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COVID-19 Vaccine Safety in Adolescents Aged 12–17 Years — United States, December 14, 2020–July 16, 2021

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As of July 30, 2021, among the three COVID-19 vaccines authorized for use in the United States, only the Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine is authorized for adolescents aged 12–17 years. The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech vaccine for use in persons aged ≥16 years on December 11, 2020 (*1*); the EUA was expanded to include adolescents aged 12–15 years on May 10, 2021 (*2*), based on results from a Phase 3 clinical trial (*3*). Beginning in June 2021, cases of myocarditis and myopericarditis (hereafter, myocarditis) after receipt of Pfizer-BioNTech vaccine began to be reported, primarily among young males after receipt of the second dose (*4*,*5*). On June 23, 2021, CDC's Advisory Committee on Immunization Practices (ACIP) reviewed available data and concluded that the benefits of COVID-19 vaccination to individual persons and the population outweigh the risks for myocarditis and recommended continued use of the vaccine in persons aged ≥12 years (*6*). To further characterize safety of the vaccine, adverse events after receipt of Pfizer-BioNTech vaccine reported to the Vaccine Adverse Event Reporting System (VAERS) and adverse events and health impact assessments reported in v-safe (a smartphone-based safety surveillance system) were reviewed for U.S. adolescents aged 12–17 years during December 14, 2020–July 16, 2021. As of July 16, 2021, approximately 8.9 million U.S. adolescents aged 12–17 years had received Pfizer-BioNTech vaccine.* VAERS received 9,246 reports after Pfizer-BioNTech vaccination in this age group; 90.7% of these were for nonserious adverse events and 9.3% were for serious adverse events, including myocarditis (4.3%). Approximately 129,000 U.S. adolescents aged 12–17 years enrolled in v-safe after Pfizer-BioNTech vaccination; they reported local (63.4%) and systemic (48.9%) reactions with a frequency similar to that reported in preauthorization clinical trials. Systemic reactions were more common after dose 2. CDC and FDA continue to monitor vaccine safety and provide data to ACIP to guide COVID-19 vaccine recommendations.

VAERS is a passive vaccine safety surveillance system comanaged by CDC and FDA that monitors adverse events after vaccination (*7*). VAERS accepts reports from anyone, including health care providers, vaccine manufacturers, and members of the public. Under COVID-19 vaccine EUA requirements, health care providers must report certain adverse events after vaccination to VAERS, including death.† Signs, symptoms, and diagnostic findings in VAERS reports are assigned Medical Dictionary for Regulatory Activities (MedDRA) preferred terms by VAERS staff members.§ VAERS reports are classified as serious if any of the following are reported:

* https://covid.cdc.gov/covid-data-tracker/#datatracker-home

† https://vaers.hhs.gov/faq.html

§ 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

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hospitalization or prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death.[¶] Reports of serious adverse events receive follow-up to obtain additional information, including medical records; for reports of death, death certificates and autopsy reports are obtained, if available. CDC physicians reviewed available information for each decedent to form an impression about cause of death.

CDC established v-safe, a voluntary smartphone-based active safety surveillance system, to monitor adverse events after COVID-19 vaccination. Adolescents who receive a COVID-19 vaccine are eligible to enroll in v-safe, through self-enrollment or as a dependent of a parent or guardian, and receive scheduled text reminders about online health surveys.[**] Health surveys sent in the first week after vaccination include questions about local injection site and systemic reactions and health impacts.[††] If a report indicated medical attention was sought, VAERS staff members contacted the reporter and encouraged completion of a VAERS report, if indicated.

VAERS and v-safe data were assessed by sex, age group, and race/ethnicity for U.S. adolescents aged 12–17 years who received Pfizer-BioNTech vaccine during December 14, 2020–July 16, 2021. VAERS reports for adolescents aged 12–15 years were excluded if vaccination occurred before EUA age expansion on May 10, 2021. FDA used empirical Bayesian data mining to monitor for disproportional reporting of adverse events by vaccine among VAERS reports for persons aged 12–17 years[§§] (*8*). SAS software (version 9.4; SAS Institute) was used to conduct all analyses. These surveillance activities were reviewed by CDC and conducted consistent with applicable federal law and CDC policy.[¶¶]

Review of VAERS Data

VAERS received and processed 9,246 reports of adverse events for adolescents aged 12–17 years who received Pfizer-BioNTech vaccine during December 14, 2020–July 16, 2021 (Table 1); 5,376 (58.1%) were in adolescents aged 12–15 years and 3,870 (41.9%)

[¶] Based on the Code of Federal Regulations Title 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr

[**] Adolescents aged <15 years must be enrolled by a parent or guardian and may not self-enroll. 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.

[††] Participants in v-safe self-identify the severity of their symptoms, defined as mild (noticeable, but not problematic), moderate (limit normal daily activities), or severe (make daily activities difficult or impossible). Health impacts include whether the vaccine recipient was unable to perform normal daily activities, missed school or work, or received care (i.e., telehealth, clinic or emergency department visit, or hospitalization) from a medical professional because of new symptoms or conditions.

[§§] FDA used the Multi-Item Gamma Poisson Shrinker algorithm to calculate the Empirical Bayes Geometric Mean and its associated 90% confidence interval (EB05, EB95). An EB05 ≥2 (more than twice expected) was considered the threshold for defining a vaccine-event pair reported disproportionately.

[¶¶] 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.

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in persons aged 16–17 years.*** No adverse events were reported disproportionately to VAERS in association with Pfizer-BioNTech vaccination. Common conditions among all reports included dizziness (1,862; 20.1%), syncope (1,228; 13.3%), and headache (1,027; 11.1%). Among the 1,228 reports of syncope, 901 met a standard case definition†††; 548 (60.8%) of these events occurred in females, and median age was 15 years. Among those who met the syncope case definition, 147 (16.3%) reported a history of anxiety around needles, and 145 (16.1%) were transported to an emergency department for further evaluation.

Overall, 8,383 (90.7%) VAERS reports were for nonserious events, and 863 (9.3%) for serious events, including death; 609 (70.6%) reports of serious events were among males, and median age was 15 years. The most commonly reported conditions and diagnostic findings among reports of serious events were chest pain (56.4%), increased troponin levels (41.7%), myocarditis (40.3%), increased c-reactive protein (30.6%), and negative SARS-CoV-2 test results (29.4%) (Table 2); these findings are consistent with a diagnosis of myocarditis. Myocarditis was listed among 4.3% (397) of all VAERS reports.

*** Processed VAERS reports are those that have been coded using MedDRA, have been deduplicated, and have undergone standard quality assurance and quality control review.

††† CDC reviewed VAERS reports of syncope for additional information. Syncopal events that occurred off-site or ≥1 hour after vaccine administration were excluded from analysis.

CDC reviewed 14 reports of death after vaccination. Among the decedents, four were aged 12–15 years and 10 were aged 16–17 years. All death reports were reviewed by CDC physicians; impressions regarding cause of death were pulmonary embolism (two), suicide (two), intracranial hemorrhage (two), heart failure (one), hemophagocytic lymphohistiocytosis and disseminated *Mycobacterium chelonae* infection (one), and unknown or pending further records (six).

Review of v-safe Data

During December 14, 2020–July 16, 2021, v-safe enrolled 66,350 adolescents aged 16–17 years who received Pfizer-BioNTech vaccine (Table 3). After Pfizer-BioNTech vaccine was authorized for adolescents aged 12–15 years (beginning May 10, 2021), v-safe enrolled 62,709 adolescents in this age group. During the week after receipt of dose 1, local (63.9%) and systemic (48.9%) reactions were commonly reported by adolescents aged 12–15 years; systemic reactions were more common after dose 2 (63.4%) than dose 1 (48.9%). Reporting trends were similar for adolescents aged 16–17 years: systemic reactions were reported among 55.7% after dose 1 and 69.9% after dose 2. For each dose and age group, reactions were reported most frequently the day after vaccination. The most frequently reported reactions for both age groups after either dose were injection site pain, fatigue, headache, and myalgia.

TABLE 1. Adverse event reports for adolescents aged 12–17 years who received the Pfizer-BioNTech COVID-19 vaccine, by demographic characteristics and reported symptoms (N = 9,246) — Vaccine Adverse Event Reporting System, United States, December 14, 2020–July 16, 2021

Characteristic	Total, % (N = 9,246)	Severity, %*		
		Nonserious (n = 8,383)	Serious, excluding death (n = 849)	Death (n = 14)
Sex				
Female	52.9	55.3	29.1	35.7
Male	45.8	43.2	70.7	64.3
Unknown	1.4	1.5	0.2	0
Age group, yrs				
12–15	58.1	58.7	53.4	28.6
16–17	41.9	41.3	46.6	71.4
Ethnicity				
Hispanic or Latino	10.4	9.6	18.4	7.1
Non-Hispanic or Latino	44.1	43.4	51.2	50.0
Unknown ethnicity	45.5	47.1	30.4	42.9
Race				
American Indian or Alaska Native	0.8	0.8	0.5	0
Asian	5.2	5.0	7.3	7.1
Black	3.2	3.0	5.3	7.1
Native Hawaiian or Pacific Islander	0.3	0.2	0.7	0
White	45.1	44.2	53.8	71.4
Multiracial	2.1	2.2	2.0	0
Other	13.1	13.9	5.4	0
Unknown race	30.2	30.8	25.0	14.3

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.

TABLE 2. Most frequent symptoms, signs, diagnostic results, and conditions* reported to the Vaccine Adverse Event Reporting System for adolescents aged 12–17 years after receipt of the Pfizer-BioNTech COVID-19 vaccine (N = 9,246) — United States, December 14, 2020–July 16, 2021

Symptom, sign, diagnostic result, or condition	% Reporting
Nonserious reports (n = 8,383)	
Dizziness	21.2
Syncope	14.4
Nausea	10.4
Headache	10.0
Fever	8.3
Loss of consciousness	7.5
Excessive sweating	7.4
Fatigue	7.2
Pallor	7.1
Product administered to patient outside of indicated age range	7.0
Product storage error	6.4
Vomiting	6.4
Difficulty breathing	5.3
Chest pain	4.9
Pain	4.6
Serious reports, including reports of death† (n = 863)	
Chest pain	56.4
Increased troponin	41.7
Myocarditis	40.3
Increased c-reactive protein	30.6
Negative SARS-CoV-2 test result	29.4
Fever	28.3
Normal echocardiogram	26.9
Abnormal electrocardiogram	25.6
Headache	22.2
Difficulty breathing	21.4
Elevated electrocardiogram ST segment	20.5
Normal chest radiograph	19.7
Intensive care	18.1
Vomiting	17.0
Nausea	16.6

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

* Signs and symptoms in VAERS reports are assigned MedDRA preferred terms by VAERS staff members. Each VAERS report might be assigned more than one MedDRA preferred term, which can include normal diagnostic findings. A MedDRA-coded event does not indicate a medically confirmed diagnosis. https://www.meddra.org/how-to-use/basics/hierarchy

† 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.

During the week after receipt of dose 2, approximately one third of adolescents in both age groups reported fever. Nearly one quarter of adolescents in both age groups reported they were unable to perform normal daily activities the day after dose 2. Fewer than 1% of adolescents aged 12–17 years required medical care in the week after receipt of either dose; 56 adolescents (0.04%) were hospitalized.

Discussion

The findings summarized in this report are consistent with the safety data observed in preauthorization trials for Pfizer-BioNTech after vaccination among persons aged 12–25 years, with the exception of myocarditis, a serious adverse event detected in postauthorization safety monitoring (*3*). Trial participants who received vaccine (1,131 aged 12–15 years; 537 aged 16–25 years) reported local and systemic reactions that were mostly mild (i.e., did not interfere with activity) or moderate (some interference with activity); no serious adverse events related to vaccination were reported (*3*). Similarly, local and systemic reactions were commonly reported by U.S. adolescents aged 12–17 years who enrolled in v-safe; a minority (<25%) reported they were unable to perform normal daily activities the day after receipt of dose 2. A small number of v-safe participants reported they were hospitalized after vaccination; however, v-safe does not record reason for hospitalization, and it cannot be determined whether hospitalization was related to vaccination.

Among 8.9 million adolescents vaccinated during the study period, VAERS reports were received for approximately one per 1,000 vaccinees, and 90% of these reports were for nonserious conditions. Syncope was among the events most commonly reported to VAERS in this age group and is common among adolescents after any vaccination (*9*). Other conditions associated with vasovagal response to vaccination were also frequently reported. Among the serious reports, myocarditis and other conditions that might be associated with myocarditis were among the most common terms reported; however, these terms did not account for a large proportion of VAERS reports overall. No reports of death to VAERS were determined to be the result of myocarditis. Impressions regarding cause of death did not indicate a pattern suggestive of a causal relationship with vaccination; however, cause of death for some decedents is pending receipt of additional information. ACIP conducted

Summary

What is already known about this topic?

In preauthorization trials of the Pfizer-BioNTech COVID-19 vaccine, adolescents aged 12–17 years reported local and systemic mild and moderate reactions. Myocarditis has been observed after vaccination with mRNA vaccines in postauthorization monitoring.

What is added by this report?

Local and systemic reactions after vaccination with Pfizer-BioNTech vaccine were commonly reported by adolescents aged 12–17 years to U.S. vaccine safety monitoring systems, especially after dose 2. A small proportion of these reactions are consistent with myocarditis.

What are the implications for public health practice?

Mild local and systemic reactions are common among adolescents following Pfizer-BioNTech vaccine, and serious adverse events are rare. The Advisory Committee on Immunization Practices conducted a risk-benefit assessment and continues to recommend the Pfizer-BioNTech COVID-19 vaccine for all persons aged ≥12 years.

TABLE 3. Reactions reported by adolescents aged 12–17 years (N = 129,059) who completed at least one v-safe health check-in survey on days 0–7 after receiving Pfizer BioNTech COVID-19 vaccine — United States, December 14, 2020–July 16, 2021

	% of v-safe enrollees reporting reaction or health impact*			
	Age 16–17 yrs, dose (no.)		Age 12–15 yrs, dose (no.)	
Event	Dose 1 (66,350)	Dose 2 (41,040)	Dose 1 (62,709)	Dose 2 (38,817)
Any injection site reaction	**62.7**	**64.4**	**63.9**	**62.4**
Itching	5.7	6.3	5.8	5.5
Pain	60.2	62.0	61.2	59.9
Redness	3.4	4.9	4.1	5.3
Swelling	7.7	9.9	7.5	8.9
Any systemic reaction	**55.7**	**69.9**	**48.9**	**63.4**
Abdominal pain	4.7	8.5	4.1	7.0
Myalgia	25.4	40.7	21.4	31.4
Chills	8.3	26.2	6.8	21.1
Diarrhea	4.2	4.9	3.1	3.3
Fatigue	34.1	52.3	27.4	44.6
Fever	9.9	31.0	9.3	29.9
Headache	29.8	50.6	25.2	43.7
Joint pain	7.9	18.2	6.3	12.4
Nausea	10.2	19.8	7.5	14.8
Rash	1.2	1.1	1.2	1.2
Vomiting	1.1	2.3	1.0	2.6
Any health impact	**11.0**	**28.6**	**10.6**	**25.4**
Unable to perform normal daily activities	9.0	24.7	9.3	23.1
Unable to work or attend school	3.7	11.6	2.4	6.1
Needed medical care	0.5	0.6	0.5	0.8
Telehealth	0.1	0.2	0.1	0.2
Clinic	0.2	0.2	0.2	0.3
Emergency department visit	0.1	0.2	0.1	0.2
Hospitalization	0.02	0.03	0.02	0.04

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

a risk-benefit assessment based in part on the data presented in this report and continues to recommend the Pfizer-BioNTech COVID-19 vaccine for all persons aged ≥12 years (*6*). An updated EUA now includes information on myocarditis after mRNA COVID-19 vaccines.[§§§]

The findings in this report are subject to at least five limitations. First, VAERS is a passive surveillance system and is subject to underreporting and reporting biases (*7*); however, under EUA, health care providers are required to report all serious events following vaccination. Second, medical review of reported deaths following vaccination is dependent on availability of medical records, death certificates, and autopsy reports, which might be unavailable or not available in a timely manner. Third, lack of a statistical safety signal in planned monitoring does not preclude a safety concern. For example, although a statistically significant data mining alert has not been observed for myocarditis following Pfizer-BioNTech vaccination, myocarditis has been identified as an adverse event following mRNA COVID-19 vaccines in multiple surveillance systems (*10*). Fourth, this study was not designed to identify all cases of myocarditis; only reports that listed the MedDRA term "myocarditis" were included. Finally, v-safe is a voluntary self-enrollment program that requires children aged <15 years be enrolled by a parent or guardian and relies on vaccine administrators to promote the program. Therefore, v-safe data might not be generalizable to the overall vaccinated adolescent population.

The initial safety findings of Pfizer-BioNTech vaccine administered to U.S. adolescents aged 12–17 years are similar to those described in the clinical trials, with the exception of myocarditis, a rare serious adverse event associated with receipt of mRNA-based COVID-19 vaccines; follow-up of reported myocarditis cases is ongoing (*6*). CDC and FDA will continue to monitor for adverse events, including myocarditis, after mRNA COVID-19 vaccination and share available data with ACIP to guide risk-benefit assessments for all COVID-19 vaccines.

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[§§§] An updated letter of authorization for the Pfizer-BioNTech COVID-19 vaccine is available at https://www.fda.gov/media/150386/download.

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Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

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During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in a town in Barnstable County, Massachusetts, were identified among Massachusetts residents; vaccination coverage among eligible Massachusetts residents was 69%. Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons (those who had completed a 2-dose course of mRNA vaccine [Pfizer-BioNTech or Moderna] or had received a single dose of Janssen [Johnson & Johnson] vaccine ≥14 days before exposure). Genomic sequencing of specimens from 133 patients identified the B.1.617.2 (Delta) variant of SARS-CoV-2, the virus that causes COVID-19, in 119 (89%) and the Delta AY.3 sublineage in one (1%). Overall, 274 (79%) vaccinated patients with breakthrough infection were symptomatic. Among five COVID-19 patients who were hospitalized, four were fully vaccinated; no deaths were reported. Real-time reverse transcription–polymerase chain reaction (RT-PCR) cycle threshold (Ct) values in specimens from 127 vaccinated persons with breakthrough cases were similar to those from 84 persons who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median = 22.77 and 21.54, respectively). The Delta variant of SARS-CoV-2 is highly transmissible (*1*); vaccination is the most important strategy to prevent severe illness and death. On July 27, CDC recommended that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial.* Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

During July 3–17, 2021, multiple summer events and large public gatherings were held in a town in Barnstable County, Massachusetts, that attracted thousands of tourists from across the United States. Beginning July 10, the Massachusetts Department of Public Health (MA DPH) received reports of an increase in COVID-19 cases among persons who reside in or recently visited Barnstable County, including in fully vaccinated persons. Persons with COVID-19 reported attending densely packed indoor and outdoor events at venues that included bars, restaurants, guest houses, and rental homes. On July 3, MA DPH had reported a 14-day average COVID-19 incidence of zero cases per 100,000 persons per day in residents of the town in Barnstable County; by July 17, the 14-day average incidence increased to 177 cases per 100,000 persons per day in residents of the town (*2*).

During July 10–26, using travel history data from the state COVID-19 surveillance system, MA DPH identified a cluster of cases among Massachusetts residents. Additional cases were identified by local health jurisdictions through case investigation. COVID-19 cases were matched with the state immunization registry. A cluster-associated case was defined as receipt of a positive SARS-CoV-2 test (nucleic acid amplification or antigen) result ≤14 days after travel to or residence in the town in Barnstable County since July 3. COVID-19 vaccine breakthrough cases were those in fully vaccinated Massachusetts residents (those with documentation from the state immunization registry of completion of COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices,† ≥14 days before exposure). Specimens were submitted for whole genome sequencing§ to either the Massachusetts State Public Health Laboratory or the Broad Institute of the Massachusetts Institute of

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html

† As of May 2021, ACIP recommended that all adults aged ≥18 years receive any of the three COVID-19 vaccines available in the United States via Emergency Use Authorization from the Food and Drug Administration, including Pfizer-BioNTech, Moderna, and Janssen; persons aged ≥12 years are eligible to receive the Pfizer-BioNTech COVID-19 vaccine. Full vaccination is defined as receipt of 2 doses of the Pfizer-BioNTech or Moderna COVID-19 vaccines or 1 dose of Janssen COVID-19 vaccine ≥14 days before exposure.

§ Genomic sequencing was performed using Illumina NovaSeq using the NEB LunaScript RT ARTIC SARS-CoV-2 Kit. Novel mutations were not identified in the spike protein of the cluster-associated genomes compared with genomes collected during the same period from ongoing genomic surveillance efforts at Broad Institute. Raw and assembled genomic data are publicly available under NCBI BioProject PRJNA715749.

Summary

What is already known about this topic?

Variants of SARS-CoV-2 continue to emerge. The B.1.617.2 (Delta) variant is highly transmissible.

What is added by this report?

In July 2021, following multiple large public events in a Barnstable County, Massachusetts, town, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 (74%) occurred in fully vaccinated persons. Testing identified the Delta variant in 90% of specimens from 133 patients. Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not.

What are the implications for public health practice?

Jurisdictions might consider expanded prevention strategies, including universal masking in indoor public settings, particularly for large public gatherings that include travelers from many areas with differing levels of SARS-CoV-2 transmission.

Technology and Harvard University. Ct values were obtained for 211 specimens tested using a noncommercial real-time RT-PCR panel for SARS-CoV-2 performed under Emergency Use Authorization at the Broad Institute Clinical Research Sequencing Platform. On July 15, MA DPH issued the first of two Epidemic Information Exchange notifications to identify additional cases among residents of U.S. jurisdictions outside Massachusetts associated with recent travel to the town in Barnstable County during July 2021. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[¶]

By July 26, a total of 469 COVID-19 cases were identified among Massachusetts residents; dates of positive specimen collection ranged from July 6 through July 25 (Figure 1). Most cases occurred in males (85%); median age was 40 years (range = <1–76 years). Nearly one half (199; 42%) reported residence in the town in Barnstable County. Overall, 346 (74%) persons with COVID-19 reported symptoms consistent with COVID-19.[**] Five were hospitalized; as of July 27, no deaths were reported. One hospitalized patient (age range = 50–59 years) was not vaccinated and had multiple underlying medical conditions.[††] Four additional, fully vaccinated patients[§§] aged 20–70 years were also hospitalized, two of whom had underlying medical conditions. Initial genomic sequencing of specimens from 133 patients identified the Delta variant in 119 (89%) cases and the Delta AY.3 sublineage in one (1%) case; genomic sequencing was not successful for 13 (10%) specimens.

Among the 469 cases in Massachusetts residents, 346 (74%) occurred in persons who were fully vaccinated; of these, 301 (87%) were male, with a median age of 42 years. Vaccine products received by persons experiencing breakthrough infections were Pfizer-BioNTech (159; 46%), Moderna (131; 38%), and Janssen (56; 16%); among fully vaccinated persons in the Massachusetts general population, 56% had received Pfizer-BioNTech, 38% had received Moderna, and 7% had received Janssen vaccine products. Among persons with breakthrough infection, 274 (79%) reported signs or symptoms, with the most common being cough, headache, sore throat, myalgia, and fever. Among fully vaccinated symptomatic persons, the median interval from completion of ≥14 days after the final vaccine dose to symptom onset was 86 days (range = 6–178 days). Among persons with breakthrough infection, four (1.2%) were hospitalized, and no deaths were reported. Real-time RT-PCR Ct values in specimens from 127 fully vaccinated patients (median = 22.77) were similar to those among 84 patients who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median = 21.54) (Figure 2).

Transmission mitigation measures included broadening testing recommendations for persons with travel or close contact with a cluster-associated case, irrespective of vaccination status; local recommendations for mask use in indoor settings, irrespective of vaccination status; deployment of state-funded mobile testing and vaccination units in the town in Barnstable County; and informational outreach to visitors and residents. In this tourism-focused community, the Community Tracing Collaborative[¶¶] conducted outreach to hospitality workers, an international workforce requiring messaging in multiple languages.

The call from MA DPH for cases resulted in additional reports of cases among residents of 22 other states who had traveled to the town in Barnstable County during July 3–17, as well as reports of secondary transmission; further analyses are ongoing. As of July 3, estimated COVID-19 vaccination coverage among the eligible population in Massachusetts was 69% (*3*). Further investigations and characterization of breakthrough infections and vaccine effectiveness among this highly vaccinated population are ongoing.

[¶] 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.

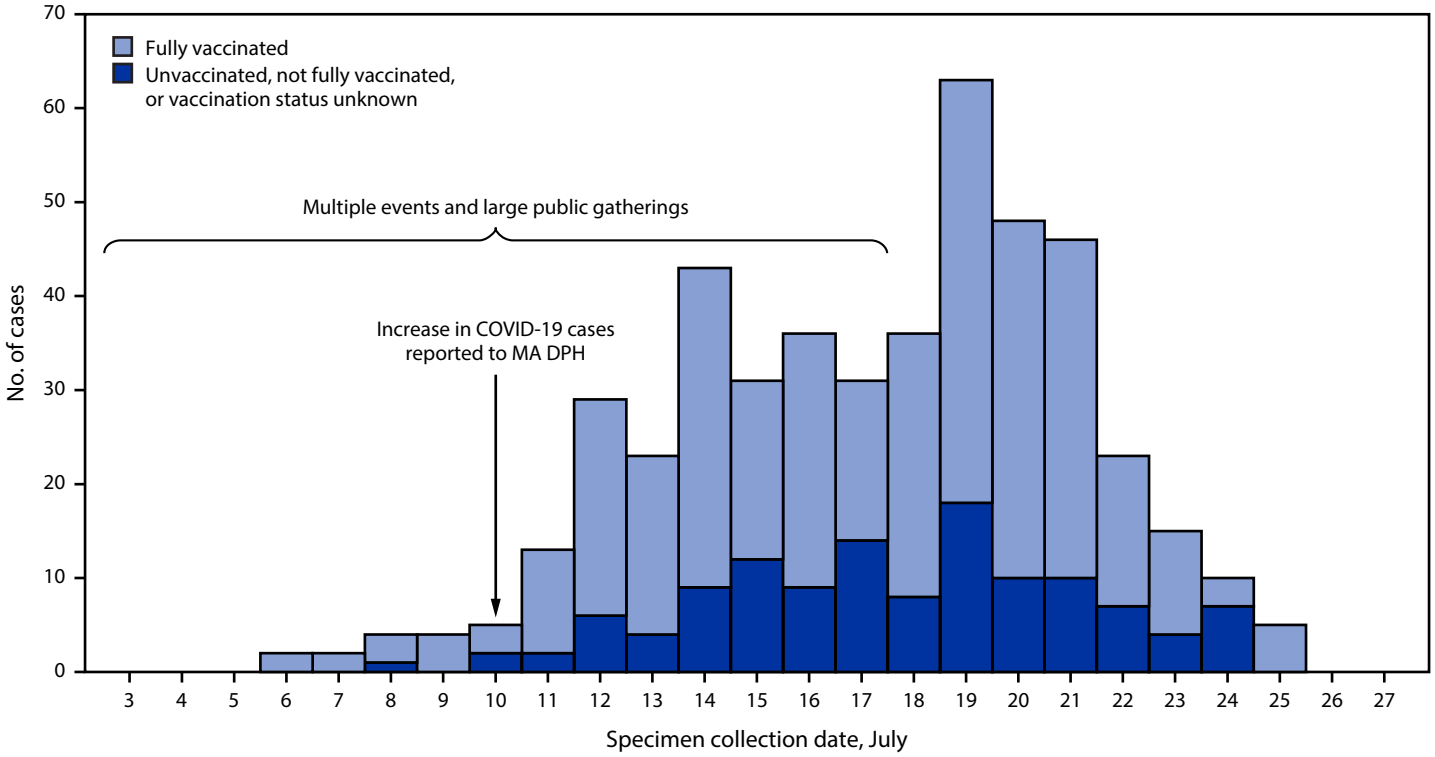
[**] COVID-like symptoms were based on the Council of State and Territorial Epidemiologists surveillance case definition for COVID-19. https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2020-08-05/

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

[§§] One vaccinated, hospitalized COVID-19 patient had received the Pfizer-BioNTech vaccine and three had received the Janssen vaccine.

[¶¶] The Community Tracing Collaborative is a multiorganization partnership that has supported COVID contact tracing and outbreak investigation in Massachusetts. https://www.mass.gov/info-details/learn-about-the-community-tracing-collaborative

FIGURE 1. SARS-CoV-2 infections (N = 469) associated with large public gatherings, by date of specimen collection and vaccination status* — Barnstable County, Massachusetts, July 2021



Abbreviation: MA DPH = Massachusetts Department of Public Health.
* Fully vaccinated was defined as ≥14 days after completion of state immunization registry–documented COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices.

Discussion

The SARS-CoV-2 Delta variant is highly transmissible (*1*), and understanding determinants of transmission, including human behavior and vaccine effectiveness, is critical to developing prevention strategies. Multipronged prevention strategies are needed to reduce COVID-19–related morbidity and mortality (*4*).

The findings in this report are subject to at least four limitations. First, data from this report are insufficient to draw conclusions about the effectiveness of COVID-19 vaccines against SARS-CoV-2, including the Delta variant, during this outbreak. As population-level vaccination coverage increases, vaccinated persons are likely to represent a larger proportion of COVID-19 cases. Second, asymptomatic breakthrough infections might be underrepresented because of detection bias. Third, demographics of cases likely reflect those of attendees at the public gatherings, as events were marketed to adult male participants; further study is underway to identify other population characteristics among cases, such as additional demographic characteristics and underlying health conditions including immunocompromising conditions.*** MA DPH, CDC, and affected jurisdictions are collaborating in this response; MA DPH is conducting additional case investigations, obtaining samples for genomic sequencing, and linking case information with laboratory data and vaccination history. Finally, Ct values obtained with SARS-CoV-2 qualitative RT-PCR diagnostic tests might provide a crude correlation to the amount of virus present in a sample and can also be affected by factors other than viral load.††† Although the assay used in this investigation was not validated to provide quantitative results, there was no significant difference between the Ct values of samples collected from breakthrough cases and the other cases. This might mean that the viral load of vaccinated and unvaccinated persons infected with SARS-CoV-2 is also similar. However, microbiological studies are required to confirm these findings.

Event organizers and local health jurisdictions should continually assess the need for additional measures, including limiting capacity at gatherings or event postponement, based on current rates of COVID-19 transmission, population vaccination coverage, and other factors.§§§ On July 27, CDC released

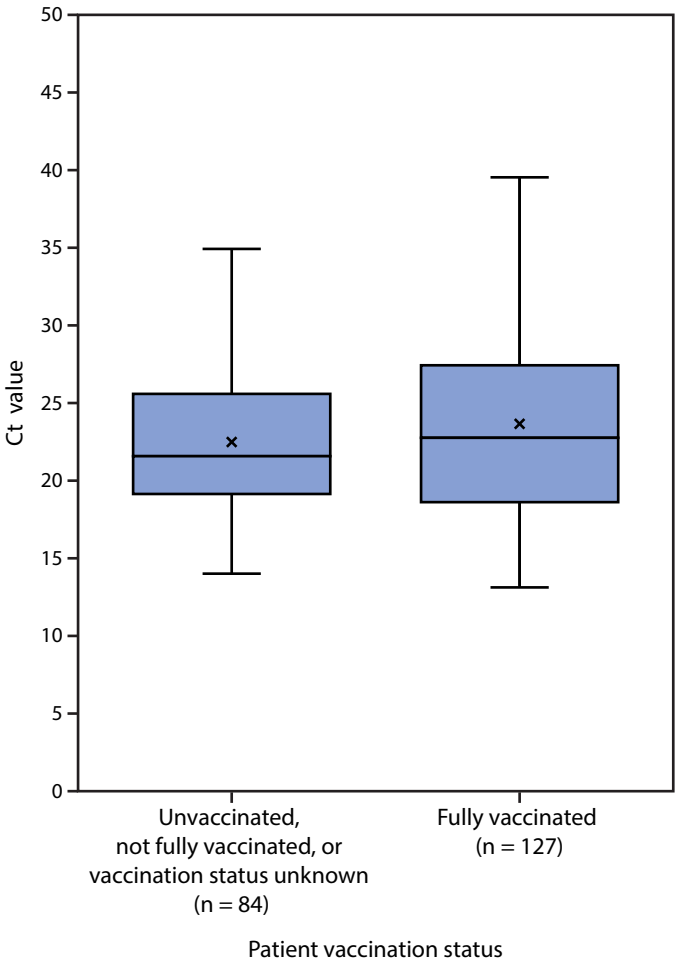
*** A preliminary analysis matching cluster-associated COVID-19 cases with the state HIV case surveillance data identified 30 (6%) cases with verified HIV infection; all were virally suppressed, and none were hospitalized as a result of infection with SARS-CoV-2.

††† https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html

§§§ https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/considerations-for-events-gatherings.html

recommendations that all persons, including those who are fully vaccinated, should wear masks in indoor public settings in areas where COVID-19 transmission is high or substantial. Findings from this investigation suggest that even jurisdictions without substantial or high COVID-19 transmission might consider expanding prevention strategies, including masking in indoor public settings regardless of vaccination status, given the potential risk of infection during attendance at large public gatherings that include travelers from many areas with differing levels of transmission.

FIGURE 2. SARS-CoV-2 real-time reverse transcription–polymerase chain reaction cycle threshold values* for specimens from patients with infections associated with large public gatherings, by vaccination status† — Barnstable County, Massachusetts, July 2021§



Abbreviations: Ct = cycle threshold; RT-PCR = reverse transcription–polymerase chain reaction.

* Specimens were analyzed using a noncommercial real-time RT-PCR panel for SARS-CoV-2 performed under Emergency Use Authorization at the Clinical Research Sequencing Platform, Broad Institute of the Massachusetts Institute of Technology and Harvard University.

† Fully vaccinated was defined as ≥14 days after completion of state immunization registry–documented COVID-19 vaccination as recommended by the Advisory Committee on Immunization Practices.

§ Whiskers represent minimum and maximum observations; top of box represents the third quartile (Q3), bottom represents the first quartile (Q1), and box height represents the interquartile range. Midline is the median; "x" is the mean.

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Notes from the Field

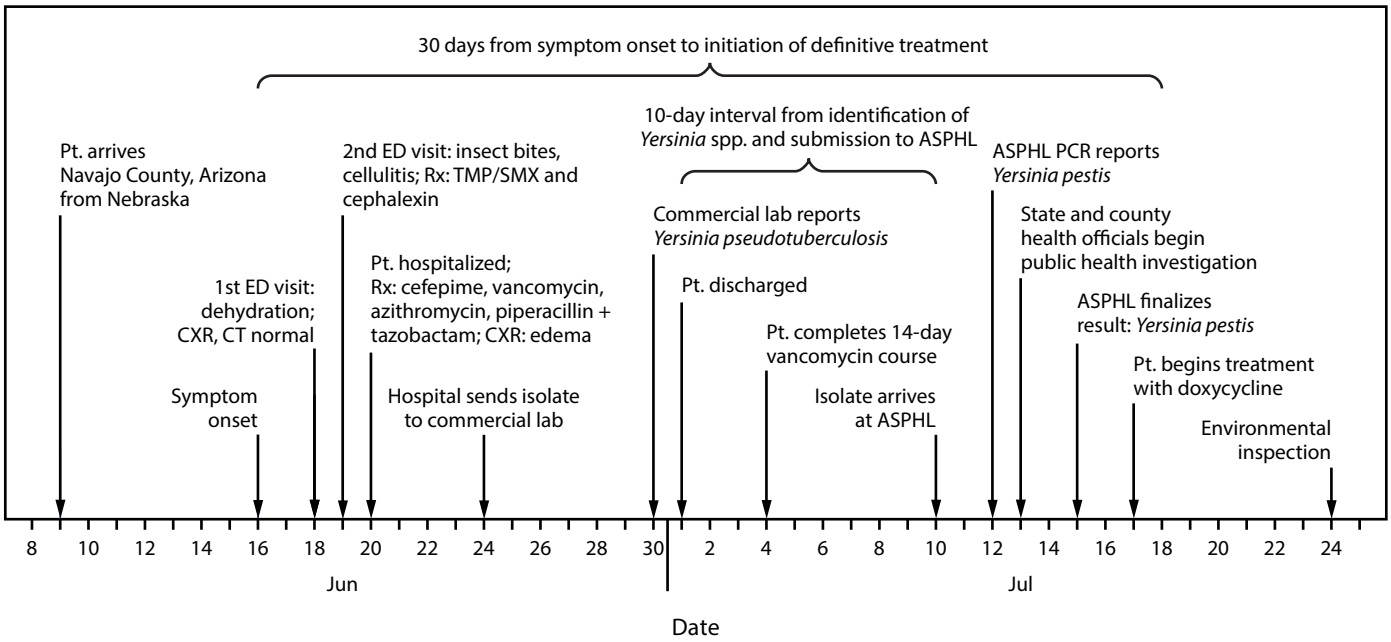
Delays in Identification and Treatment of a Case of Septicemic Plague — Navajo County, Arizona, 2020

Ariella P. Dale, PhD[1,2,3]; Melissa Kretschmer, MA[3]; Irene Ruberto, PhD[2]; David M. Wagner, PhD[4]; Cathy Solomon[5]; Kenneth Komatsu, MPH[2]; Heather Venkat, DVM[2,6]

On June 18, 2020, a White non-Hispanic man aged 67 years sought care at an emergency department (ED) in Navajo County, Arizona, complaining of dehydration, nausea, weakness, and a chronic cough of 1.5 years' duration. He had arrived in Navajo County from Nebraska approximately 9 days earlier. On physical exam, he was tachycardic and tachypneic. His chest radiograph and computed tomographic angiography chest scan with contrast were normal, and he was discharged after receiving intravenous fluids. He returned to the ED the next day (June 19) for treatment of three red and painful suspected insect bites on his leg and was discharged the same day with a diagnosis of cellulitis and two antibiotic prescriptions (Figure). He returned to the ED the following day (June 20) complaining of fever, dizziness, productive worsening cough, "swollen glands" (location not noted), weakness, and chills. He was hospitalized and received treatment with four antibiotics for a presumptive diagnosis of sepsis. Test results of nasopharyngeal specimens collected on June 18 and June 21 were negative for SARS-CoV-2, the virus that causes COVID-19, and other respiratory pathogens. On June 24, the hospital laboratory reported an atypical gram-negative isolate from a blood specimen, which was sent that day to a commercial reference laboratory for further identification using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF). The organism was identified as *Yersinia pseudotuberculosis,* a gram-negative, rod-shaped organism, and reported to the hospital on June 30. The patient was discharged from the hospital on July 1 with a peripherally inserted central catheter line and 3 additional days of a 14-day course of intravenous vancomycin.

On July 10, the hospital laboratory sent a blood culture isolate to Arizona State Public Health Laboratory (ASPHL) and *Yersinia pestis* was presumptively identified on July 12 using reverse transcriptase polymerase chain reaction testing. The hospital was notified of the presumptive results. After ASPHL culture confirmed *Y. pestis* on July 15 and classified the case as septicemic plague, the patient was prescribed a 10-day course of oral doxycycline and completed it. Delays in identification of the isolate as *Y. pestis* were attributed to initial misidentification of the pathogen and delays in laboratory reporting.

FIGURE. Timeline of patient illness and laboratory identification of *Yersinia pestis* in a case of plague — Arizona, 2020



Abbreviations: ASPHL = Arizona State Public Health Laboratory; CT = computed tomography scan; CXR = chest radiograph; ED = emergency department; PCR = polymerase chain reaction; Pt. = patient; Rx = treatment; TMP/SMX = trimethoprim-sulfamethoxazole.

Blood samples collected on June 20 were cultured in the hospital. Arizona Administrative Code R9–6-204A requires laboratories to submit all *Yersinia* spp. isolates and report to ASPHL within 1 working day (*1*); in this case, a 10-day delay in submission of the isolate and report to ASPHL occurred. The reason for delay in testing or reporting by the reference laboratory or hospital laboratory is unclear.

Timely identification of a pathogen and treatment of the patient are critical to public health response and investigation of highly infectious pathogens such as *Y. pestis.* Plague is rare in Arizona and was last reported in 2017 in a Navajo County resident. The patient identified in 2020 had reported gloved handling of a dead pack rat before symptom onset; an environmental investigation noted many rodent habitats, but no fleas were collected. Typical transmission of *Y. pestis* to humans occurs through fleabites, exposure to sick animals (e.g., pets), or contact with contaminated tissues or body fluids (*2*). With rare pathogens, particularly in the context of the COVID-19 pandemic, timely laboratory identification is crucial for accurate clinical diagnosis and treatment; reeducation was conducted with the laboratories regarding the reporting requirements. This patient did not receive high-efficacy antibiotic treatment, a tetracycline, until approximately 30 days after symptom onset; he recovered, possibly in part because he received antibiotics with some demonstrated efficacy against *Y. pestis*, including trimethoprim/sulfamethoxazole, early in the illness course (*3*).

Misidentification of *Y. pestis* isolates as *Y. pseudotuberculosis* can occur with MALDI-TOF and other automated systems (*4*,*5*). Timely use of high-efficacy therapies including aminoglycosides and tetracyclines significantly increases the odds of survival in patients with plague (*6*). Rapid reporting might have led to timelier diagnosis of his acute illness and initiation of a more effective antibiotic therapy closer to disease onset.

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Arizona State Public Health Laboratory; Jeff P. Lee, Wade Kartchner, Janelle Linn, Kathryn Mathewson, Randall Walton, Joshua Smith, Navajo County Department of Public Health Services, Arizona; Kris Bisgard, Kiersten Kugeler, Grace Marx, Amy Schwartz, CDC.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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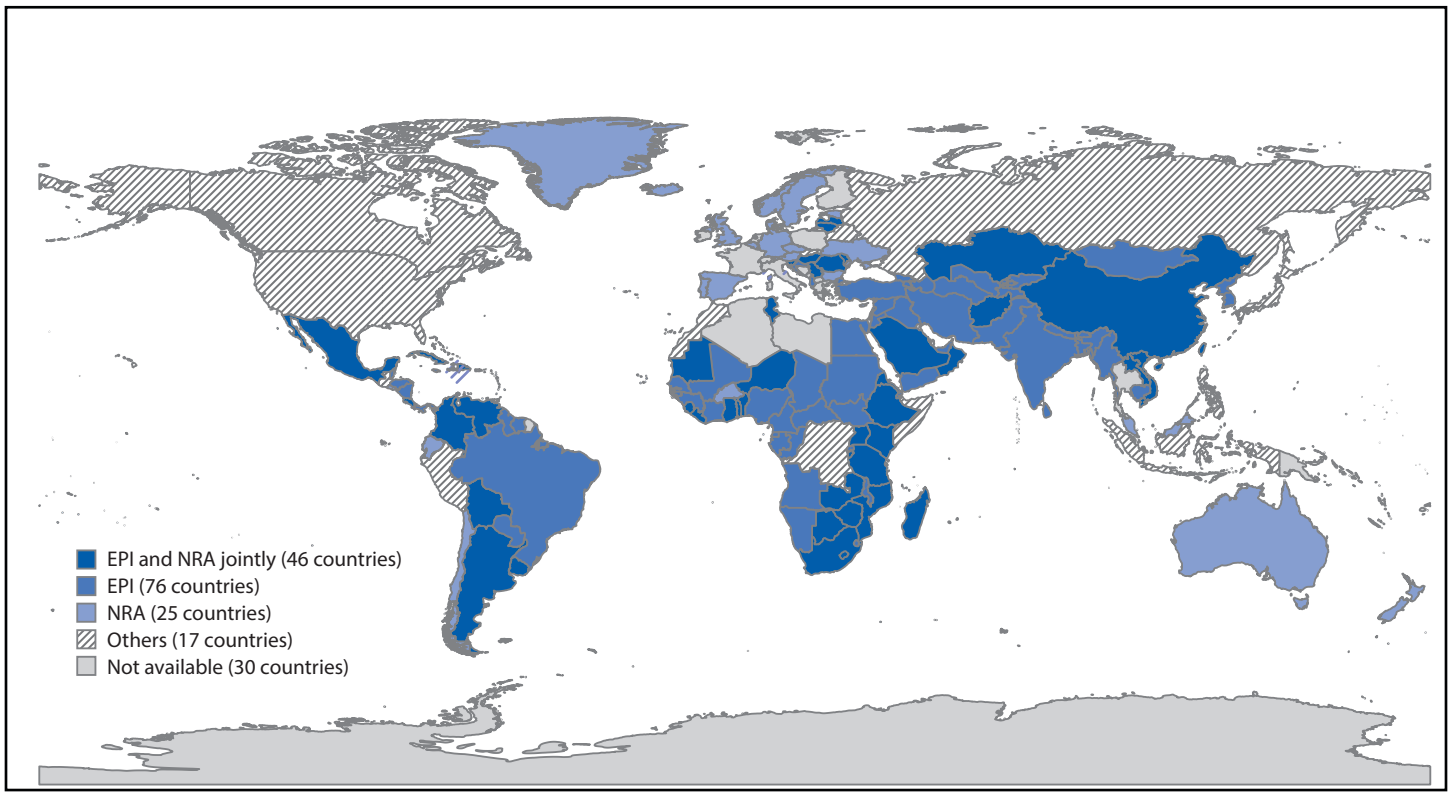
Erratum

Vol. 70, No. 15

In the report, "Progress in Immunization Safety Monitoring — Worldwide, 2010–2019," in the figure on p. 548 (Figure 1), six countries were depicted on the map as having data sources "not available," but should have been depicted as having the following data sources: Djibouti, Expanded Programmes on Immunization (EPI); Ecuador, national regulatory authorities (NRA); Guinea-Bissau, EPI; Mauritius, EPI; Saint Vincent and the Grenadines, EPI; and Seychelles, EPI. The corrected figure is below.

FIGURE 1. Sources of data for adverse events following immunization reported on the WHO/UNICEF Joint Reporting Form — worldwide, 2019

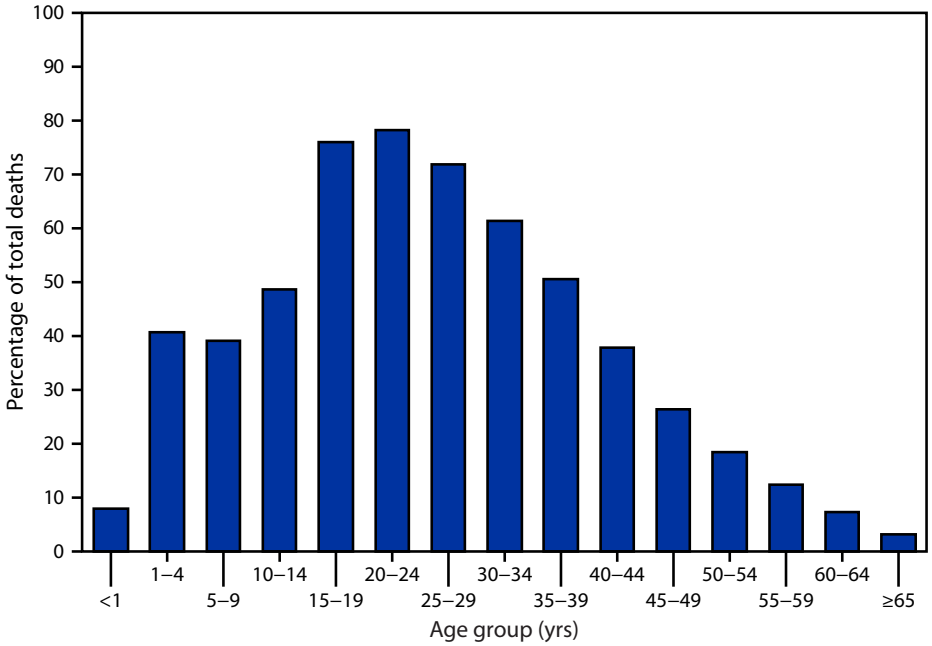


Abbreviations: EPI = Expanded Programmes on Immunization; NRA = national regulatory authorities; WHO = World Health Organization.

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Injury Deaths* as a Percentage of Total Deaths, by Age Group — National Vital Statistics System, United States, 2019



* Injury deaths were identified using *International Classification of Diseases, Tenth Revision* underlying cause-of-death codes U01–U03, V01–Y36, Y85–Y87, and Y89 and include all intents (unintentional, suicide, homicide, undetermined intent, and legal intervention).

Injuries accounted for the majority of deaths among persons aged 15–39 years, with the highest percentages among those aged 15–19 (76.0%) and 20–24 years (78.2%). The percentage of injury deaths was lowest among those aged <1 year (7.9%), 60–64 years (7.5%), and ≥65 years (3.4%).

Source: National Center for Health Statistics, National Vital Statistics System, Mortality Data, 2019. https://www.cdc.gov/nchs/nvss/deaths.htm

Reported by: Holly Hedegaard, MD, hdh6@cdc.gov, 301-458-4460; Matthew F. Garnett, MPH; Merianne R. Spencer, MPH.

For more information on this topic, CDC recommends the following link: https://www.cdc.gov/injury

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