the nose. During the past 12 months, have you had a flu vaccination?” Annual calendar-year estimates of vaccinations are presented, which might differ from seasonal influenza vaccination totals that reflect vaccinations obtained during the influenza season.

<sup>§</sup> Health insurance coverage is based on the status at the time of interview. Private insurance includes plans obtained through an employer, purchased directly, and received through local and community programs. Public insurance includes persons without private insurance who reported Medicaid, Children’s Health Insurance Program, or other state-sponsored health plans. In addition to those without coverage, uninsured includes a very small percentage of children and adolescents who only have Indian Health Service coverage or a private plan that paid for only one type of service.

<sup>¶</sup> Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population.

Throughout calendar years 2019–2020, 52.4% of children and adolescents aged 1–17 years received an influenza vaccine within the previous 12 months. The percentage was highest in children and adolescents with private insurance (56.6%), followed by those with public insurance (48.6%), and lowest in the uninsured (34.2%). This pattern was seen in each age group. The percentage of children and adolescents who received an influenza vaccine decreased with increasing age from 60.3% in children aged 1–5 years, to 53.0% in those aged 6–11 years, to 45.9% in adolescents aged 12–17 years. The decrease with age group was seen for each insurance type. Privately insured children aged 1–5 years had the highest rate of influenza vaccination, and uninsured adolescents aged 12–17 years had the lowest rate.

**Source:** National Center for Health Statistics, National Health Interview Survey, 2019–2020. <https://www.cdc.gov/nchs/nhis.htm>

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For more information on this topic, CDC recommends the following link: <https://www.cdc.gov/flu/prevent/vaccinations.htm>

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