

Short Sleep Duration Among Infants, Children, and Adolescents Aged 4 Months–17 Years — United States, 2016–2018

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Infants, children, and adolescents who do not get sufficient sleep are at increased risk for injuries, obesity, type 2 diabetes, poor mental health, attention and behavior problems, and poor cognitive development (1). The American Academy of Sleep Medicine (AASM) provides age-specific sleep duration recommendations to promote optimal health (1). CDC analyzed data from the 2016–2018 National Survey of Children's Health (NSCH) to assess the prevalence of short sleep duration among persons in the United States aged 4 months–17 years. Overall, on the basis of parent report, 34.9% of persons aged 4 months–17 years slept less than recommended for their age. The prevalence of short sleep duration was higher in southeastern states and among racial and ethnic minority groups, persons with low socioeconomic status, and those with special health care needs. The prevalence of short sleep duration ranged from 31.2% among adolescents aged 13–17 years to 40.3% among infants aged 4–11 months. Persons aged 4 months–17 years with a regular bedtime were more likely to get enough sleep. Public health practitioners, educators, and clinicians might advise parents on the importance of meeting recommended sleep duration and implementing a consistent bedtime for healthy development.

NSCH is a population-based, nationally representative online and paper survey of parents or primary caregivers (parents) of noninstitutionalized U.S. persons aged ≤17 years. The survey is conducted by the U.S. Census Bureau under the direction of the Health Resources and Services Administration's Maternal and Child Health Bureau.* NSCH asks parents about the physical and emotional health of one person aged ≤17 years selected at random from the household, as well as

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* <https://mchb.hrsa.gov/>



health care access and family characteristics. The weighted overall response rates were 40.7% in 2016, 37.4% in 2017, and 43.1% in 2018.[†] Sleep duration questions were “During the past week, how many hours of sleep did this child get on an average day (count both nighttime sleep and naps)?”[§] for infants and children aged 0–5 years, and for children and adolescents aged 6–17 years, “During the past week, how many hours of sleep did this child get on an average weeknight?”[¶] On the basis of AASM recommendations (1), short sleep duration was defined as <12 hours for children aged 4–11 months, <11 hours for children aged 1–2 years, <10 hours for children aged 3–5 years, <9 hours for children aged 6–12 years, and <8 hours for adolescents aged 13–17 years. The bedtime question for all ages was “How often does this child go to bed at about the same time on weeknights?”^{**} Regular bedtime was defined as a response of “always.” The study included 99,842

persons aged 4 months–17 years^{††} with responses to the sleep duration question (48,748 in 2016, 21,124 in 2017, and 29,970 in 2018).

Prevalence and 95% confidence interval (CI) of short sleep duration and regular bedtime were calculated for persons aged 4 months–17 years overall, by age group, by state, and by selected characteristics of the child and parent. Pairwise differences by sex, race/ethnicity, special health care needs status, overall health status, and regular bedtime were determined using t-tests. Tests for linear trend were conducted for family income level^{§§} and parent education level. P-values <0.05 were considered statistically significant. Analyses accounted for weighting^{¶¶} of the data and for the complex sampling design. SAS-callable SUDAAN (version 11.0.3; RTI International) was used to conduct all analyses. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.^{***}

Overall, 34.9% of persons aged 4 months–17 years slept less than recommended for their age (Table 1). The prevalence of short sleep duration ranged from 31.2% among adolescents aged 13–17 years to 40.3% among infants aged 4–11 months.

[†] <https://www.census.gov/content/dam/Census/programs-surveys/nsch/technical-documentation/methodology/2016-NSCH-Methodology-Report.pdf>; <https://www.census.gov/content/dam/Census/programs-surveys/nsch/technical-documentation/methodology/2017-NSCH-Methodology-Report.pdf>; <https://www2.census.gov/programs-surveys/nsch/technical-documentation/methodology/2018-NSCH-Methodology-Report.pdf>

[§] Response options were “less than 7 hours,” “7 hours,” “8 hours,” “9 hours,” “10 hours,” “11 hours,” and “12 or more hours.”

[¶] The question changed slightly in 2018, when parents were asked, “During the past week, how many hours of sleep did this child get on most weeknights?” Response options for 2016–2018 were “less than 6 hours,” “6 hours,” “7 hours,” “8 hours,” “9 hours,” “10 hours,” and “11 or more hours.”

^{**} Response options were “always,” “usually,” “sometimes,” “rarely,” and “never.”

^{††} AASM did not include recommendations for persons aged <4 months; therefore, short sleep duration was not assessed for this age group.

^{§§} <https://www.census.gov/content/dam/Census/programs-surveys/nsch/technical-documentation/methodology/2016-NSCH-Methodology-Report.pdf>

^{¶¶} Weighted estimates were used to generalize to state and national resident populations.

^{***} 45 C.F.R. part 46.102(l)(2), 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.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. *MMWR Morb Mortal Wkly Rep* 2021;70:[inclusive page numbers].

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TABLE 1. Prevalence of short sleep duration* and regular bedtime† among persons aged 4 months–17 years, by age group — National Survey of Children’s Health, United States, 2016–2018

Characteristic	% (95% CI) [§]					
	All persons aged 4 mos–17 yrs (n = 99,842)	Infants aged 4–11 mos (n = 2,499)	Children aged 1–2 yrs (n = 10,147)	Children aged 3–5 yrs (n = 15,290)	Children aged 6–12 yrs (n = 36,179)	Adolescents aged 13–17 yrs (n = 35,727)
Short sleep duration	34.9 (34.2–35.6)	40.3 (35.9–44.7)	33.3 (31.2–35.4)	34.8 (33.1–36.7)	37.4 (36.3–38.6)	31.2 (30.1–32.4)
Regular bedtime	33.9 (33.2–34.6)	43.5 (39.1–47.9)	40.9 (38.7–43.0)	37.3 (35.5–39.1)	37.0 (35.9–38.2)	23.8 (22.7–24.9)

Abbreviation: CI = confidence interval.

* Short sleep duration is defined as <12 hours for infants aged 4–11 months, <11 hours for children aged 1–2 years, <10 hours for children aged 3–5 years, <9 hours for children aged 6–12 years, and <8 hours for adolescents aged 13–17 years.

† Regular bedtime is defined as a response of “always” to the question about how often the person aged <18 years goes to bed at approximately the same time on weeknights.

§ Weighted percentages. The National Survey of Children’s Health is weighted to be representative of the U.S. population of noninstitutionalized persons aged ≤17 years. <https://www2.census.gov/programs-surveys/nsch/technical-documentation/methodology/NSCH-Guide-to-Multi-Year-Estimates.pdf>

The percentage of persons aged 4 months–17 years with a regular bedtime was 33.9% overall and ranged from 23.8% among adolescents to 43.5% among infants. Among children aged 4 months–17 years, the prevalence of short sleep duration was lowest among non-Hispanic White children (28.8%) and higher among non-Hispanic Black children (50.8%) than among Hispanic children (39.1%) or non-Hispanic children of any other race (other race) (34.6%) (Table 2). The prevalence decreased with increasing family income level and parent educational attainment. The prevalence of short sleep duration was higher among persons aged 4 months–17 years with special health care needs than among those without special health care needs (38.3% versus 34.1%); and among those with good, fair, or poor health than among those with excellent or very good health (46.8% versus 33.5%). Overall, the prevalence of short sleep duration was lower among persons aged 4 months–17 years with a regular bedtime than among those without a regular bedtime (27.5% versus 38.6%). Similar patterns were observed within each age group.

State-level prevalence of short sleep duration overall ranged from 25.3% in Maine to 48.9% in Mississippi (Table 2). States with the highest prevalence of short sleep duration were concentrated in the Southeast (Figure).

Discussion

During 2016–2018, approximately one third of persons aged 4 months–17 years (34.9%) got less sleep than is recommended for their age (1). Younger persons within this age group were particularly at risk for short sleep duration; the prevalence of short sleep duration decreased with age from infancy (40.3%) to adolescence (31.2%). Previous prevalence estimates of short sleep duration among adolescents were significantly higher: based on self-report from the 2015 Youth Risk Behavior Surveys,^{†††} nearly three quarters of high school

students nationally and approximately one half of middle school students in nine states reported getting less sleep than recommended for their age (2). This difference might be explained by NSCH’s reliance on parent report rather than self-report with Youth Risk Behavior Surveys. Parents might overestimate the amount of sleep their older children or adolescents receive (3). However, one study that compared total sleep time based on parent report and child or adolescent report with that measured by a sleep study (i.e., polysomnography^{§§§}) found that children and adolescents overestimated total sleep time to a lesser extent than did their parents, but the difference between child or adolescent and parent reports was small (4). Agreement between parent and child or adolescent report was similar for children aged 9–12 years and adolescents aged 13–17 years (4).

Before 2016, the NSCH did not ask parents about hours of sleep, but rather asked, “During the past week, on how many nights did [child] get enough sleep for a child his/her age?” Patterns in the prevalence of inadequate sleep (defined as not enough sleep ≥1 night during the past week) contrast with the current report; specifically, the prevalence of inadequate sleep was highest among adolescents aged 14–17 years and lowest among children aged 6–9 years (5). Trends based on parent education and household income also differed (5).

In the current study, short sleep duration was elevated among racial and ethnic minority groups, especially among Black persons aged 4 months–17 years, among whom approximately one half had short sleep duration. Short sleep duration was also more prevalent among families with lower income or lower parental educational attainment. In previous research, sleep disparity was associated with various social determinants of health (e.g., poverty, food insecurity, and perceived racism), which can increase chronic and acute stress and result in environmental and psychological factors that negatively affect sleep

††† <https://www.cdc.gov/healthyyouth/data/yrbs/index.htm>

§§§ <https://www.nhlbi.nih.gov/health-topics/sleep-studies>

TABLE 2. Prevalence of short sleep duration* among persons aged 4 months–17 years, by age group and selected characteristics — National Survey of Children's Health, United States, 2016–2018

Characteristic	% (95% CI) [†]					
	All persons aged 4 mos–17 yrs	Infants aged 4–11 mos	Children aged 1–2 yrs	Children aged 3–5 yrs	Children aged 6–12 yrs	Adolescents aged 13–17 yrs
Sex						
Male	35.0 (34.0–36.0)	40.6 (34.4–47.0)	32.8 (29.9–35.7)	35.2 (32.8–37.7)	38.4 (36.8–40.0)	30.4 (28.9–32.1)
Female	34.7 (33.7–35.7)	39.9 (34.0–46.1)	33.8 (30.8–36.8)	34.5 (31.9–37.1)	36.4 (34.8–38.1)	32.1 (30.3–33.8)
Race/Ethnicity						
Hispanic	39.1 (37.1–41.1)	41.5 (29.9–54.1) [§]	40.5 (34.6–46.7)	42.4 (37.3–47.7)	43.3 (40.1–46.6)	30.3 (27.1–33.7)
White, non-Hispanic	28.8 (28.1–29.5)	32.9 (28.2–38.0)	26.1 (24.2–28.2)	27.9 (26.2–29.7)	30.1 (29.0–31.1)	28.1 (27.1–29.2)
Black, non-Hispanic	50.8 (48.6–53.0)	64.2 (51.1–75.5) [§]	50.2 (42.7–57.7)	51.7 (46.1–57.4)	56.4 (53.0–59.8)	42.2 (38.5–46.0)
Other, [¶] non-Hispanic	34.6 (32.9–36.4)	46.8 (36.8–57.2) [§]	35.6 (29.7–41.9)	32.3 (28.7–36.1)	34.8 (32.1–37.6)	33.4 (30.5–36.5)
Family income level**						
FPL<100%	45.6 (43.6–47.7)	54.2 (41.5–66.4) [§]	45.4 (39.5–51.5)	49.2 (44.1–54.3)	51.6 (48.4–54.8)	33.4 (30.1–36.9)
100%≤FPL<200%	39.2 (37.3–41.2)	49.9 (39.6–60.2) [§]	39.1 (33.6–44.8)	41.4 (36.4–46.5)	41.1 (38.1–44.1)	34.0 (30.9–37.2)
200%≤FPL<400%	33.2 (31.9–34.6)	33.3 (25.3–42.4)	32.7 (28.3–37.3)	32.7 (29.4–36.2)	35.8 (33.7–37.9)	30.4 (28.3–32.5)
FPL≥400%	26.0 (25.0–27.0)	29.2 (23.7–35.5)	21.9 (18.9–25.4)	22.5 (20.1–25.0)	26.3 (24.8–27.7)	28.7 (27.1–30.5)
Parent education						
Less than high school	46.2 (42.4–50.0)	60.3 (34.7–81.2) [§]	39.7 (27.8–53.0) [§]	54.0 (43.1–64.5) [§]	53.7 (47.7–59.5)	34.1 (28.6–40.1)
High school	43.3 (41.4–45.2)	54.1 (43.8–64.1) [§]	49.0 (42.7–55.4)	47.4 (42.2–52.7)	46.3 (43.3–49.3)	34.2 (31.2–37.3)
Some college	39.3 (37.8–40.7)	49.2 (40.3–58.2)	39.2 (34.7–44.0)	40.6 (36.8–44.4)	43.0 (40.7–45.3)	32.2 (30.0–34.5)
College graduate	27.2 (26.5–28.0)	28.6 (24.3–33.3)	24.9 (22.6–27.3)	25.0 (23.2–26.8)	27.8 (26.6–29.0)	28.7 (27.4–30.1)
Special health care needs^{††}						
Yes	38.3 (36.8–39.7)	30.5 (19.5–44.2) [§]	30.9 (25.3–37.1)	38.3 (34.3–42.6)	42.8 (40.7–45.1)	33.7 (31.4–36.1)
No	34.1 (33.3–34.9)	40.7 (36.2–45.3)	33.5 (31.3–35.7)	34.3 (32.3–36.3)	35.9 (34.6–37.3)	30.4 (29.1–31.8)
Health status						
Excellent or very good	33.5 (32.8–34.2)	39.4 (35.0–44.0)	32.4 (30.4–34.5)	33.8 (31.9–35.6)	35.3 (34.2–36.5)	30.3 (29.1–31.5)
Good, fair, or poor	46.8 (44.1–49.5)	59.8 (40.2–76.7) [§]	45.4 (35.1–56.1) [§]	45.6 (38.1–53.3)	54.6 (50.5–58.7)	38.0 (33.8–42.4)
Regular bedtime^{§§}						
Yes	27.5 (26.3–28.9)	34.6 (27.6–42.3)	28.5 (25.5–31.7)	29.1 (25.8–32.6)	30.5 (28.6–32.6)	17.4 (15.5–19.6)
No	38.6 (37.8–39.4)	44.8 (39.5–50.2)	36.6 (33.8–39.4)	38.1 (36.0–40.2)	41.4 (40.0–42.8)	35.6 (34.2–37.0)
State						
Alabama	42.5 (39.3–45.8)	46.7 (28.3–66.2) [§]	41.7 (32.0–52.0)	39.2 (32.1–46.8)	49.6 (44.3–54.9)	34.4 (29.3–39.9)
Alaska	27.7 (24.7–30.8)	32.1 (19.6–47.8) [§]	28.3 (20.8–37.3)	26.6 (20.1–34.2)	31.9 (26.9–37.4)	20.5 (16.2–25.8)
Arizona	35.6 (32.3–38.9)	27.1 (13.8–46.2) [§]	36.7 (27.1–47.4) [§]	35.9 (28.1–44.5)	38.1 (32.9–43.6)	32.2 (26.8–38.0)
Arkansas	40.8 (37.4–44.2)	47.6 (31.5–64.1) [§]	35.7 (26.3–46.4) [§]	45.9 (37.7–54.4)	44.2 (38.8–49.7)	34.0 (28.2–40.4)
California	34.2 (30.9–37.6)	44.9 (24.2–67.6) [§]	30.3 (22.0–40.1)	33.8 (26.1–42.4)	38.2 (32.9–43.8)	28.5 (23.4–34.2)
Colorado	26.8 (24.1–29.7)	27.1 (15.7–42.6) [§]	25.8 (17.6–36.1)	28.2 (22.0–35.3)	26.9 (22.6–31.6)	26.3 (21.7–31.6)
Connecticut	32.8 (29.9–36.0)	46.5 (27.0–67.0) [§]	27.8 (19.0–38.6)	36.7 (28.5–45.7)	31.7 (27.1–36.7)	32.8 (28.2–37.8)
Delaware	39.1 (35.9–42.5)	46.2 (29.0–64.3) [§]	35.9 (26.4–46.6) [§]	42.4 (34.0–51.3)	42.1 (37.0–47.3)	33.5 (28.4–39.0)
District of Columbia	36.5 (32.8–40.3)	31.2 (17.9–48.6) [§]	36.7 (27.7–46.7)	25.9 (19.4–33.7)	44.5 (38.0–51.1)	34.7 (27.5–42.6)
Florida	38.6 (35.3–41.9)	50.0 (29.0–71.0) [§]	36.0 (27.5–45.6)	43.3 (34.6–52.5)	38.4 (33.4–43.6)	36.2 (30.5–42.2)
Georgia	40.3 (37.0–43.6)	38.9 (22.2–58.7) [§]	33.5 (24.2–44.3) [§]	39.4 (31.4–48.1)	47.1 (41.8–52.5)	32.9 (28.0–38.2)
Hawaii	38.4 (35.5–41.3)	41.6 (26.2–58.9) [§]	32.2 (23.9–41.7)	32.2 (25.6–39.6)	43.0 (38.3–47.9)	38.4 (33.6–43.5)
Idaho	26.9 (24.4–29.6)	22.0 (12.5–35.6) [§]	25.0 (18.5–32.8)	28.6 (21.9–36.4)	28.4 (24.3–32.9)	25.1 (21.2–29.5)
Illinois	30.1 (27.2–33.1)	53.4 (36.1–69.9) [§]	23.6 (16.5–32.6)	27.9 (20.7–36.4)	32.2 (27.5–37.2)	28.4 (23.7–33.5)
Indiana	38.6 (35.5–41.7)	36.7 (20.8–56.0) [§]	45.8 (36.6–55.3)	35.4 (28.3–43.2)	40.4 (35.3–45.6)	36.0 (31.0–41.3)
Iowa	29.0 (26.3–32.0)	28.7 (12.9–52.4) [§]	20.5 (13.3–30.3)	28.9 (22.6–36.2)	34.3 (29.6–39.4)	25.0 (21.3–29.2)
Kansas	30.3 (27.3–33.4)	39.9 (21.3–62.0) [§]	27.0 (18.0–38.5) [§]	31.0 (24.2–38.8)	32.5 (27.9–37.5)	26.7 (22.2–31.8)
Kentucky	35.8 (32.8–39.0)	28.9 (12.8–53.0) [§]	31.0 (23.2–40.2)	28.8 (22.3–36.3)	46.0 (40.6–51.5)	29.4 (25.1–34.3)
Louisiana	46.6 (43.2–49.9)	34.0 (19.7–51.9) [§]	44.9 (34.8–55.6) [§]	47.0 (39.3–54.9)	53.1 (47.7–58.5)	39.0 (33.5–44.9)
Maine	25.3 (22.7–28.1)	29.0 (14.1–50.3) [§]	24.9 (17.2–34.7)	20.4 (14.9–27.4)	25.6 (21.3–30.4)	27.8 (23.6–32.3)
Maryland	37.4 (34.3–40.7)	16.7 (6.9–35.0) [§]	36.7 (27.3–47.2)	43.5 (35.4–51.8)	41.8 (36.8–47.1)	30.5 (25.7–35.8)
Massachusetts	30.0 (27.1–33.1)	35.9 (21.1–54.0) [§]	25.7 (17.3–36.3)	30.7 (23.4–39.1)	30.9 (26.1–36.2)	29.5 (24.9–34.5)
Michigan	32.4 (29.5–35.6)	40.1 (22.0–61.3) [§]	29.7 (21.2–39.9)	34.5 (27.0–42.9)	33.9 (29.1–39.0)	29.6 (25.1–34.6)
Minnesota	25.4 (22.6–28.4)	37.9 (22.9–55.6) [§]	27.4 (17.8–39.7) [§]	27.3 (20.9–34.8)	26.2 (21.9–31.1)	20.6 (16.3–25.6)
Mississippi	48.9 (45.5–52.2)	52.6 (30.0–74.2) [§]	45.1 (35.9–54.7)	44.5 (36.6–52.6)	60.7 (55.5–65.7)	36.2 (30.8–42.0)
Missouri	35.8 (32.7–38.9)	24.0 (12.7–40.8) [§]	35.9 (26.8–46.1)	37.0 (29.8–44.8)	37.6 (32.5–42.9)	33.8 (29.1–38.8)
Montana	27.5 (24.7–30.5)	35.5 (20.6–53.9) [§]	30.4 (21.7–40.7)	29.1 (22.4–36.9)	28.0 (23.4–33.1)	23.5 (19.6–27.9)
Nebraska	30.8 (27.7–34.0)	49.8 (31.8–67.9) [§]	29.1 (21.3–38.3)	26.0 (19.8–33.2)	31.0 (26.3–36.2)	31.2 (25.6–37.4)
Nevada	32.4 (29.2–35.6)	33.1 (19.0–51.2) [§]	33.4 (24.1–44.3) [§]	28.9 (22.1–36.8)	35.9 (30.8–41.3)	29.1 (23.7–35.1)
New Hampshire	27.0 (24.5–29.7)	28.9 (15.9–46.7) [§]	23.1 (14.4–34.8) [§]	23.4 (17.7–30.3)	26.4 (22.5–30.6)	30.8 (26.7–35.4)

See table footnotes on the next page.

TABLE 2. (Continued) Prevalence of short sleep duration* among persons aged 4 months–17 years, by age group and selected characteristics — National Survey of Children’s Health, United States, 2016–2018

Characteristic	% (95% CI) [†]					
	All persons aged 4 mos–17 yrs	Infants aged 4–11 mos	Children aged 1–2 yrs	Children aged 3–5 yrs	Children aged 6–12 yrs	Adolescents aged 13–17 yrs
New Jersey	34.6 (31.5–37.9)	41.4 (21.3–64.8) [§]	34.8 (24.8–46.3) [§]	37.7 (30.2–45.9)	33.0 (28.0–38.3)	34.2 (29.1–39.6)
New Mexico	33.8 (30.4–37.2)	42.5 (23.9–63.5) [§]	34.5 (24.8–45.8) [§]	35.9 (28.1–44.5)	35.7 (30.3–41.5)	28.6 (23.2–34.6)
New York	36.2 (32.9–39.6)	39.5 (22.0–60.2) [§]	25.5 (17.5–35.4)	32.2 (24.7–40.8)	39.7 (34.4–45.3)	37.4 (31.7–43.5)
North Carolina	36.8 (33.5–40.3)	48.6 (31.2–66.2) [§]	36.5 (26.3–48.0) [§]	38.9 (31.2–47.3)	37.7 (32.4–43.4)	33.0 (27.6–38.9)
North Dakota	25.4 (22.6–28.4)	24.1 (13.3–39.8) [§]	33.4 (24.4–43.8)	24.1 (17.7–31.8)	24.6 (20.2–29.6)	23.2 (19.3–27.7)
Ohio	34.8 (31.8–38.0)	44.3 (24.8–65.7) [§]	32.9 (23.8–43.5)	26.3 (20.2–33.4)	38.7 (33.7–43.9)	34.2 (29.0–39.8)
Oklahoma	35.3 (32.3–38.5)	37.1 (20.7–57.1) [§]	42.3 (32.5–52.6) [§]	30.6 (23.9–38.2)	36.0 (31.3–40.9)	34.2 (29.0–39.8)
Oregon	27.6 (24.6–30.7)	31.9 (18.0–50.1) [§]	33.5 (23.9–44.7) [§]	35.8 (27.7–44.8)	23.9 (19.7–28.7)	25.3 (20.8–30.5)
Pennsylvania	32.8 (29.9–35.9)	40.9 (24.3–59.8) [§]	27.5 (20.4–36.0)	32.9 (25.6–41.2)	35.9 (31.0–41.0)	29.0 (24.5–33.9)
Rhode Island	33.9 (30.8–37.1)	58.2 (40.0–74.4) [§]	25.5 (18.4–34.2)	30.2 (22.9–38.6)	35.5 (30.6–40.7)	33.7 (28.3–39.5)
South Carolina	40.2 (37.0–43.5)	30.6 (12.8–57.1) [§]	45.6 (36.2–55.4)	41.8 (33.5–50.5)	41.7 (36.6–47.0)	35.5 (30.2–41.1)
South Dakota	30.0 (27.2–32.9)	46.8 (33.0–61.2) [§]	29.1 (22.3–37.0)	31.3 (24.4–39.1)	28.9 (24.4–33.9)	27.7 (23.1–32.8)
Tennessee	39.1 (36.0–42.4)	58.3 (39.8–74.7) [§]	41.5 (32.4–51.1)	39.7 (32.4–47.6)	42.5 (37.4–47.7)	30.2 (25.5–35.4)
Texas	36.7 (33.3–40.2)	35.3 (21.1–52.6) [§]	41.8 (32.0–52.4) [§]	40.4 (31.9–49.6)	38.0 (32.6–43.8)	30.7 (25.0–37.1)
Utah	29.3 (26.5–32.3)	25.9 (14.0–42.8) [§]	31.6 (22.6–42.4)	24.0 (18.6–30.3)	32.3 (27.7–37.3)	28.0 (23.1–33.5)
Vermont	25.6 (22.9–28.6)	47.5 (29.4–66.2) [§]	26.5 (19.0–35.5)	26.6 (19.8–34.7)	25.6 (21.3–30.5)	21.8 (17.9–26.2)
Virginia	32.7 (29.7–35.8)	45.1 (26.0–65.7) [§]	33.1 (24.0–43.6)	32.2 (25.0–40.4)	35.1 (30.3–40.3)	28.5 (24.0–33.4)
Washington	30.5 (27.5–33.7)	43.4 (26.6–61.9) [§]	32.4 (23.4–42.9)	30.4 (23.6–38.3)	31.3 (26.3–36.7)	27.1 (22.1–32.7)
West Virginia	42.9 (39.7–46.3)	45.2 (30.0–61.2) [§]	47.4 (36.3–58.8) [§]	46.2 (38.3–54.3)	42.9 (37.9–48.1)	38.8 (33.4–44.5)
Wisconsin	28.9 (26.2–31.9)	46.3 (28.0–65.8) [§]	26.5 (19.0–35.8)	23.1 (17.3–30.3)	30.6 (26.3–35.4)	28.5 (24.0–33.4)
Wyoming	31.9 (28.9–35.0)	32.3 (18.0–50.8) [§]	33.6 (25.6–42.7)	30.2 (23.1–38.3)	36.4 (31.5–41.7)	25.1 (20.6–30.1)

Abbreviations: CI = confidence interval; FPL = federal poverty level.

* Short sleep duration is defined as <12 hours for infants aged 4–11 months, <11 hours for children aged 1–2 years, <10 hours for children aged 3–5 years, <9 hours for children aged 6–12 years, and <8 hours for adolescents aged 13–17 years.

[†] Weighted percentages. Weighted estimates generalize to state and national resident populations. <https://www2.census.gov/programs-surveys/nsch/technical-documentation/methodology/NSCH-Guide-to-Multi-Year-Estimates.pdf>; <https://www.census.gov/content/dam/Census/programs-surveys/nsch/tech-documentation/methodology/2016-NSCH-Methodology-Report.pdf>; <https://www.census.gov/content/dam/Census/programs-surveys/nsch/tech-documentation/methodology/2017-NSCH-Methodology-Report.pdf>; <https://www2.census.gov/programs-surveys/nsch/technical-documentation/methodology/2018-NSCH-Methodology-Report.pdf>

[§] Estimate might be unreliable. The absolute CI width is >20% or the relative CI width is >120% (1.2 times the estimate). https://www.childhealthdata.org/docs/default-source/drc/nsch_data-suppression-and-display_revised_03-01-19.pdf

[¶] Includes American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Asian, other race, or multiracial.

** FPL is based on family income and family size and composition using the U.S. Census Bureau’s poverty thresholds. Imputed income was used for persons aged 4 months–17 years without reported family income. <https://www.census.gov/topics/income-poverty/poverty/guidance/poverty-measures.html>

^{††} Special health care needs status is based on responses to the Children with Special Health Care Needs standardized five-item screener that included 1) the need for or use of medications (other than vitamins) prescribed by a doctor; 2) the need for or use of medical care, mental health, or educational services beyond those of a similarly aged person (referred to as “average use”); 3) limitation in the ability to do things most persons of the same age can do; 4) the need for or use of specialized therapies such as physical, occupational, or speech therapy; and 5) the need for or receipt of treatment or counseling for an emotional, behavioral, or developmental problem. <https://www.census.gov/content/dam/Census/programs-surveys/nsch/tech-documentation/methodology/2016-NSCH-Methodology-Report.pdf>; <https://www.census.gov/content/dam/Census/programs-surveys/nsch/tech-documentation/methodology/2017-NSCH-Methodology-Report.pdf>; <https://www2.census.gov/programs-surveys/nsch/technical-documentation/methodology/2018-NSCH-Methodology-Report.pdf>

^{§§} Regular bedtime is defined as a response of “always” to the question about how often the person aged 4 months–17 years goes to bed at approximately the same time on weeknights.

duration and can compound long-term health risks (6). Some parents, particularly those affected by socioeconomic and racial disparities, might face additional challenges to ensuring their infants, children, and adolescents get sufficient, quality sleep. For example, parents who work multiple jobs or do shift work might have difficulty implementing a consistent bedtime (6). In addition, a family’s housing situation could make achieving a quiet, comfortable sleep environment difficult because of noise, lack of sleeping space, or disruptive, unsafe, or violent neighborhoods (6).

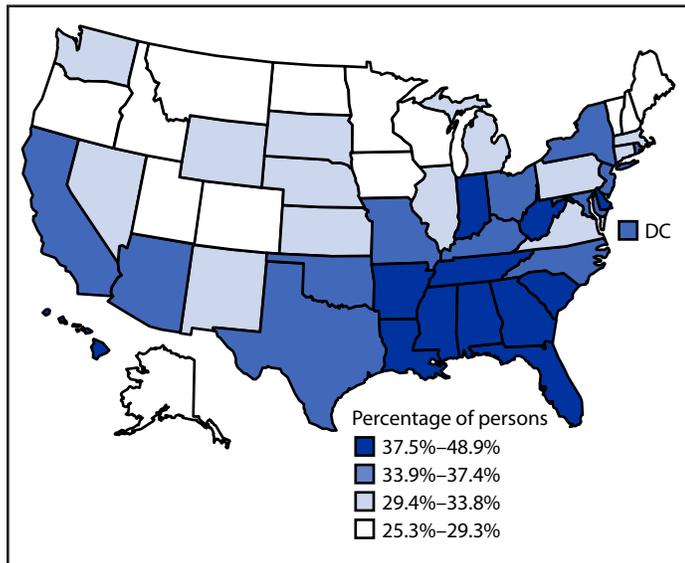
The prevalence of short sleep duration was higher among persons aged 4 months–17 years whose current health was rated less positively and among those with special health care needs.

Multiple conditions, including attention deficit/hyperactivity syndrome or other neurodevelopmental disorders, have been associated with sleep problems as well as sleep behaviors that might be amenable to behavioral intervention (7).

The prevalence of short sleep duration was highest in the Southeast, similar to geographic variation in adequate sleep observed for adults (8). This pattern might be partially explained by a higher prevalence of risks associated with poverty and racial and ethnic minority status in these states.^{¶¶¶} In a previous report of short sleep duration among high school students in 30 states, most of the states with a high prevalence of short sleep duration

^{¶¶¶} <https://www.census.gov/library/visualizations/interactive.html>

FIGURE. Prevalence of short sleep duration* among persons aged 4 months–17 years, by state — National Survey of Children’s Health, United States, 2016–2018



Abbreviation: DC = District of Columbia.

* Short sleep duration is defined as <12 hours for infants aged 4–11 months, <11 hours for children aged 1–2 years, <10 hours for children aged 3–5 years, <9 hours for children aged 6–12 years, and <8 hours for adolescents aged 13–17 years.

were in the Midwest and Northeast (2). However, that report relied on self-report rather than parent report, did not include younger children, and excluded 20 states.

The findings in this report are subject to at least five limitations. First, sleep duration was obtained by parent report without objective measures, such as actigraphy**** or polysomnography. Second, parent reports of sleep duration might be less reliable than are self-report for older children or adolescents (3). Third, responses might be affected by recall bias, interpretation of items, or social desirability. Fourth, the statistical weighting might not completely account for non-response bias. Finally, the analyses with race/ethnicity were univariate and did not adjust for other covarying sociodemographic characteristics.

Insufficient sleep is an important risk factor for poor physical and mental health in infants, children, and adolescents (1). Parents can help persons aged 4 months–17 years get the sleep they need by supporting good sleep habits. Establishing a regular bedtime is a good foundation and is associated with more sleep (9,10). The AASM’s Bedtime Calculator†††† identifies appropriate bedtimes based on age-specific sleep duration recommendations and provides tips on bedtime routines

**** <https://sleepeducation.org/patients/actigraphy/>

†††† <https://sleepeducation.org/healthy-sleep/bedtime-calculator/>

Summary

What is already known about this topic?

Infants, children, and adolescents who do not get sufficient sleep are at increased risk for adverse health outcomes. Most adolescents report sleeping less than the recommended amount. Little is known about sleep duration in infants and children.

What is added by this report?

During 2016–2018, approximately one third of children aged 4 months–17 years slept less than recommended for their age, particularly those from racial and ethnic minority groups, of low socioeconomic status, and with special health care needs. Infants, children, and adolescents with regular bedtimes were more likely to get enough sleep.

What are the implications for public health practice?

Public health practitioners, educators, and clinicians can advise parents about the importance of infants, children, and adolescents meeting recommended sleep durations, investigate the social and environmental context that affects sleep, and support parents in implementing consistent bedtimes.

for parents of infants and children and for adolescents and adults. Clinicians and educators can guide parents about the importance of sleep at all ages and discuss sleep routines and sleep problems with parents, children, and adolescents, paying attention to those with special health care needs (7). When advising parents on how to improve their infant’s, child’s, or adolescent’s sleep, challenges that they might face because of their social and environmental context should be considered. School districts can support adequate sleep for adolescents by delaying school start times as recommended by several medical associations (2).

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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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Increasing Access to HIV Testing Through Direct-to-Consumer HIV Self-Test Distribution — United States, March 31, 2020–March 30, 2021

Jen Hecht, MPH¹; Travis Sanchez, DVM²; Patrick S. Sullivan, PhD²; Elizabeth A. DiNenno, PhD³; Natalie Cramer, MSSW⁴; Kevin P. Delaney, PhD³

During 2019, approximately 34,800 new HIV infections occurred in the United States (1), and it is estimated that approximately 80% of HIV transmission occurs from persons who either do not know they have HIV infection or are not receiving regular care (2). Since 2006, CDC has recommended that persons who are disproportionately affected by HIV (including men who have sex with men [MSM]) should test for HIV at least annually (3,4). However, data from multiple sources indicate that these recommendations are not being fully implemented (5,6). TakeMeHome, a novel public-private partnership to deliver HIV self-testing kits to persons seeking HIV testing in the United States, was launched during March 2020 as home care options for testing became increasingly important during the COVID-19 pandemic. The initiation of the program coincided with the national COVID-19 Public Health Emergency declaration, issuance of stay-at-home orders, and other restrictions that led to disruption of traditional HIV testing services. During March 31, 2020–March 30, 2021, 17 state and local health departments participating in the program allowed residents of their jurisdictions to order test kits. Marketing for TakeMeHome focused on reaching gay, bisexual, and MSM through messages and embedded links in gay dating applications. Most participants in the program reported that they had either never tested for HIV (36%) or that they had last tested >1 year before receiving their self-test kit (56%). After receiving the self-test kit, >10% of respondents reported accessing additional prevention services. Health departments can increase options for HIV testing by distributing publicly funded self-test kits to persons without proximate access to clinic-based testing or who prefer to test at home. Increased and regular HIV testing among MSM will help meet annual testing goals.

Self-testing is an effective HIV screening method for MSM (7) that can facilitate access to antiretroviral treatment, preexposure prophylaxis (PrEP), and other prevention services (8). The COVID-19 pandemic disrupted HIV testing services, persons reported not being able to access HIV testing services (9), and hundreds of thousands of HIV screening tests were either delayed or skipped (10). CDC sent a “Dear Colleague” letter on April 28, 2020* recommending that grantees consider HIV self-testing as an option to fill the gap in prevention services.

* https://www.cdc.gov/nchstp/dear_colleague/2020/dcl-042820-HIV-self-testing-guidance.html

This report describes the use and results of TakeMeHome,[†] a centralized system established during March 2020 to distribute HIV self-test kits.

TakeMeHome offers rapid HIV self-tests (OraQuick In-Home HIV Test), paid for by state and local health departments or other partners at no cost to persons in participating jurisdictions. The program was developed by Building Healthy Online Communities (BHOC)[§] in partnership with the National Alliance of State and Territorial AIDS Directors (NASTAD)[¶] and Emory University.** From its inception on March 31, 2020, TakeMeHome established eligibility criteria included residence in a participating zip code, age ≥18 years, and report of no HIV test in the past 12 months. Eligibility was later expanded to persons reporting more recent HIV tests in some participating locations, per jurisdiction request. Several jurisdictions also chose to allow up to two kits per order. All participants were offered a nonincentivized follow-up survey 10 days after their HIV test kit was mailed. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy. CDC’s role was to provide technical assistance.^{††} Results of the evaluation were analyzed using SPSS software (version 26; IBM).

Characteristics of persons who ordered kits are summarized for all participants. For the subset of persons who ordered kits and responded to the BHOC follow-up survey, reasons for ordering a self-test kit and the proportion of persons who reported accessing other HIV and sexually transmitted infection (STI) prevention services were calculated. To date, two participating health departments established matches between persons who ordered kits and HIV case surveillance to document new diagnoses in persons who had participated in HIV self-testing.

Seventeen health jurisdictions supported self-test kit distribution for their residents during the first year of the program (14 for 6–12 months and three for <6 months). During this time, 5,325 kits were mailed to 4,904 persons. Sixty-seven percent of participants were cisgender men; 6% were transgender, nonbinary, or genderqueer (Table 1). Overall, 1,764 participants (36%) reported never having tested for HIV

[†] <https://takemehome.org/>

[§] <https://bhocpartners.org/>

[¶] <https://www.nastad.org/domestic/hiv-prevention>

** <https://prismhealth.emory.edu/>

^{††} 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.

before ordering an HIV self-test. Among 855 respondents to the follow-up survey (17% of persons who received kits), 73% reported male-to-male sexual contact (Table 2). Most survey respondents reported hearing about the program through marketing by BHOC within gay dating applications (71%),

TABLE 1. Number and percentage of HIV self-test kit orders, overall and by selected characteristics — TakeMeHome program, United States, March 31, 2020–March 30, 2021

Characteristic	No. (%)
Total number of orders	4,904 (100)
Sex at birth*	
Male	4,398 (90)
Female	506 (10)
Current gender identity†	
Man	3,304 (67)
Woman	348 (7)
Transgender/Nonbinary/Genderqueer	282 (6)
Missing	970 (20)
Age group, yrs	
18–24	1,461 (30)
25–34	1,907 (39)
35–44	785 (16)
45–54	343 (7)
≥55	147 (3)
Missing	261 (5)
Race/Ethnicity (multiple responses permitted)§	
American Indian/Alaskan Native	51 (1)
Asian or Pacific Islander	334 (7)
Black/African American	358 (7)
Hispanic or Latino¶	1,295 (26)
Multiple races/Other	170 (3)
White	1,863 (38)
Missing	833 (17)
Number of sex partners in past 12 months	
0	7 (<1)
1	1,656 (34)
2	461 (9)
≥3	1,281 (26)
Missing	1,499 (31)
Time since last HIV test**	
Never tested	1,764 (36)
>1 year	2,746 (56)
≤1 year	117 (2)
Missing	277 (6)

* Sex at birth was categorized as male or female.

† Gender identity is based on the participant's self-categorization in one of three groups at the time of the survey. Thus, man and woman could include persons whose birth sex differs from their current identity. Other gender identities were identified using the umbrella category of transgender/nonbinary/genderqueer regardless of their sex assigned at birth.

§ Race/ethnicity was asked as a single question, and persons could select multiple responses, including "Hispanic or Latino". If someone selected more than one race and did not select "Hispanic or Latino," they were categorized as multiracial.

¶ Hispanic/Latino includes anyone who selected this option regardless of whether or not they selected any other race/ethnicity category.

** Time since last HIV test was recorded as "Never," "Less than 3 months ago," "4–6 months ago," "7–12 months ago," and "More than a year ago," and recategorized to differentiate those who never tested, tested within the past year, and who last tested >1 year ago. Through March 2021, only four of 17 health jurisdictions participating in TakeMeHome allowed orders from persons who reported testing in the past year

believing that the program addressed issues of convenience (63%) and privacy (46%), and being willing to recommend the program to a friend (90%). After receiving the self-test kit, 10% of respondents reported accessing additional STI testing, and 8% reported accessing PrEP. Among persons who had never previously tested for HIV, 8% reported additional STI testing, and 6% reported accessing PrEP after participating in the program (Figure). The two health departments that matched kit orders to HIV case surveillance estimated that 0.6%–0.8% of those who received a kit were subsequently reported to have newly diagnosed HIV.

Discussion

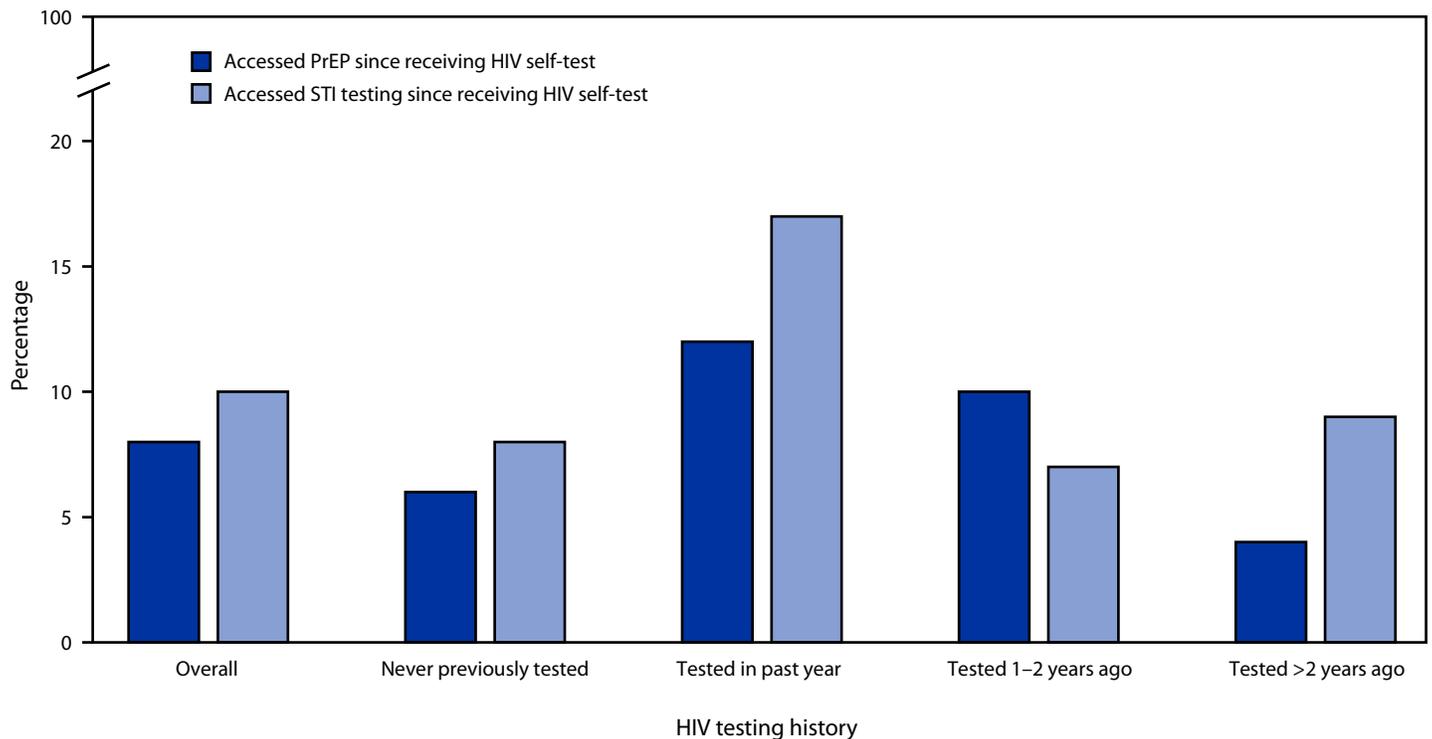
TakeMeHome demonstrates the opportunity to provide options for HIV testing to persons who might be reticent or unable to seek clinic- or community-based testing. The program reached critical populations for HIV testing; 36% of participants reported no previous HIV test, and 86% reported recent HIV risk. Most participants stated they would recommend the program to others, and >10% of participants reported that after using the HIV self-test, they sought other HIV and STI prevention services. In addition, 34% of participants reported using

TABLE 2. Follow-up survey results, overall and by selected respondent characteristics — TakeMeHome program, United States, March 31, 2020–March 30, 2021

Characteristic	No. (%)
Total	855 (100)
How did you hear about TakeMeHome?	
Dating app	605 (71)
Public health campaign	105 (12)
Friend	25 (3)
Google/Other website	97 (11)
Missing	23 (3)
Risk category (multiple responses permitted)	
Male-to-male sexual contact	625 (73)
Injection drug use	29 (3)
Partner injection drug use or partner HIV-positive	57 (7)
Multiple sex partners	484 (57)
STI diagnosis or treatment for TB or HCV	60 (7)
No HIV risk reported	85 (10)
Missing	35 (4)
Reasons for participating (multiple responses permitted)	
It was free	549 (64)
It was convenient	542 (63)
I prefer testing in the privacy of my home	395 (46)
I feel uncomfortable going to a doctor in my area	267 (31)
I don't know where to go	160 (19)
COVID-19 has limited regular testing in my area	294 (34)
Missing	40 (5)
Would you recommend TakeMeHome to a friend?	
Yes	770 (90)
Maybe	32 (4)
No	6 (1)
Missing	47 (5)

Abbreviations: HCV = hepatitis C virus; STI = sexually transmitted infection; TB = tuberculosis.

FIGURE. Self-reported access to preexposure prophylaxis or testing for sexually transmitted infection after receiving an HIV self-test kit,* by reported HIV testing history — TakeMeHome HIV self-test kit distribution program, March 31, 2020–March 30, 2021†



Abbreviations: PrEP = preexposure prophylaxis; STI = sexually transmitted infection.

* Among 569 TakeMeHome program participants who responded to a follow-up survey and completed the HIV testing history question.

† As of March 30, 2021, only four of 17 health departments participating in the TakeMeHome program allowed persons who had tested in the past year to order HIV self-test kits; all others required that the participant had not tested in the past year.

TakeMeHome because of decreased availability of HIV testing in their area due to COVID-19, which highlights changing healthcare needs due to the COVID-19 pandemic.

Partnerships between BHOC and dating apps allowed for extensive in-kind promotion of TakeMeHome to specific populations. The program also created social media posts and images to share with jurisdiction partners and provided support for jurisdiction-specific plans to promote the program. States participating in TakeMeHome are also listed on CDC's HIV self-testing information page,^{§§} and NASTAD and BHOC continue to encourage participation by other jurisdictions. This project also served as a predecessor to a national TakeMeHome demonstration project^{¶¶}; the national demonstration project is open to persons aged >17 years living in the United States and Puerto Rico and has partnered with CDC's Let's Stop HIV Together Campaign^{***} to promote the distribution of free HIV self-tests within the most affected populations. The national program model overcame the need to establish

separate contractual agreements for each jurisdiction, allowing for nationwide expansion. Through the Let's Stop HIV Together campaign, self-tests are marketed directly to priority populations using social media, paid media, and partner outreach. The national demonstration project began during February 2021, and through July 2021, a total of 43,568 orders were placed for 76,232 HIV self-test kits by persons from all 50 states, the District of Columbia, and Puerto Rico.

The findings in this report are subject to at least one limitation. Compared with traditional HIV testing programs, self-testing presents additional challenges to documenting whether the test was used and by whom, as well as challenges documenting a test result and linkage to HIV care or prevention services. TakeMeHome offers multiple resources to help participants interpret their self-test results and access services after testing, but a low response rate for the follow-up survey limited the data available to evaluate accessing of these services and might have introduced bias in the responses. Encouraging participants to access services following a self-test is one method for getting test results reported to public health organizations, but the findings in this report indicate a need to explore other

^{§§} <https://www.cdc.gov/hiv/basics/hiv-testing/hiv-self-tests.html>

^{¶¶} <https://together.takemehome.org>

^{***} <https://www.cdc.gov/stophivtogether/index.html>

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

Gay, bisexual, and other men who have sex with men (MSM) should be tested for HIV at least annually. Major disruptions to HIV testing services occurred during the COVID-19 pandemic.

What is added by this report?

During March 2020–March 2021, a novel public-private partnership provided free HIV self-test kits directly to MSM. Most participants reported they had never tested (36%) or tested >1 year ago (56%); approximately 10% reported accessing services including sexually transmitted infection testing and preexposure prophylaxis after using the self-test.

What are the implications for public health practice?

Public funding of HIV self-testing can engage MSM who never previously tested and might increase HIV testing frequency among this population.

strategies to increase follow-up survey response rates and obtain information about the use of HIV prevention and care after self-testing. For example, HIV prevention and care programs and the HIV surveillance system can document use of HIV self-tests with their clients and among persons with newly diagnosed HIV infection, respectively.

HIV self-testing is a proven intervention (7) that represents a paradigm shift in testing practices and is a key strategy to support the goals of the Ending the HIV Epidemic in the United States initiative (EHE).^{†††} TakeMeHome was conceived to help achieve EHE testing goals; the onset of the COVID-19 pandemic accelerated implementation as home health care options became necessary. This report provides data indicating that implementation of Internet-based self-test distribution reached populations of MSM who had never tested or who tested less frequently than annually. Further, HIV self-test distribution addresses many privacy concerns, and this program demonstrated, among the subset who provided follow-up data, that self-testing served as a bridge to additional HIV and STI prevention services for persons who needed them. However, data from this report suggest limited coverage of the program among Black persons. Further expansion to include marketing tailored to minority groups disproportionately affected by HIV, especially Black and Hispanic MSM, as well as engaging health department jurisdictions with higher proportions of disproportionately affected populations will be necessary as the program expands. Local and national public health programs can further expand access to HIV testing through self-testing

^{†††} TakeMeHome is intended to help mitigate the impact of undiagnosed and untreated HIV by expanding access to testing and treatment nationwide to achieve the goal of diagnosing persons with HIV as early as possible after infection. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>

programs and, through focused advertising, might be able to increase the number of persons tested and testing frequency among MSM and other populations disproportionately affected by HIV to help achieve the goals of EHE.

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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. Jen Hecht reports institutional funding from Gilead Sciences. Patrick S. Sullivan reports institutional funding from the National Institutes of Health (NIH), Elsevier, Gilead Sciences, Insignia Consulting, and Guardant Health, and consulting fees from NIH and Merck. No other potential conflicts of interest were disclosed.

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Nonvoluntary or Forced Sex Among Women, by Sexual Identity, Attraction, and Behavior — National Survey of Family Growth, United States, 2011–2017

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Nonheterosexual (sexual minority) women report experiencing more sexual violence than heterosexual (sexual majority) women (1,2). Sexual minority women are often categorized as a collective whole, which fails to capture the nuances in sexual violence among subgroups of sexual minority women, such as bisexual and lesbian women (3). To estimate the prevalence of lifetime forced vaginal intercourse (forced sex) and of nonvoluntary first vaginal intercourse among women aged 18–44 years in the United States, CDC analyzed data from female respondents who were interviewed during 2011–2017 for the National Survey of Family Growth (NSFG); respondents were stratified by self-reported sexual identity, attraction, and behavior. Log-binomial regressions and analyses of variance (ANOVAs) were performed to compare experiences across each dimension of sexual orientation, controlling for demographic characteristics. Compared with sexual majority women,* prevalence of any male-perpetrated nonvoluntary first vaginal intercourse or forced sex (nonvoluntary or forced sex) was higher among women who identified as bisexual (36.1% versus 17.5%), reported attraction to the opposite and same sex (30.3% versus 15.8%), and reported sexual behavior with the opposite and same sex (35.7% versus 15.9%). These sexual minority women reported that their earliest experience of nonvoluntary or forced sex occurred at younger ages than did that of sexual majority women. Among women who were unsure of their sexual attraction, the prevalence of nonvoluntary first vaginal intercourse was also higher than among sexual majority women. These findings underscore the need for comprehensive prevention approaches tailored for sexual minority women and prevention of child sexual abuse, given the average ages at earliest nonvoluntary or forced sex experience among sexual minority women (range = 12.5–16.3 years). Additional research is needed into the circumstances of and norms or attitudes that influence perpetration of nonvoluntary or forced sex and broader sexual violence against sexual minority women. Prevention of nonvoluntary or forced sex victimization among sexual minority women will require comprehensive approaches to prevent sexual violence and child sexual abuse. Engaging sexual minority women in the development of sexual violence

* Sexual majority refers to those whose sexual orientation aligns with the presumed majority of the population. The term is used here to include respondents who identified as being heterosexual or straight, reported attraction to the opposite sex only, or reported sexual behavior with the opposite sex only.

prevention efforts and research would help ensure that the experiences of sexual minority women across the spectrum are represented.

NSFG is a nationally representative, cross-sectional household survey conducted continuously by CDC's National Center for Health Statistics (NCHS) that collects data on factors influencing reproductive health in the United States.[†] Data from women aged 18–44 years[§] in the three most recent releases (2011–2013, 2013–2015, and 2015–2017) were combined. Response rates for female participants ranged from 66.7% to 73.4%. To account for the multistage probability-based cluster sample design, 6-year weights provided by NSFG were applied during analysis using complex survey design functions in R statistical software (version 3.6.1; R Foundation) to reflect the female household population of the United States at the midpoint of data collection (July 2014). Sexual orientation, a multidimensional function of sexual identity, attraction, and behavior, was captured through measures of self-reported sexual identity[¶] and attraction^{**} at time of interview and lifetime sexual behavior^{††} (any sexual contact). Respondents aged ≥18 years were asked about experiences with nonvoluntary and forced sex: “Did you choose to have [first vaginal intercourse] of your own free will or not?” (nonvoluntary first vaginal intercourse), and “At any time in your life (besides the time you already reported), have you ever been forced by a male to have

[†] <https://www.cdc.gov/nchs/nsfg/index.htm>

[§] From 2011 to 2015, NSFG was conducted among females aged 15–44 years. This age range was expanded in 2015 to include women aged 45–49 years. To maintain a consistent age range and apply NCHS-provided weights, respondents aged 45–49 years interviewed during 2015–2017 were excluded in analysis. Respondents aged <18 years were not asked questions relating to nonvoluntary or forced sex.

[¶] Sexual identity was assessed by asking the respondents whether they thought of themselves (at the time of the interview) as heterosexual or straight; homosexual, gay, or lesbian; or bisexual.

^{**} Sexual attraction to other persons (at time of the interview) was assessed through self-reports of being only attracted to the opposite sex; mostly attracted to the opposite sex; equally attracted to the opposite and same sex; mostly attracted to the same sex; only attracted to the same sex; or not sure. Respondents who reported being mostly attracted to the opposite sex, equally attracted to the opposite and same sex, or mostly attracted to the same sex were coded as being attracted to both the opposite and same sex.

^{††} Lifetime sexual behavior was measured using experiences of oral, vaginal, or anal sex with male or female partners at any time in the respondent's life. Based on responses to two separate survey questions about sexual experiences with male partners and female partners, a composite sexual behavior variable was created with four categories: opposite sex only, same sex only, opposite and same sex, and no sexual behavior.

vaginal intercourse against your will?” (forced sex). Responses from both questions were used to create the collective measure of nonvoluntary or forced sex. Age at the earliest experience of nonvoluntary or forced sex was used in this analysis.

Estimated prevalence and associated 95% confidence intervals of any nonvoluntary or forced sex were calculated for respondents with nonmissing responses. Log-binomial regression models were used to generate prevalence ratios and test associations between each dimension of sexual orientation and nonvoluntary first vaginal intercourse or forced sex, adjusting for age, race and ethnicity, highest educational degree received, and poverty status.^{§§} ANOVAs were performed to compare mean age at first nonvoluntary or forced sex experience between women of different sexual orientations. Because of small cell sizes, results for nonvoluntary or forced sex among women with same-sex-only sexual behavior were omitted from the main findings in this report.^{¶¶} This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.^{***}

The aggregated analytic sample included 14,309 female respondents.^{†††} Significant differences in demographic characteristics (i.e., race and ethnicity, educational attainment, and federal poverty level) were found (Table 1); 18.7% of respondents reported experiencing nonvoluntary or forced sex in their lifetime (Table 2). Lifetime prevalence of nonvoluntary or forced sex was higher among women identifying as bisexual (36.1%), those reporting attraction to the opposite and same sex (30.3%), and those reporting sexual contact with the opposite and same sex (35.7%) than among sexual majority women; among women not sure of their sexual attraction, prevalence was 28.9% (Table 2). Compared with sexual majority women, prevalence of nonvoluntary first vaginal intercourse

was significantly higher among women identifying as lesbian (adjusted prevalence ratio [aPR] = 2.0) or bisexual (aPR = 2.4), reporting attraction to the same sex only (aPR = 2.2) or to the opposite and same sex (aPR = 1.9) or reporting sexual contact with the opposite and same sex (aPR = 1.9). Prevalence of nonvoluntary first vaginal intercourse was 3.7 times as high among women not sure of their sexual attraction as among women reporting opposite sex only attraction (Table 3).

Compared with sexual majority women, the prevalence of forced sex was significantly higher among women who identified as bisexual (aPR = 2.0), reported attraction to the opposite and same sex (aPR = 2.1), or reported sexual behavior with the opposite and same sex (aPR = 2.5) (Table 3). Prevalence of overall nonvoluntary or forced sex was approximately twice as high among women identifying as bisexual, reporting attraction to the opposite and same sex, and reporting sexual contact with the opposite and same sex as among sexual majority women and was significantly higher among women not sure of their sexual attraction than among those attracted only to the opposite sex (aPR = 1.7). Average age of earliest experience of nonvoluntary or forced sex was significantly younger among all sexual minority women (except women not sure of their sexual attraction) than among sexual majority women (ranges = 12.5–16.3 versus 17.0–17.3 years). Average age of first nonvoluntary or forced sex experience was youngest among women reporting no sexual behavior with males (9.9 years).^{§§§}

Discussion

These results are consistent with past findings that sexual minority women experience higher risk for nonvoluntary or forced sex than do sexual majority women, and that sexual minority women experience initial nonvoluntary or forced sex at younger ages than sexual majority women (1,2). These findings extend past research to demonstrate differences in prevalence of nonvoluntary or forced sex among subgroups of women along the spectrum of minority sexual identity, attraction, and behavior. A prominent explanation for the higher prevalence of violence experienced by sexual minority women is sexual minority stress theory, which hypothesizes that chronic stigma and discrimination contribute to the marginalization of sexual minorities (4); however, additional research is needed to understand the link between the early age of onset of violence given that some sexual minority women might not have identified as such when the violence occurred. Restrictive and harmful social norms regarding gender and sexuality might explain perpetration of violence against sexual

^{§§} Sociodemographic characteristics included in the analysis were age at the time of interview, race and ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic, or other), highest degree received (no diploma or general education development certificate [GED], high school diploma or GED, associate or bachelor's degree, or master's degree or higher), and poverty status (at or below or above 130% of the federal poverty level).

^{¶¶} Among the 97 persons reporting a history of same-sex-only sexual behavior, lifetime prevalence of nonvoluntary or forced sex was 3.7% (5; 95% confidence interval [CI] = 0.9–9.7). Compared with women reporting sexual behavior with the opposite sex only, among women reporting sexual history with the same sex only the prevalence of forced sex (aPR = 0.3; 95% CI = 0.1–1.0) and lifetime nonvoluntary or forced sex (aPR = 0.3; 95% CI = 0.1–0.8) were significantly lower. Average age of first experience of nonvoluntary or forced sex was significantly younger among those with same-sex-only sexual behavior than among those with opposite sex only sexual behavior (13.7 versus 17.3 years).

^{***} 45 C.F.R. part 46.102(l)(2); 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 16,954 female respondents from the 2011–2017 surveys, 11.2% (1,893) were missing data on nonvoluntary or forced sex, 0.6% (105) had no data for any sexual orientation components, and 4.5% (763) were missing survey weights. Altogether, 2,645 respondents were excluded from analysis because of incomplete data.

^{§§§} Reports of nonvoluntary or forced sex among women who report no history of sexual behavior with males are likely due to a distinction between forced sex as an act of violence rather than a sexual experience.

TABLE 1. Sociodemographic characteristics of women aged 18–44 years (N = 14,309), by nonvoluntary or forced sex experience* — National Survey of Family Growth, United States, 2011–2017

Characteristic	Unweighted no. (weighted %)			p-value
	Overall (N = 14,309)	No nonvoluntary or forced sex (n = 11,402)	Any nonvoluntary or forced sex* (n = 2,907)	
Age, mean (SD), yrs	30.9 (7.7)	30.7 (7.7)	31.8 (7.7)	<0.001
Race or ethnicity				
White, non-Hispanic	6,824 (58.3)	5,351 (58.1)	1,473 (59.0)	<0.001
Black, non-Hispanic	3,193 (14.6)	2,472 (13.7)	721 (18.6)	
Hispanic	3,385 (20.1)	2,831 (20.9)	554 (16.7)	
Other	907 (7.1)	748 (7.3)	159 (5.8)	
Highest degree received				
No diploma or GED	1,875 (10.5)	1,457 (10.3)	418 (11.6)	<0.001
High school or equivalent	7,492 (50.2)	5,835 (48.5)	1,657 (57.6)	
Associate or bachelor's	3,668 (28.7)	3,009 (29.6)	659 (24.5)	
Master's or higher	1,274 (10.6)	1,101 (11.5)	173 (6.4)	
Federal poverty level				
≤130%	5,641 (32.9)	4,247 (31.1)	1,394 (40.6)	<0.001
>130%	8,668 (67.1)	7,155 (68.9)	1,513 (59.4)	

Abbreviations: GED = general education development certificate; SD = standard deviation.

* Nonvoluntary or forced sex experience was measured using responses to two questions: whether first vaginal intercourse was “voluntary or not voluntary, that is, did you choose to have sex of your own free will or not?” and “At any time in your life (besides the time you already reported), have you ever been forced by a male to have vaginal intercourse against your will?”

and gender minorities (5). Bisexual women represent a unique subpopulation of sexual minority women who might further experience discrimination not experienced by their homosexual or lesbian peers (6). Rape myths portraying bisexual women as promiscuous and confused about their sexuality could increase perpetration against these women and explain their elevated risk for sexual violence victimization (6). Understanding harmful attitudes toward bisexual women in relation to sexual victimization and perpetration might help explain this higher prevalence ratio for bisexual women. Further research is needed to understand the social mechanisms, including circumstances of nonvoluntary or forced sex and norms and attitudes about sex and sexuality, that underlie differences in nonvoluntary or forced sex experiences among sexual minority women and bisexual women specifically (7).

Harmful attitudes and norms might also partly explain early occurrences of nonvoluntary or forced sex and high prevalence of nonvoluntary first vaginal intercourse among sexual minority women (6). By measuring sexual orientation in a multidimensional way, this study demonstrates the high prevalence of lifetime nonvoluntary or forced sex, and nonvoluntary first vaginal intercourse in particular, among women who are unsure of their sexual attraction. Disproportionate risk for nonvoluntary or forced sex, and potentially sexual violence more broadly, accompany minority sexual identity, attraction, and behavior. Approaching sexual orientation as a function of sexual identity, attraction, and behavior is critical to fully understanding the disparities in female sexual victimization, associations between sexuality and violence victimization and

perpetration, and the early age at which sexual minority women first experience nonvoluntary or forced sex (7).

The findings in this report are subject to at least four limitations. First, gender identity (i.e., a person's internalization of their own gender) or expression (i.e., a person's outward presentation of their gender), which can further exacerbate risks of sexual violence associated with sexual identity (2), is not captured in NSFG. Sociodemographic characteristics were also accounted for but not evaluated in depth. Additional research is needed to understand how intersecting social identities of gender identity, race/ethnicity, and sexual minority status might interact in complex ways that could affect persons' disproportionate experiences of nonvoluntary or forced sex (8). Second, this survey does not capture female-perpetrated nonvoluntary or forced sex, other types of penetration, or nonpenetration forms of sexual violence (e.g., attempted rape or sexual harassment), nor does it account for underreporting of nonvoluntary or forced sex (9). Third, cross-sectional surveys have the potential for recall bias and cannot confirm whether observed associations are causal. Longitudinal studies are needed to further understand experiences of sexual minority women across their lifetime, including the circumstances preceding nonvoluntary or forced sex. Finally, estimates of experience with nonvoluntary or forced sex among women reporting no sexual behavior with male partners are likely a reflection of the distinction between forced sex as an act of violence rather than a sexual experience (10). Inability to determine whether this distinction was consistent among all responses is a limitation of the sexual behavior measure; this

TABLE 2. Estimated prevalence of nonvoluntary or forced sex* among women aged 18–44 years (N = 14,309), by sexual orientation — National Survey of Family Growth, United States, 2011–2017

Sexual orientation	Unweighted no.	Any nonvoluntary or forced sex*		p-value [†]
		Unweighted no.	Weighted % (95% CI)	
Total	14,309	2,907	18.7 (17.7–19.6)	N/A
Sexual identity[§]				
Heterosexual or straight (sexual majority)	12,843	2,425	17.5 (16.5–18.4)	
Lesbian or gay	295	73	18.2 (12.7–24.8)	<0.001
Bisexual	991	362	36.1 (31.8–40.5)	
Sexual attraction[¶]				
Opposite sex only (sexual majority)	11,141	1,934	15.8 (14.8–16.9)	
Same sex only	194	51	19.8 (12.7–28.3)	<0.001
Opposite and same sex	2,740	850	30.3 (27.7–32.9)	
Not sure	213	67	28.9 (21.3–37.4)	
Lifetime sexual behavior^{**}				
Opposite sex only (sexual majority)	10,801	1,854	15.9 (14.9–16.9)	
Same sex only ^{††}	—	—	—	<0.001
Opposite and same sex	2,715	1,031	35.7 (33.1–38.4)	
No sexual behavior	667	9	1.8 (0.4–5.1) ^{§§}	

Abbreviations: CI = confidence interval; N/A = not applicable.

* Nonvoluntary or forced sex experience was measured using responses to two questions: whether first vaginal intercourse was “voluntary or not voluntary, that is, did you choose to have sex of your own free will or not?” and “At any time in your life (besides the time you already reported), have you ever been forced by a male to have vaginal intercourse against your will?”

[†] Comparisons within subgroups were evaluated on weighted prevalence estimates via chi-square tests. Statistical significance was evaluated at a threshold of $\alpha = 0.05$.

[§] Sexual identity was assessed by asking the respondents whether they thought of themselves (at time of the interview) as heterosexual or straight; homosexual, gay, or lesbian; or bisexual.

[¶] Sexual attraction to other persons (at time of the interview) was assessed through self-reports of being only attracted to the opposite sex; mostly attracted to the opposite sex; equally attracted to the opposite and same sex; mostly attracted to the same sex; only attracted to the same sex; or not sure. Respondents who reported being mostly attracted to the opposite, equally attracted to the opposite and same sex, or mostly attracted to the same sex were coded as being attracted to both the opposite and same sex.

^{**} Lifetime sexual behavior was measured using experiences of oral, vaginal, or anal sex with male or female partners at any time in the respondent’s life. Based on responses to two separate survey questions regarding sexual experiences with male partners and female partners, a composite sexual behavior variable was created with four categories: opposite sex only, same sex only, opposite and same sex, and no sexual behavior.

^{††} Because of small cell sizes for reported nonvoluntary or forced sex among women reporting same sex only sexual behavior and ambiguity regarding interpretation, analysis results for this sexual behavior group have been omitted from main findings.

^{§§} Estimates for women reporting no sexual behavior with male partners are likely a reflection of the distinction between forced sex as an act of violence rather than a sexual experience.

inability highlights a need for expanded health research to more accurately and comprehensively capture the impact experienced by all subgroups of sexual minority women. Despite these limitations, these analyses provide nationally representative estimates of nonvoluntary or forced sex among sexual minority women, stratified by sexual identity, attraction, and behavior, in the United States.

Given the higher prevalence of nonvoluntary or forced sex associated with minority sexual identity, attraction, and behavior, comprehensive efforts to prevent victimization of sexual minority women are warranted. These findings highlight the need to engage sexual minority women in the development of targeted primary prevention efforts. Comprehensive efforts based on best available evidence, including emphasizing approaches to changing gender and sexuality norms and attitudes, improving bystander behaviors, empowering sexual minority women and girls, and creating protective environments, could be enhanced to address perpetration of nonvoluntary or forced sex and victimization among sexual

Summary

What is already known about this topic?

Sexual minority women are more likely to experience sexual violence than sexual majority women.

What is added by this report?

Among women aged 18–44 years surveyed during 2011–2017, lifetime prevalence of nonvoluntary or forced sex was highest among bisexual women (36.1%). Compared with sexual majority women, nonvoluntary first vaginal intercourse was more prevalent among sexual minority women; first experience of nonvoluntary or forced sex occurred at younger ages.

What are the implications for public health practice?

Prevention of nonvoluntary or forced sex victimization among sexual minority women will require comprehensive approaches to prevent sexual violence and child sexual abuse. Engaging sexual minority women across the spectrum in primary prevention efforts could help ensure intervention effectiveness.

TABLE 3. Prevalence ratios of experiences of nonvoluntary or forced sex among women aged 18–44 years (N = 14,309), by sexual orientation — National Survey of Family Growth, United States, 2011–2017

Characteristic	Adjusted PR* (95% CI) [†]			Mean (SE) [§]
	Nonvoluntary first vaginal intercourse [¶]	Forced sex ^{**}	Any nonvoluntary or forced sex ^{††}	Age at earliest occurrence of nonvoluntary or forced sex, yrs
Sexual identity^{§§}				
Heterosexual or straight (sexual majority)	Ref	Ref	Ref	17.0 (0.2)
Lesbian or gay	2.0 (1.3–3.1) ^{¶¶}	1.1 (0.7–1.6)	1.0 (0.7–1.4)	12.7 (1.1) ^{***}
Bisexual	2.4 (1.8–3.2) ^{***}	2.0 (1.8–2.4) ^{***}	2.1 (1.8–2.3) ^{***}	15.7 (0.4) ^{¶¶}
Sexual attraction^{†††}				
Opposite sex only (sexual majority)	Ref	Ref	Ref	17.1 (0.2)
Same sex only	2.2 (1.4–3.5) ^{¶¶}	1.2 (0.8–2.0)	1.3 (0.8–1.8)	12.5 (1.3) ^{***}
Opposite and same sex	1.9 (1.5–2.4) ^{***}	2.1 (1.9–2.4) ^{***}	2.0 (1.8–2.2) ^{***}	16.3 (0.3) ^{¶¶}
Not sure	3.7 (2.6–5.3) ^{***}	0.9 (0.6–1.5)	1.7 (1.2–2.2) ^{***}	17.1 (1.2)
Lifetime sexual behavior^{§§§}				
Opposite sex only (sexual majority)	Ref	Ref	Ref	17.3 (0.2)
Same sex only ^{¶¶¶}	—	—	—	—
Opposite and same sex	1.7 (1.4–2.1) ^{***}	2.5 (2.2–2.7) ^{***}	2.2 (2.0–2.4) ^{***}	16.0 (0.3) ^{***}
No sexual behavior	N/A	0.2 (0.1–0.6) ^{¶¶}	0.1 (0.0–0.5) ^{¶¶}	9.9 (2.1) ^{***}

Abbreviations: ANOVA = analysis of variance; CI = confidence interval; GED = general education development certificate; N/A = not applicable; PR = prevalence ratio; Ref = referent group; SE = standard error.

* Adjusted PRs were controlled for age (years), at the time of interview race (non-Hispanic White, non-Hispanic Black, Hispanic, or other), highest degree received (no diploma or GED, high school diploma or GED, associate or bachelor's degree, or master's degree or higher), and poverty status (at or below or above federal poverty level).

[†] Comparisons within subgroups were evaluated on weighted prevalence estimates via log-binomial regressions used to calculate a prevalence ratio, 95% CI, and p-value (not shown). Statistical significance was evaluated at a threshold of $\alpha = 0.05$.

[§] Comparisons within subgroups were evaluated on weighted means via one-way ANOVA used to calculate a standard error and p-value. Statistical significance was evaluated at a threshold of $\alpha = 0.05$.

[¶] Nonvoluntary first vaginal intercourse was measured using responses to the question of whether first vaginal intercourse was "voluntary or not voluntary, that is, did you choose to have sex of your own free will or not?"

^{**} Forced sex was measured using the survey question, "At any time in your life (besides the time you already reported), have you ever been forced by a male to have vaginal intercourse against your will?"

^{††} Nonvoluntary or forced sex experience used responses from both survey questions regarding nonvoluntary first vaginal intercourse and forced sex.

^{§§} Sexual identity was assessed by asking the respondents whether they thought of themselves (at time of the interview) as heterosexual or straight; homosexual, gay, or lesbian; or bisexual.

^{¶¶} P-value is statistically significant ($p \leq 0.01$).

^{***} P-value is statistically significant ($p \leq 0.001$).

^{†††} Sexual attraction to other persons (at time of the interview) was assessed through self-reports of being only attracted to the opposite sex, mostly attracted to the opposite sex, equally attracted to the opposite and same sex, mostly attracted to the same sex, only attracted to the same sex, or not sure. Respondents who reported being mostly attracted to the opposite, equally attracted to the opposite and same sex, or mostly attracted to the same sex were coded as being attracted to both the opposite and same sex.

^{§§§} Lifetime sexual behavior was measured using experiences of oral, vaginal, or anal sex with male or female partners at any time in the respondent's life. Based on responses to two separate survey questions regarding sexual experiences with male partners and female partners, a composite sexual behavior variable was created with four categories: opposite sex only, same sex only, opposite and same sex, and no sexual behavior.

^{¶¶¶} Because of small cell sizes for reported nonvoluntary or forced sex among women reporting same-sex-only sexual behavior and ambiguity regarding interpretation, analysis results for this sexual behavior group have been omitted from main findings.

minority women (7). The finding that sexual minority women experienced nonvoluntary or forced sex at younger ages than sexual majority women might also suggest a history of more frequent adverse childhood experiences and an increased risk for revictimization later in life (5). Therefore, in addition to expanding sexual assault measures in existing surveys, cohort studies are needed to better understand the marginalization and experiences of sexual minority women, including across intersecting identities (e.g., race and ethnicity, education level, and socioeconomic status) (8). Findings can guide tailoring of primary prevention efforts for sexual violence and adverse childhood experiences, such as child sexual abuse and teen dating violence. Sex education curricula that are inclusive of

sexual and gender minority experiences might also promote healthy sexuality and safe intimate relationship skills that help sexual minority women (and all other sexual and gender minority persons) stay safe and healthy (7).

Acknowledgments

Association of Schools and Programs of Public Health; Tom Simon, National Center For Injury Prevention and Control, CDC; Julio Dient Taillepierre, Office of Minority Health and Health Equity, 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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Decreased Incidence of Infections Caused by Pathogens Transmitted Commonly Through Food During the COVID-19 Pandemic — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2017–2020

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Foodborne illnesses are a substantial and largely preventable public health problem; before 2020 the incidence of most infections transmitted commonly through food had not declined for many years. To evaluate progress toward prevention of foodborne illnesses in the United States, the Foodborne Diseases Active Surveillance Network (FoodNet) of CDC's Emerging Infections Program monitors the incidence of laboratory-diagnosed infections caused by eight pathogens transmitted commonly through food reported by 10 U.S. sites.* FoodNet is a collaboration among CDC, 10 state health departments, the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS), and the Food and Drug Administration. This report summarizes preliminary 2020 data and describes changes in incidence with those during 2017–2019. During 2020, observed incidences of infections caused by enteric pathogens decreased 26% compared with 2017–2019; infections associated with international travel decreased markedly. The extent to which these reductions reflect actual decreases in illness or decreases in case detection is unknown. On March 13, 2020, the United States declared a national emergency in response to the COVID-19 pandemic. After the declaration, state and local officials implemented stay-at-home orders, restaurant closures, school and child care center closures, and other public health interventions to slow the spread of SARS-CoV-2, the virus that causes COVID-19 (*I*). Federal travel restrictions were declared (*I*). These widespread interventions as well as other changes to daily life and hygiene behaviors, including increased handwashing, have likely changed exposures to foodborne pathogens. Other factors, such as changes in health care delivery, health care-seeking behaviors, and laboratory testing practices, might have decreased the detection of enteric infections. As the pandemic continues, surveillance of illness combined with data from other sources might help to elucidate the factors that led to the large changes in 2020; this understanding could lead to

improved strategies to prevent illness. To reduce the incidence of these infections concerted efforts are needed, from farm to processing plant to restaurants and homes. Consumers can reduce their risk of foodborne illness by following safe food-handling and preparation recommendations.

FoodNet conducts active, population-based surveillance of laboratory-diagnosed infections caused by *Campylobacter*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC), *Shigella*, *Vibrio*, and *Yersinia* reported from 10 sites covering approximately 15% of the U.S. population (approximately 50 million persons per U.S. Census Bureau estimates in 2019). Bacterial infections are defined as isolation of bacteria from a clinical specimen by culture or detection of pathogen antigen, nucleic acid sequence, or, for STEC,[†] Shiga toxin or Shiga toxin genes by a culture-independent diagnostic test (CIDT).[§] *Listeria* infections are defined as isolation of *L. monocytogenes* or detection of its nucleic acid sequences from a normally sterile site, or from placental or fetal tissue in the instance of miscarriage or stillbirth. *Cyclospora* infections are defined as detection of the parasite using ultraviolet fluorescence microscopy, specific stains, or polymerase chain reaction.

In this analysis, patients with no history of international travel or unknown travel were considered to have domestically acquired infection.[¶] Death was attributed to infection when it occurred during hospitalization or within 7 days after specimen collection for nonhospitalized patients. Incidence (cases per 100,000 population) was calculated by dividing the number of infections in 2020 by the U.S. Census estimates of the surveillance area population for 2019. Incidence measures included all laboratory-diagnosed infections. A negative binomial model with 95% confidence intervals (CIs) was used to estimate change in incidence during 2020 compared with those during 2017–2019, adjusting for changes in the population over time.

[†] STEC infections are defined as identification of Shiga toxin or its genes by any laboratory.

[§] A CIDT detects the presence of a specific antibody or antigen or the DNA of an organism.

[¶] History of international travel in the 30 days before illness began for *Listeria* and *Salmonella* serotypes Typhi and Paratyphi, 15 days before illness began for *Cyclospora*, and 7 days before illness began for other pathogens.

* Data were obtained from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York (<https://www.cdc.gov/foodnet>).

Surveillance for physician-diagnosed post-diarrheal hemolytic uremic syndrome (HUS), a complication of STEC infection characterized by renal failure, thrombocytopenia, and microangiopathic anemia, was conducted through a network of nephrologists and infection preventionists and by hospital discharge data review. This report includes HUS data for children aged <18 years for 2019, the most recent year for which data are available. FoodNet surveillance activities were reviewed by CDC and were conducted consistent with applicable federal law and CDC policy.**

During 2020, FoodNet identified 18,462 cases of infection, 4,788 hospitalizations, and 118 deaths (Table). The overall incidence was highest for *Campylobacter* (14.4 per 100,000 population), followed by *Salmonella* (13.3), STEC (3.6), *Shigella* (3.1), *Yersinia* (0.9), *Vibrio* (0.7), *Cyclospora* (0.6), and *Listeria* (0.2). During 2020, 26% fewer infections were reported compared with the average annual number reported during 2017–2019; the incidence in 2020 was significantly lower for all pathogens except *Yersinia* and *Cyclospora*. The percentage of infections resulting in hospitalization increased

2% compared with 2017–2019 (Figure 1). During 2020, 5% (958) of infections were associated with international travel compared with 14% during 2017–2019. In 2020, most (798; 83%) of these infections occurred during January–March.

Overall, 59% of bacterial infections were diagnosed using a CIDT (range = 14% [*Listeria*] to 100% [STEC]) (Figure 2); this was a 2% increase from 2017–2019. The percentage diagnosed using only a CIDT (i.e., including specimens with negative cultures and those not cultured) was 1% higher during 2020 than the percentage during 2017–2019. Among specimens with a positive CIDT result during 2020, a reflex culture^{††} was performed for 73%, which was 2% lower than during 2017–2019. Reflex cultures decreased for *Vibrio* (by 15%), *Yersinia* (7%), *Campylobacter* (5%), and STEC (2%); increased for *Salmonella* (2%), and *Shigella* (2%); and did not change for *Listeria*.

Among 5,336 (91%) fully serotyped *Salmonella* isolates in 2020, the seven most common serotypes were Enteritidis (1.6 per 100,000 population), Newport (1.5), Javiana (1.0),

^{††} Culture of a specimen with a positive CIDT result.

** 45 C.F.R. part 46.102(l)(2), 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.

TABLE. Number of laboratory-diagnosed bacterial and parasitic infections, hospitalizations, deaths, and outbreak-associated cases, incidence, and percentage change compared with 2017–2019 average annual incidence, by pathogen — Foodborne Diseases Active Surveillance Network, 10 U.S. sites,* 2017–2020[†]

Pathogens	No. of infections [§]	No. (%)			Incidence ^{§§}	% change in incidence, 2017–2019 to 2020 (95%CI) ^{¶¶}
		Hospitalizations [¶]	Deaths ^{**}	Outbreak-associated cases ^{††}		
Bacteria						
<i>Campylobacter</i>	7,208	1,524 (21)	25 (0.3)	19 (0.3)	14.4	-23 (-29 to -16)
<i>Salmonella</i>	6,694	1,971 (29)	48 (0.7)	631 (9)	13.3	-22 (-26 to -17)
STEC ^{***}	1,824	441 (24)	7 (0.4)	27 (1)	3.6	-37 (-47 to -26)
<i>Shigella</i>	1,534	524 (34)	3 (0.2)	145 (9)	3.1	-41 (-54 to -23)
<i>Yersinia</i>	455	119 (26)	5 (1.1)	0 (—)	0.9	-10 (-29 to 14)
<i>Vibrio</i>	330	88 (27)	8 (2.4)	0 (—)	0.7	-25 (-39 to -8)
<i>Listeria</i>	104	99 (95)	22 (21.2)	2 (2)	0.2	-27 (-43 to -7)
Parasite						
<i>Cyclospora</i>	313	22 (7)	0 (—)	116 (37)	0.6	-17 (-50 to 37)
Total	18,462	4,788 (26)	118 (0.6)	940 (5)	N/A	N/A

Abbreviations: CI = confidence interval; CIDT = culture-independent diagnostic test; N/A = not applicable; STEC = Shiga toxin-producing *Escherichia coli*.

* Data were obtained from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York.

[†] Data for 2020 are preliminary.

[§] Bacterial infections were diagnosed by positive CIDT or isolation by culture, or for STEC by detection of Shiga toxin or Shiga toxin genes. *Cyclospora* infections were diagnosed by detection of parasite by ultraviolet fluorescence microscopy or polymerase chain reaction.

[¶] Defined as hospitalizations occurring within 7 days before or after specimen collection and emergency department stays of >24 hours during the same time frame. Change in percentage of infections resulting in hospitalization during 2020 compared with 2017–2019: *Campylobacter* (+1), *Salmonella* (+2), STEC (+2), *Shigella* (+8), *Yersinia* (+3), *Vibrio* (-3), *Listeria* (-1), *Cyclospora* (+2).

^{**} Defined as deaths occurring during hospitalization or within 7 days after specimen collection for persons who were not hospitalized. Change in percentage of infections resulting in death during 2020 compared with 2017–2019: *Campylobacter* (0.0), *Salmonella* (+0.2), STEC (0.0), *Shigella* (+0.1), *Yersinia* (+0.2), *Vibrio* (0.0), *Listeria* (+2.0), *Cyclospora* (-0.1).

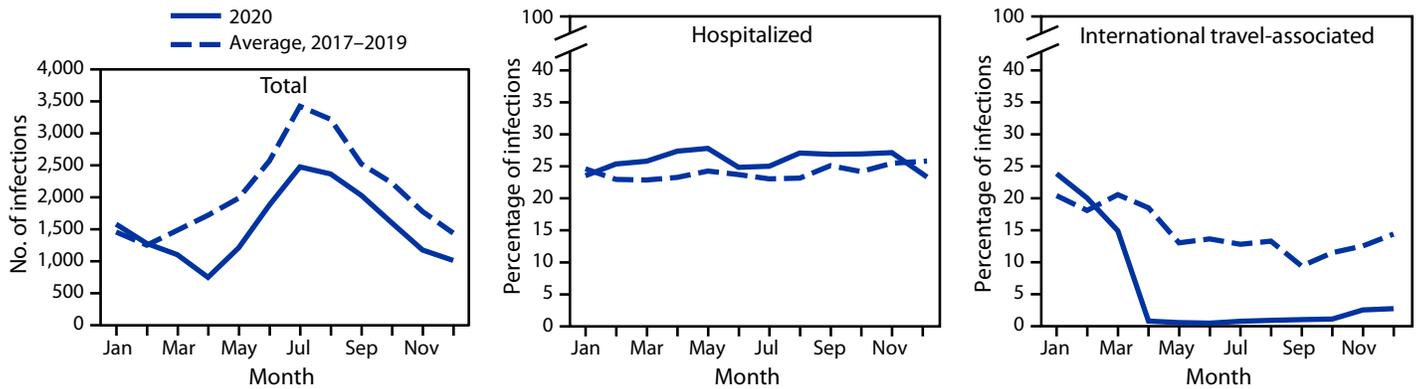
^{††} Change in percentage of infections associated with outbreaks during 2020 compared with 2017–2019: *Campylobacter* (-0.1), *Salmonella* (+2), STEC (-4), *Shigella* (+6), *Yersinia* (0.0), *Vibrio* (-4), *Listeria* (-3), *Cyclospora* (+8).

^{§§} Per 100,000 population.

^{¶¶} Percentage change reported as increase or decrease.

^{***} The incidence of STEC O157 infections (0.5 per 100,000 population) changed by -37% (95% CI = -49 to -22) compared with 2017–2019; the incidence of non-O157 STEC infections (1.4) changed by -43% (95% CI = -51 to -34).

FIGURE 1. Number of laboratory-diagnosed bacterial and parasitic infections, percentage of patients hospitalized,* and percentage with international travel,† by month — Foodborne Diseases Active Surveillance Network, 10 U.S. sites,‡ 2017–2020¶



* Hospital admission in the 7 days before or after specimen collection among those with known information; it was unknown for 8% of infections during 2020 and 4% during 2017–2019.

† History of international travel in the 30 days before illness began for *Listeria* and *Salmonella* serotypes Typhi and Paratyphi, 15 days before illness began for *Cyclospora*, and 7 days before illness began for other pathogens. International travel was unknown for 26% of infections during 2020 and 17% during 2017–2019. During 2020, 5% (958) of infections were associated with international travel compared with 14% during 2017–2019. In 2020, most (798; 83%) of these infections occurred during January–March.

‡ Data were obtained from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York.

¶ Data for 2020 are preliminary.

Typhimurium (0.9), I 4,[5],12:i:- (0.5), Hadar (0.4), and Infantis (0.3). Compared with 2017–2019, incidence during 2020 was significantly lower for I 4,[5],12:i:- (48% lower), Typhimurium (37% lower), Enteritidis (36% lower), and Javiana (31% lower). Incidence was significantly higher for Hadar (617% higher; 95% CI = 382–967) and did not change significantly for Newport or Infantis. Most (73%) of the 631 outbreak-associated *Salmonella* infections during 2020 were caused by three serotypes: Newport (220; 35%), Hadar (135; 21%), and Enteritidis (108; 17%). All outbreak-associated Hadar infections were from one multistate outbreak linked to contact with backyard poultry; 47 (35%) illnesses resulted in hospitalization. Four serogroups accounted for 63% of the 955 culture-positive STEC isolates. Serogroup O157 was most common (264; 28%), followed by O26 (148; 15%), O103 (115; 12%), and O111 (78; 8%).

FoodNet identified 63 cases of post-diarrheal HUS in children aged <18 years (0.6 cases per 100,000 population) during 2019; 55 (87%) had evidence of STEC infection and 41 (65%) were in children aged <5 years (1.4 per 100,000 population). These rates were similar to those during 2016–2018.

Discussion

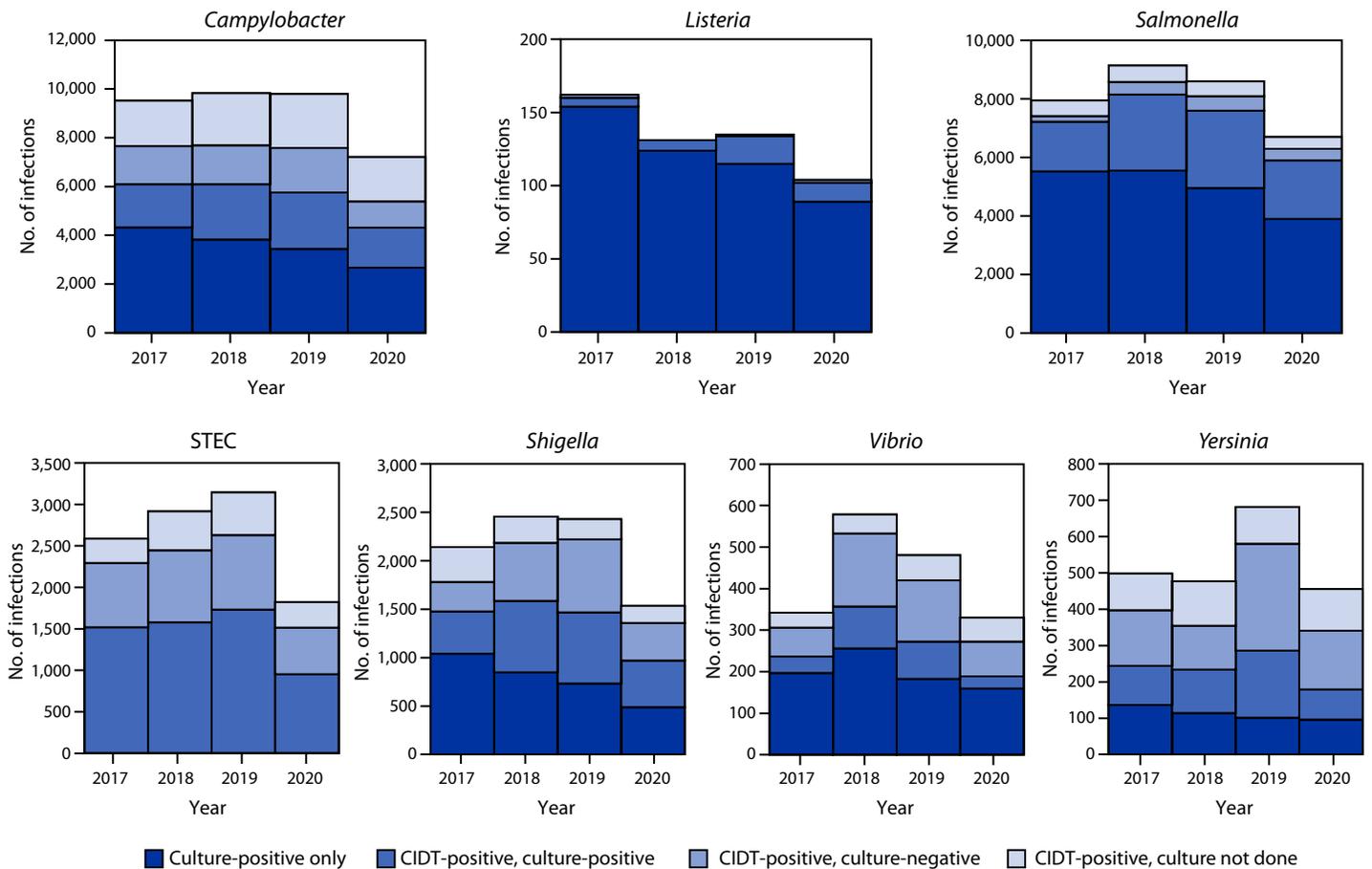
The 26% decrease in incidence of infections caused by pathogens transmitted commonly through food during 2020 was the largest single-year variation in incidence during 25 years of FoodNet surveillance; widespread public health interventions implemented to prevent SARS-CoV-2 transmission might have

contributed to this decrease. For example, infections associated with international travel decreased markedly after pandemic-related travel restrictions were imposed. Other interventions, such as restaurant closures, might have contributed to declines in incidence. However, a higher than usual proportion of infections might have been undetected because factors such as changes in health care-seeking behaviors, and broader use of telehealth might have limited the number of stool specimens tested. Marked decreases in emergency department visits for abdominal pain and other digestive or abdominal signs and symptoms occurred early in the pandemic (2). The proportion of infections resulting in hospitalization increased slightly; possible explanations include disproportionate decreases in health care-seeking among those with milder illness or delayed health care-seeking resulting in more severe illness at the time of clinical presentation.

The proportion of infections diagnosed by culture versus CIDs was stable during 2020, suggesting that a change in clinical laboratory testing practices was not a major contributor to the decreased incidence of infections. Before 2020, the incidence of *Campylobacter*, *Salmonella*, STEC, *Vibrio*, *Yersinia*, and *Cyclospora* infections had been increasing; the addition of infections diagnosed by CIDs to FoodNet surveillance beginning in 2012, and the introduction of DNA-based syndrome panels^{§§} in 2016 likely contributed to the increases (3).

^{§§} Syndromic panels are commercial CIDs that simultaneously detect multiple pathogens associated with clinical syndromes, such as diarrheal illness.

FIGURE 2. Number of infections diagnosed by culture or culture-independent diagnostic test, by pathogen, year, and culture status — Foodborne Diseases Active Surveillance Network, 10 U.S. sites,* 2017–2020†



Abbreviations: CIDT = culture-independent diagnostic test; STEC = Shiga toxin-producing *Escherichia coli*.

* Data were obtained from Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York.

† Data for 2020 are preliminary.

Changes in clinical and public health laboratory capacity in response to the COVID-19 pandemic might have contributed to observed decreases in reflex culturing. Before 2020, reflex culture of specimens positive for *Campylobacter*, *Salmonella*, *Shigella*, and *Yersinia* increased in FoodNet sites, augmented by CDC funding. Until metagenomic CIDTs are developed, culture is necessary to identify pathogen subtypes, antimicrobial resistance patterns, and whole-genome sequences (4). Fewer cultures decrease the ability to detect and investigate outbreaks and sporadic cases of emerging pathogens, which relies on sequencing.

The incidences of *Salmonella* *Infantis*, *Cyclospora*, and *Yersinia* infections, which had previously been increasing, did not change, possibly because of continuing prepandemic factors that led to rising incidences during previous years (5); the stable incidences despite the pandemic suggest that they might have increased otherwise. As pandemic-related restrictions are

lifted, illnesses caused by these pathogens and by Hadar, the one *Salmonella* serotype with increasing incidence, should be closely monitored. Rising multidrug resistant *Salmonella* *Infantis* infections have been linked to consumption of chicken (6–8). Hadar infections have been linked to backyard flocks and to consumption of turkey (8,9). USDA-FSIS did not detect a significantly higher percentage of *Salmonella* Hadar in raw poultry samples collected in 2020 compared with 2017–2019 (USDA-FSIS, unpublished data, 2021). Typhimurium continued to decline in rank among *Salmonella* serotypes, dropping to fourth most common for the first time.

The findings in this report are subject to at least three limitations. First, the pandemic and corresponding public health response make explaining changes in the observed incidences of infections challenging. Second, changes in health care-seeking behaviors and health care delivery during the pandemic likely limited ascertainment of cases. Finally, sites reported decreases

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

Before 2020, the incidence of infections transmitted commonly by food had not declined for many years.

What is added by this report?

During 2020, FoodNet identified 26% fewer infections compared with the average annual number during 2017–2019, including decreased infections associated with international travel.

What are the implications for public health practice?

The pandemic and resulting public health response present challenges to explaining changes in observed foodborne illness incidences. Continued surveillance might help elucidate the impact of the COVID-19 pandemic on foodborne illness and identify strategies to decrease illnesses. Concerted efforts are needed to reduce the incidence of these infections from farm to processing plant to restaurants and homes. Consumers can reduce their risk of foodborne illness by following safe food-handling and preparation recommendations.

that varied over time in the willingness of ill persons to be interviewed and in staff member capacity to conduct case interviews; these factors might have resulted in missing data and recall bias.

Public health interventions to prevent SARS-CoV-2 transmission likely influenced exposures associated with enteric diseases, resulting in real declines in incidence, as evidenced by decreased numbers of infections associated with international travel. Continued surveillance might improve the understanding of how the pandemic affected foodborne illness and might help identify prevention measures and strategies that target particular pathogens and foods. To reduce the incidence of these infections concerted efforts are needed, from farm to processing plant to restaurants and homes. Consumers can reduce their risk of foodborne illness by following safe food-handling and preparation recommendations.

Acknowledgments

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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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Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March–August 2021

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On September 17, 2021, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

Three COVID-19 vaccines are authorized or approved for use among adults in the United States (1,2). Two 2-dose mRNA vaccines, mRNA-1273 from Moderna and BNT162b2 from Pfizer-BioNTech, received Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) in December 2020 for persons aged ≥18 years and aged ≥16 years, respectively. A 1-dose viral vector vaccine (Ad26.COV2 from Janssen [Johnson & Johnson]) received EUA in February 2021 for persons aged ≥18 years (3). The Pfizer-BioNTech vaccine received FDA approval for persons aged ≥16 years on August 23, 2021 (4). Current guidelines from FDA and CDC recommend vaccination of eligible persons with one of these three products, without preference for any specific vaccine (4,5). To assess vaccine effectiveness (VE) of these three products in preventing COVID-19 hospitalization, CDC and collaborators conducted a case-control analysis among 3,689 adults aged ≥18 years who were hospitalized at 21 U.S. hospitals across 18 states during March 11–August 15, 2021. An additional analysis compared serum antibody levels (anti-spike immunoglobulin G [IgG] and anti-receptor binding domain [RBD] IgG) to SARS-CoV-2, the virus that causes COVID-19, among 100 healthy volunteers enrolled at three hospitals 2–6 weeks after full vaccination with the Moderna, Pfizer-BioNTech, or Janssen COVID-19 vaccine. Patients with immunocompromising conditions were excluded. VE against COVID-19 hospitalizations was higher for the Moderna vaccine (93%; 95% confidence interval [CI] = 91%–95%) than for the Pfizer-BioNTech vaccine (88%; 95% CI = 85%–91%) ($p = 0.011$); VE for both mRNA vaccines was higher than that for the Janssen vaccine (71%; 95% CI = 56%–81%) (all $p < 0.001$). Protection for the

Pfizer-BioNTech vaccine declined 4 months after vaccination. Postvaccination anti-spike IgG and anti-RBD IgG levels were significantly lower in persons vaccinated with the Janssen vaccine than the Moderna or Pfizer-BioNTech vaccines. Although these real-world data suggest some variation in levels of protection by vaccine, all FDA-approved or authorized COVID-19 vaccines provide substantial protection against COVID-19 hospitalization.

For the VE analysis, adults aged ≥18 years without an immunocompromising condition admitted to 21 hospitals within the Influenza and Other Viruses in the Acutely Ill (IVY) Network were prospectively recruited for a case-control analysis (6,7). Case-patients were admitted to a hospital with COVID-19–like illness[†] and a positive SARS-CoV-2 reverse transcription–polymerase chain reaction (RT-PCR) or antigen test result. Control-patients were adults admitted to a hospital[§] who received a negative SARS-CoV-2 RT-PCR test result.

Patients or their proxies were interviewed to obtain information about demographic characteristics, clinical history, and COVID-19 vaccination.[¶] Information regarding vaccine product received by patients was collected by interview and source verification (e.g., state vaccination registries, hospital

[†] COVID-19–like illness was defined as having one or more of the following: fever, cough, shortness of breath, loss of taste, loss of sense of smell, use of respiratory support for the acute illness, or new pulmonary findings on chest imaging consistent with pneumonia.

[§] Control-patients included test-negative controls (persons with COVID-19–like illness who received negative SARS-CoV-2 RT-PCR test results) and syndrome-negative controls (a second control group of persons without COVID-19–like illness who also received negative SARS-CoV-2 RT-PCR test results). VE estimates stratified by control groups were highly similar and control groups were combined for this analysis.

[¶] Vaccine was considered to have been administered if vaccination dates and product names were verified through medical records, state immunization registries, vaccination record cards, or provider or pharmacy records, or if plausibly reported by patient or proxy with date and location of vaccination.

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electronic medical records, and pharmacy records), including vaccine lot numbers, when these were documented. A patient was considered fully vaccinated if the final vaccine dose (second dose for Moderna and Pfizer-BioNTech and the single Janssen dose) was received ≥ 14 days before illness onset.** Patients were excluded if they received a COVID-19 vaccine other than Moderna, Pfizer-BioNTech, or Janssen; received ≥ 1 vaccine dose but did not meet criteria for full vaccination; or received doses of two different COVID-19 vaccine products.

For the postvaccination antibody analysis, healthy adults aged ≥ 18 years with no known prior SARS-CoV-2 infection were recruited during April 6–June 4, 2021, at three IVY sites. Blood was collected 2–6 weeks after receipt of the second Moderna and Pfizer-BioNTech vaccine dose or the single Janssen vaccine dose. Sera were shipped to CDC, where they underwent testing for IgG against three SARS-CoV-2 antigens: the spike protein (anti-spike); the spike RBD (anti-RBD); and nucleocapsid (anti-nucleocapsid). IgG levels were measured using the V-PLEX SARS-CoV-2 panel 2 kit (Meso Scale Diagnostics) and reported in international binding antibody units (BAU) per milliliter. Two participants with anti-nucleocapsid antibodies (>11.8 BAU), which is suggestive of a prior SARS-CoV-2 infection, were excluded.

VE against COVID-19 hospitalization was estimated using logistic regression, comparing the odds of being fully vaccinated versus unvaccinated between case-patients and controls using the equation $VE = 100 \times (1 - \text{adjusted odds ratio})$ (6,7). The regression model included an indicator variable for vaccine type (Moderna, Pfizer-BioNTech, or Janssen) and was adjusted for admission date, geographic region, age, sex, and race and Hispanic ethnicity. A separate model added an interaction term between product type and time since vaccination. Using these models, VE for mRNA vaccine products was estimated for the full surveillance period (March 11–August 15), as well as 14–120 days and >120 days after the receipt of the second dose. Because a limited number of patients received Janssen vaccine >120 days before illness onset (19 total), VE for the Janssen vaccine was not stratified by time. In addition to a VE estimate defining full vaccination as 14 days after a Janssen vaccine dose, a sensitivity analysis was conducted defining full vaccination as 28 days after a Janssen vaccine dose. Statistical differences by vaccine product and time were assessed based on p-values generated using the Tukey method for pair-wise multiple comparisons.

** The date of illness onset was used for cases and controls with COVID-19–like illness with median value imputed if missing. For controls without COVID-19–like illness, the date of admission minus the median number of days between illness onset and admission for patients with COVID-19 was used for a date of illness onset, also referred to as illness onset for this report.

In the postvaccination antibody analysis, pairwise comparisons of the quantity of anti-spike IgG and anti-RBD IgG were made among participants, by vaccine product received, using the Wilcoxon rank-sum test. Analyses were conducted using R statistical software (version 4.0.3; R Foundation) and STATA (version 16; StataCorp). Procedures were approved as public health surveillance by each participating site and CDC†† and were conducted consistent with applicable federal law and CDC policy.§§

After excluding 1,786 patients from the VE analysis (936 for having an immunocompromising condition,¶¶ 566 who received ≥ 1 vaccine dose but were not fully vaccinated, and 284 who did not meet other eligibility criteria), 3,689 patients were included (1,682 case-patients and 2,007 control-patients). Overall, 2,362 (64.0%) patients were unvaccinated; 476 (12.9%) were fully vaccinated with the Moderna vaccine; 738 (20.0%) were fully vaccinated with the Pfizer-BioNTech vaccine; and 113 (3.1%) were fully vaccinated with the Janssen vaccine. Among all participants, median age was 58 years, 48% were female, 23% were non-Hispanic Black, and 18% were Hispanic (Table 1). VE against COVID-19 hospitalization during March 11–August 15, 2021, was higher for the Moderna vaccine (VE = 93%) than for the Pfizer-BioNTech vaccine (VE = 88%) ($p = 0.011$); VE for both mRNA vaccines was higher than that for the Janssen vaccine (VE = 71%) (all $p < 0.001$) (Table 2). VE for the Moderna vaccine was 93% at 14–120 days (median = 66 days) after receipt of the second vaccine dose and 92% at >120 days (median = 141 days) ($p = 1.000$). VE for the Pfizer-BioNTech vaccine was 91% at 14–120 days (median = 69 days) after receipt of the second vaccine dose but declined significantly to 77% at >120 days (median = 143 days) ($p < 0.001$).

The postvaccination antibody analysis included 100 healthy volunteers, 32 fully vaccinated with Moderna (median age = 31 years; median interval from second vaccine dose to blood draw = 28 days), 51 fully vaccinated with Pfizer-BioNTech (median age = 27 years; median interval from second dose to blood draw = 27 days), and 17 fully vaccinated with Janssen (median age = 31 years; median interval from vaccine dose to blood draw = 35 days). Anti-RBD levels were

†† All activities were approved by participating institutions as public health surveillance activities, except postvaccination blood collection that received institutional review board approval at a single site (Wake Forest University).

§§ 45 C.F.R. part 46.102(l)(2), 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.

¶¶ Immunocompromising conditions included having one or more of the following: active solid organ cancer (active cancer defined as treatment for the cancer or newly diagnosed cancer in the past 6 months), active hematologic cancer (such as leukemia, lymphoma, or myeloma), HIV infection without AIDS, AIDS, congenital immunodeficiency syndrome, prior splenectomy, prior solid organ transplant, immunosuppressive medication, systemic lupus erythematosus, rheumatoid arthritis, psoriasis, scleroderma, or inflammatory bowel disease including Crohn's disease or ulcerative colitis.

TABLE 1. Characteristics of participants in the vaccine effectiveness analysis, including case-patients hospitalized with COVID-19 and control-patients hospitalized without COVID-19, by COVID-19 vaccine product received — 21 hospitals* in 18 U.S. states, March–August 2021

Characteristic [†]	No./Total no. (%)				
	Vaccine (fully vaccinated participants) [§]				Unvaccinated participants (n = 2,362)
	All participants (N = 3,689)	Moderna (n = 476)	Pfizer-BioNTech (n = 738)	Janssen (Johnson & Johnson) (n = 113)	
COVID-19 case	1,682/3,689 (45.6)	54/476 (11.3)	128/738 (17.3)	37/113 (32.7)	1,463/2,362 (61.9)
Median age (IQR, yrs)	58 (44–69)	66 (56–75)	68 (57–77)	61 (48–67)	53 (40–64)
Age group, yrs					
18–49	1,243/3,689 (33.7)	77/476 (16.2)	112/738 (15.2)	32/113 (28.3)	1,022/2,362 (43.3)
50–64	1,125/3,689 (30.5)	127/476 (26.7)	191/738 (25.9)	45/113 (39.8)	762/2,362 (32.3)
≥65	1,321/3,689 (35.8)	272/476 (57.1)	435/738 (58.9)	36/113 (31.9)	578/2,362 (24.5)
Sex					
Female	1,777/3,689 (48.2)	233/476 (49.0)	371/738 (50.3)	46/113 (40.7)	1,127/2,362 (47.7)
Race/Ethnicity[¶]					
White, non-Hispanic	1,960/3,689 (53.1)	291/476 (61.1)	480/738 (65.0)	58/113 (51.3)	1,131/2,362 (47.9)
Black, non-Hispanic	861/3,689 (23.3)	93/476 (19.5)	129/738 (17.5)	26/113 (23.0)	613/2,362 (26.0)
Any race, Hispanic	649/3,689 (17.6)	69/476 (14.5)	93/738 (12.6)	20/113 (17.7)	467/2,362 (19.8)
All other races, non-Hispanic	160/3,689 (4.3)	16/476 (3.4)	32/738 (4.3)	5/113 (4.4)	107/2,362 (4.5)
Unknown	59/3,689 (1.6)	7/476 (1.5)	4/738 (0.5)	4/113 (3.5)	44/2,362 (1.9)
U.S. Census region**					
Northeast	552/3,689 (15.0)	78/476 (16.4)	112/738 (15.2)	21/113 (18.6)	341/2,362 (14.4)
South	1,501/3,689 (40.7)	125/476 (26.3)	315/738 (42.7)	40/113 (35.4)	1,021/2,362 (43.2)
Midwest	836/3,689 (22.7)	155/476 (32.6)	166/738 (22.5)	27/113 (23.9)	488/2,362 (20.7)
West	800/3,689 (21.7)	118/476 (24.8)	145/738 (19.7)	25/113 (22.1)	512/2,362 (21.7)
Residence in long-term care facility^{††}	155/3,557 (4.4)	29/463 (6.3)	68/712 (9.6)	4/111 (3.6)	54/2,271 (2.4)
Has health insurance	3,347/3,687 (90.8)	462/476 (97.1)	719/737 (97.6)	106/112 (94.6)	2,060/2,362 (87.2)
Employed	1,115/3,045 (36.6)	129/415 (31.1)	168/644 (26.1)	31/102 (30.4)	787/1,884 (41.8)
Health care worker	181/3,045 (5.9)	26/415 (6.3)	42/644 (6.5)	4/102 (3.9)	109/1,884 (5.8)
Attended some college or more	1,360/2,725 (49.9)	212/363 (58.4)	359/599 (59.9)	50/92 (54.4)	739/1,671 (44.2)
≥1 hospital admission in past year	1,380/3,434 (40.2)	233/456 (51.1)	325/701 (46.4)	52/109 (47.7)	770/2,168 (35.5)
Underlying medical conditions^{§§}					
Chronic cardiovascular disease (including hypertension)	2201/3,688 (59.7)	341/475 (71.8)	567/738 (76.8)	75/113 (66.4)	1,218/2,362 (51.6)
Chronic lung disease	925/3,688 (25.1)	145/475 (30.5)	224/738 (30.4)	35/113 (31.0)	521/2,362 (22.1)
Diabetes mellitus	1,091/3,688 (29.6)	173/475 (36.4)	267/738 (36.2)	33/113 (29.2)	618/2,362 (26.2)
Obesity by body mass index	1,829/3,648 (50.1)	203/474 (42.8)	335/733 (45.7)	53/113 (46.9)	1,238/2,328 (53.2)
Self-reported prior laboratory-confirmed SARS-CoV-2 infection	226/3,687 (6.1)	34/476 (7.1)	44/737 (6.0)	11/113 (9.7)	137/2,361 (5.8)
Interval between second vaccine dose and symptom onset (or hospital admission for syndrome-negative control group), median no. of days (IQR)^{¶¶}	N/A	79 (46–112)	86 (51–119)	68 (36–111)	N/A

Abbreviations: IQR = interquartile range; N/A = not applicable.

* Hospitals by region included *Northeast*: Baystate Medical Center (Springfield, Massachusetts), Beth Israel Deaconess Medical Center (Boston, Massachusetts), Montefiore Medical Center (Bronx, New York); *South*: Vanderbilt University Medical Center (Nashville, Tennessee), University of Miami Medical Center (Miami, Florida), Emory University Medical Center (Atlanta, Georgia), Johns Hopkins Hospital (Baltimore, Maryland), Wake Forest University Baptist Medical Center (Winston-Salem, North Carolina), Baylor Scott & White Health (Temple, Texas); *Midwest*: University of Iowa Hospitals and Clinics (Iowa City, Iowa), University of Michigan Hospital (Ann Arbor, Michigan), Hennepin County Medical Center (Minneapolis, Minnesota), Barnes-Jewish Hospital (St. Louis, Missouri), Cleveland Clinic (Cleveland, Ohio), Ohio State University Wexner Medical Center (Columbus, Ohio); *West*: Stanford University Medical Center (Stanford, California), UCLA Medical Center (Los Angeles, California), UCHealth University of Colorado Hospital (Aurora, Colorado), Oregon Health & Science University Hospital (Portland, Oregon), Intermountain Medical Center (Murray, Utah), University of Washington (Seattle, Washington).

[†] Data are not complete for all characteristics in the table; denominators are included in the table indicating the number of patients with available data for each characteristic.

[§] Fully vaccinated with mRNA COVID-19 vaccines defined as ≥14 days from dose 2; fully vaccinated with Janssen (Johnson & Johnson) vaccine defined as ≥14 days from dose 1.

[¶] Racial and ethnic groups were reported by the patient or proxy.

** *Northeast*: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont; *Midwest*: Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; *South*: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia; *West*: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

^{††} Long-term care facility included reporting living in a nursing home, assisted living home, or rehabilitation hospital or other subacute or chronic facility before the hospital admission.

^{§§} Underlying medical condition categories were obtained through medical chart review by trained personnel.

^{¶¶} Among fully vaccinated patients.

TABLE 2. COVID-19 vaccine effectiveness* against COVID-19–associated hospitalization among adults without immunocompromising conditions, by vaccine product — 21 hospitals in 18 U.S. states,† March–August 2021

Vaccine/Period	Vaccinated patients/Total patients (%)		VE against COVID-19 hospitalization (95% CI)
	Case-patients	Control-patients	
Moderna VE after full vaccination			
Full surveillance period [§]	54/1,517 (3.6)	422/1,321 (31.9)	93 (91–95)
14–120 days after full vaccination	36/1,499 (2.4)	345/1,244 (27.7)	93 (90–95)
>120 days after full vaccination	18/1,481 (1.2)	77/976 (7.9)	92 (87–96)
Pfizer-BioNTech VE after full vaccination			
Full surveillance period	128/1,591 (8.0)	610/1,509 (40.4)	88 (85–91)
14–120 days after full vaccination	65/1,528 (4.3)	495/1,394 (35.5)	91 (88–93)
>120 days after full vaccination	63/1,526 (4.1)	115/1,014 (11.3)	77 (67–84)
Janssen (Johnson & Johnson) VE after full vaccination			
Full surveillance period	37/1,500 (2.5)	76/975 (7.8)	71 (56–81)
>28 days after full vaccination	33/1,496 (2.2)	59/958 (6.2)	68 (49–80)

Abbreviations: CI = confidence interval; VE = vaccine effectiveness.

* VE was estimated using logistic regression comparing the odds of being fully vaccinated with the Moderna, Pfizer-BioNTech or Janssen (Johnson & Johnson) COVID-19 vaccine versus being unvaccinated in case-patients and control-patients using the equation $VE = 100 \times (1 - \text{odds ratio})$. Models were adjusted for date of hospital admission (biweekly intervals), U.S. Department of Health and Human Services region of hospital, age group (18–49, 50–64, ≥65 years), sex, and race/ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic of any race, non-Hispanic Other, or unknown). Binary time since full vaccination was added to the model with results for 14–120 days and >120 days shown.

† Hospitals by region included *Northeast*: Baystate Medical Center (Springfield, Massachusetts), Beth Israel Deaconess Medical Center (Boston, Massachusetts), Montefiore Medical Center (Bronx, New York); *South*: Vanderbilt University Medical Center (Nashville, Tennessee), University of Miami Medical Center (Miami, Florida), Emory University Medical Center (Atlanta, Georgia), Johns Hopkins Hospital (Baltimore, Maryland), Wake Forest University Baptist Medical Center (Winston-Salem, North Carolina), Baylor Scott & White Health (Temple, Texas); *Midwest*: University of Iowa Hospitals and Clinics (Iowa City, Iowa), University of Michigan Hospital (Ann Arbor, Michigan), Hennepin County Medical Center (Minneapolis, Minnesota), Barnes-Jewish Hospital (St. Louis, Missouri), Cleveland Clinic (Cleveland, Ohio), Ohio State University Wexner Medical Center (Columbus, Ohio); *West*: Stanford University Medical Center (Stanford, California), UCLA Medical Center (Los Angeles, California), UHealth University of Colorado Hospital (Aurora, Colorado), Oregon Health & Science University Hospital (Portland, Oregon), Intermountain Medical Center (Murray, Utah), University of Washington (Seattle, Washington).

[§] The full surveillance period included hospital admissions during March 11–August 15, 2021.

higher in participants vaccinated with the Moderna vaccine (median = 4,333; interquartile range [IQR] = 3,134–7,197; geometric mean = 4,274; 95% CI = 3,393–5,384 BAU/mL) than in those who received the Pfizer-BioNTech vaccine (median = 3,217; IQR = 2,048–4,668; geometric mean = 2,950; 95% CI = 2,325–3,742 BAU/mL) ($p = 0.033$) or the Janssen vaccine (median = 57; IQR = 26–94; geometric mean = 51; 95% CI = 30–90 BAU/mL) ($p < 0.001$) (Figure). Anti-spike IgG levels in participants vaccinated with the Moderna vaccine (median = 3,236; IQR = 2,125–4,975, geometric mean = 3,059; 95% CI = 2,479–3,774 BAU/mL) did not significantly differ from those in recipients of the Pfizer-BioNTech vaccine (median = 2,983; IQR = 1,954–4,059; geometric mean = 2,444; 95% CI = 1,936–3,085 BAU/mL) ($p = 0.217$), but were significantly higher than levels in participants who received the Janssen vaccine (median = 59; IQR = 30–104; geometric mean = 56; 95% CI = 32–97 BAU/mL) ($p < 0.001$).

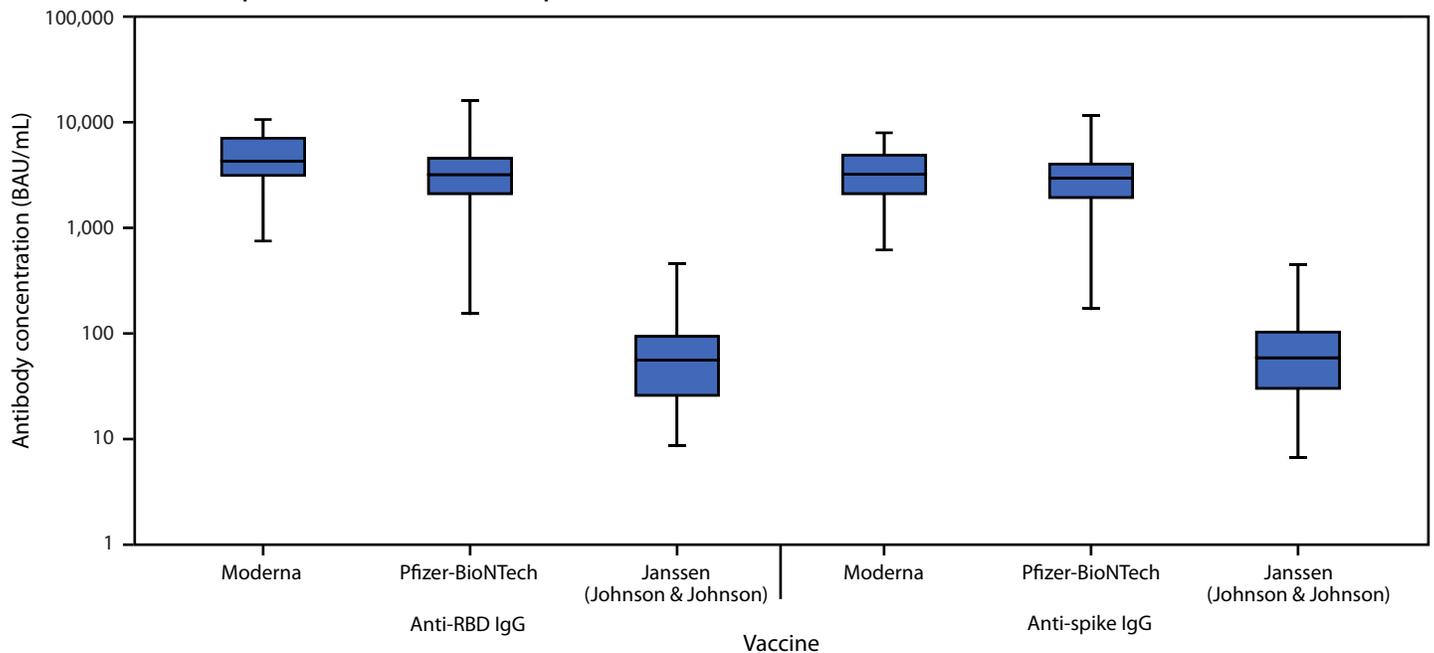
Discussion

Two-dose regimens of the Moderna and Pfizer-BioNTech mRNA vaccines provided a high level of protection against COVID-19 hospitalizations in a real-world evaluation at 21 U.S. hospitals during March–August 2021. VE against COVID-19 hospitalization for Moderna and Pfizer-BioNTech vaccines was 93% and 88%, respectively, whereas the

single-dose Janssen vaccine had somewhat lower VE at 71%. Persons vaccinated with Janssen vaccine also had lower postvaccination anti-SARS-CoV-2 antibody levels than did recipients of mRNA vaccines. Although an immunologic correlate of protection has not been established for COVID-19 vaccines, antibody titers after infection and vaccination have been associated with protection (8). These real-world data suggest that the 2-dose Moderna and Pfizer-BioNTech mRNA vaccine regimens provide more protection than does the 1-dose Janssen viral vector vaccine regimen. Although the Janssen vaccine had lower observed VE, 1 dose of Janssen vaccine still reduced risk for COVID-19–associated hospitalization by 71%.

VE against COVID-19 hospitalization was slightly lower for the 2-dose Pfizer-BioNTech vaccine than the Moderna vaccine, with this difference driven by a decline in VE after 120 days for the Pfizer-BioNTech but not the Moderna vaccine. The Moderna vaccine also produced higher postvaccination anti-RBD antibody levels than did the Pfizer-BioNTech vaccine. Differences in VE between the Moderna and Pfizer-BioNTech vaccine might be due to higher mRNA content in the Moderna vaccine, differences in timing between doses (3 weeks for Pfizer-BioNTech versus 4 weeks for Moderna), or possible differences between groups that received each vaccine that were not accounted for in the analysis (9).

FIGURE. Serum anti-receptor binding domain and anti-spike immunoglobulin G levels 2–6 weeks after full vaccination among healthy adult volunteers — three hospitals in three U.S. states,^{*,†} April–June 2021



Abbreviations: BAU = binding antibody units; IgG = immunoglobulin G; IQR = interquartile range; RBD = receptor binding domain.

* Anti-RBD and anti-spike IgG levels were measured in sera of healthy volunteers 2–6 weeks after a second dose of the Moderna or Pfizer-BioNTech COVID-19 vaccine and the first dose of the Janssen COVID-19 vaccine. In these box and whisker plots, the central horizontal line of each box plot represents the median, with the box denoting the IQR, and the whiskers representing the minimum and maximum values. Two volunteers with anti-nucleocapsid IgG antibodies, indicative of a prior SARS-CoV-2 infection, were excluded from this analysis.

† Hospitals that recruited healthy adult volunteers included Beth Israel Deaconess Medical Center (Boston, Massachusetts), Vanderbilt University Medical Center (Nashville, Tennessee), and Wake Forest University Baptist Medical Center (Winston-Salem, North Carolina).

Summary

What is already known about this topic?

Two 2-dose mRNA COVID-19 vaccines (from Pfizer-BioNTech and Moderna) and a 1-dose viral vector vaccine (from Janssen [Johnson & Johnson]) are currently used in the United States.

What is added by this report?

Among U.S. adults without immunocompromising conditions, vaccine effectiveness against COVID-19 hospitalization during March 11–August 15, 2021, was higher for the Moderna vaccine (93%) than the Pfizer-BioNTech vaccine (88%) and the Janssen vaccine (71%).

What are the implications for public health practice?

Although these real-world data suggest some variation in levels of protection by vaccine, all FDA-approved or authorized COVID-19 vaccines provide substantial protection against COVID-19 hospitalization.

The findings in this report are subject to at least six limitations. First, this analysis did not consider children, immunocompromised adults, or VE against COVID-19 that did not result in hospitalization. Second, the CIs for the Janssen VE estimates were wide because of the relatively small number of patients

who received this vaccine. Third, follow-up time was limited to approximately 29 weeks since receipt of full vaccination, and further surveillance of VE over time is warranted. Fourth, although VE estimates were adjusted for relevant potential confounders, residual confounding is possible. Fifth, product-specific VE by variant, including against Delta variants (B.1.617.2 and AY sublineages), was not evaluated. Finally, antibody levels were measured at only a single time point 2–6 weeks after vaccination and changes in antibody response over time as well as cell-mediated immune responses were not assessed.

Two-dose series of the Moderna and Pfizer-BioNTech mRNA COVID-19 vaccines provided high VE for the prevention of COVID-19 hospitalizations during March–August 2021. Protection for the Pfizer-BioNTech vaccine declined 4 months after vaccination. A single dose of the Janssen viral vector vaccine had comparatively lower anti-SARS-CoV-2 antibody response and VE against COVID-19 hospitalizations. Understanding differences in VE by vaccine product can guide individual choices and policy recommendations regarding vaccine boosters. All FDA-approved or authorized COVID-19 vaccines provide substantial protection against COVID-19 hospitalization.

IVY Network

Nicole Calhoun, Baylor Scott & White Health; Kempapura Murthy, Baylor Scott & White Health; Judy Herrick, Baylor Scott & White Health; Amanda McKillop, Baylor Scott & White Health; Eric Hoffman, Baylor Scott & White Health; Martha Zayed, Baylor Scott & White Health; Michael Smith, Baylor Scott & White Health; Natalie Seattle, Baylor Scott & White Health; Jason Ettlinger, Baylor Scott & White Health; Elisa Priest, Baylor Scott & White Health; Jennifer Thomas, Baylor Scott & White Health; Alejandro Arroliga, Baylor Scott & White Health; Madhava Beeram, Baylor Scott & White Health; Ryan Kindle, Baystate Medical Center; Lori-Ann Kozikowski, Baystate Medical Center; Lesley De Souza, Baystate Medical Center; Scott Ouellette, Baystate Medical Center; Sherell Thornton-Thompson, Baystate Medical Center; Omar Mehkri, Cleveland Clinic; Kiran Ashok, Cleveland Clinic; Susan Gole, Cleveland Clinic; Alexander King, Cleveland Clinic; Bryan Poynter, Cleveland Clinic; Nicholas Stanley, Emory University; Audrey Hendrickson, Hennepin County Medical Center; Ellen Maruggi, Hennepin County Medical Center; Tyler Scharber, Hennepin County Medical Center; Jeffrey Jorgensen, Intermountain Medical Center; Robert Bowers, Intermountain Medical Center; Jennifer King, Intermountain Medical Center; Valerie Aston, Intermountain Medical Center; Brent Armbruster, Intermountain Medical Center; Richard E. Rothman, Johns Hopkins University; Rahul Nair, Montefiore Medical Center; Jen-Ting (Tina) Chen, Montefiore Medical Center; Sarah Karow, Ohio State University; Emily Robart, Ohio State University; Paulo Nunes Maldonado, Ohio State University; Maryiam Khan, Ohio State University; Preston So, Ohio State University; Joe Levitt, Stanford University; Cynthia Perez, Stanford University; Anita Visweswaran, Stanford University; Jonasel Roque, Stanford University; Adreanne Rivera, University of California, Los Angeles; Trevor Frankel, University of California, Los Angeles; Jennifer Goff, UCHealth University of Colorado Hospital; David Huynh, UCHealth University of Colorado Hospital; Michelle Howell, UCHealth University of Colorado Hospital; Jennifer Friedel, UCHealth University of Colorado Hospital; Michael Tozier, UCHealth University of Colorado Hospital; Conner Driver, UCHealth University of Colorado Hospital; Michael Carricato, UCHealth University of Colorado Hospital; Alexandra Foster, UCHealth University of Colorado Hospital; Paul Nassar, University of Iowa; Lori Stout, University of Iowa; Zita Sibenaller, University of Iowa; Alicia Walter, University of Iowa; Jasmine Mares, University of Iowa; Logan Olson, University of Iowa; Bradley Clinansmith, University of Iowa; Carolina Rivas, University of Miami; Hayley Gershengorn, University of Miami; EJ McSpadden, University of Michigan; Rachel Truscon, University of Michigan; Anne Kaniclides, University of Michigan; Lara Thomas, University of Michigan; Ramsay Bielak, University of Michigan; Weronika Damek Valvano, University of Michigan; Rebecca Fong, University of Michigan; William J. Fitzsimmons, University of Michigan; Christopher Blair, University of Michigan; Andrew L. Valesano, University of Michigan; Julie Gilbert, University of Michigan; Christine D.

Crider, University of Washington; Kyle A. Steinbock, University of Washington; Thomas C. Paulson, University of Washington; Layla A. Anderson, University of Washington; Christy Kampe, Vanderbilt University Medical Center; Jakea Johnson, Vanderbilt University Medical Center; Rendie McHenry, Vanderbilt University Medical Center; Marcia Blair, Vanderbilt University Medical Center; Douglas Conway, Vanderbilt University Medical Center; Mary LaRose, Wake Forest University; Leigha Landreth, Wake Forest University; Madeline Hicks, Wake Forest University; Lisa Parks, Wake Forest University; Jahnvi Bongu, Washington University; David McDonald, Washington University; Candice Cass, Washington University; Sondra Seiler, Washington University; David Park, Washington University; Tiffany Hink, Washington University; Meghan Wallace, Washington University; Carey-Ann Burnham, Washington University; Olivia G. Arter, Washington University.

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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. Wesley H. Self reports grants and consultant fees from Merck and consultant fees from Aerpio Pharmaceuticals. Adit A. Ginde reports grant support from AbbVie and Faron Pharmaceuticals. Jonathan D. Casey reports a grant (N23HL153584) from the National Institutes of Health (NIH). D. Clark Files reports consultant fees from Cytovale and membership on a Medpace Data Safety Monitoring Board (DSMB). David N. Hager reports salary support from Incyte Corporation, EMPACT Precision Medicine, and the Marcus Foundation. Michelle N. Gong reports grant support from NIH and the Agency for Healthcare Research and Quality (AHRQ) and fees for participating on a DSMB for Regeneron and for participating on a scientific advisory panel for Philips Healthcare. Daniel J. Henning reports consulting fees from Cytovale and Opticyte. Ithan D. Peltan reports grants from NIH and Janssen Pharmaceuticals, institutional fees from Asahi Kasei Pharma and from Regeneron. Samuel M. Brown reports fees from Hamilton for chairing a DSMB, and institutional fees from Faron, Sedana, and Janssen; grants from Sedana, Janssen, NIH, and the Department of Defense (DoD); book royalties from Oxford

University and Brigham Young University; and personal fees from New York University for service on a DSMB. Emily T. Martin reports personal fees from Pfizer for unrelated work and a grant from Merck for unrelated work. Akram Khan reports grants from United Therapeutics, Johnson & Johnson, 4D Medical, Lung LLC, and Reata Pharmaceuticals. Arnold S. Monto reports consulting fees from Sanofi-Pasteur and Seqirus. Steven Y. Chang was a speaker for La Jolla Pharmaceuticals and a Consultant for PureTech Health. Jennie H. Kwon reports grant support from NIH. Matthew C. Exline reports talks on nutrition in COVID pneumonia at APEN conference sponsored by Abbott Labs. Natasha Halasa reports grants from Sanofi and Quidel. James D. Chappell reports a grant from the National Center for Advancing Translational Sciences, NIH. Adam S. Lauring reports consultant fees from Sanofi and fees from Roche for membership on a trial steering committee. Carlos G. Grijalva reports consultant fees from Pfizer, Merck, and Sanofi-Pasteur and grants from Campbell Alliance/Syneos Health, NIH, the Food and Drug Administration, AHRQ, and Sanofi. Todd W. Rice reports personal fees from Cumberland Pharmaceuticals, Inc., as the Director of Medical Affairs, consultant fees from Avisia Pharma, LLC; and DSMB membership fees from Sanofi. Christopher J. Lindsell reports grants from NIH, DoD, and the Marcus Foundation; organizational contract fees from bioMerieux, Endpoint LLC, and Entegriion, Inc.; and a patent issued to Cincinnati Children's Hospital Medical Center for risk stratification in sepsis and septic shock. No other potential conflicts of interest were disclosed.

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Use of Pfizer-BioNTech COVID-19 Vaccine in Persons Aged ≥ 16 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2021

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On September 21, 2021, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

The Pfizer-BioNTech COVID-19 vaccine (BNT162b2) is a lipid nanoparticle-formulated, nucleoside mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 intramuscular doses (30 μ g, 0.3 mL each) administered 3 weeks apart. In December 2020, the vaccine was granted Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) as well as an interim recommendation for use among persons aged ≥ 16 years by the Advisory Committee on Immunization Practices (ACIP) (1). In May 2021, the EUA and interim ACIP recommendations for Pfizer-BioNTech COVID-19 vaccine were extended to adolescents aged 12–15 years (2). During December 14, 2020–September 1, 2021, approximately 211 million doses of Pfizer-BioNTech COVID-19 vaccine were administered in the United States.* On August 23, 2021, FDA approved a Biologics License Application for use of the Pfizer-BioNTech COVID-19 vaccine, Comirnaty (Pfizer, Inc.), in persons aged ≥ 16 years (3). The ACIP COVID-19 Vaccines Work Group's conclusions regarding the evidence for the Pfizer-BioNTech COVID-19 vaccine were presented to ACIP at a public meeting on August 30, 2021. To guide its deliberations regarding the Pfizer-BioNTech COVID-19 vaccine, ACIP used the Evidence to Recommendation (EtR) Framework,[†] and incorporated a Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.[§] In addition to initial clinical trial data, ACIP considered new information gathered in the 8 months since issuance of the interim recommendation for Pfizer-BioNTech COVID-19 vaccine, including additional follow-up time in the clinical trial, real-world vaccine effectiveness studies, and postauthorization vaccine safety monitoring. The additional information increased certainty that benefits from

prevention of asymptomatic infection, COVID-19, and associated hospitalization and death outweighs vaccine-associated risks. On August 30, 2021, ACIP issued a recommendation[¶] for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19.

During June 2020–August 2021, ACIP has convened 18 public meetings to review data on the epidemiology of COVID-19 and considerations for use of COVID-19 vaccines, including the Pfizer-BioNTech COVID-19 vaccine (4). The ACIP COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics, has held one to two meetings each week to review COVID-19 surveillance data; evidence for vaccine efficacy, effectiveness, and safety; and implementation considerations for COVID-19 vaccines. After a systematic review of published and unpublished scientific evidence for benefits and harms, the Work Group used a GRADE approach to assess the certainty of evidence for outcomes related to the vaccine, rated on a scale of 1 (high certainty) to 4 (very low certainty). Within the EtR Framework, ACIP considered the importance of COVID-19 as a public health problem, benefits and harms (including GRADE-assessed evidence), patients' values and preferences, issues of resource use, acceptability to stakeholders, feasibility of implementation, and anticipated impact on health equity. Work Group conclusions regarding the evidence for the Pfizer-BioNTech COVID-19 vaccine were presented to ACIP at a public meeting on August 30, 2021.**

The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was guided by one large randomized, double-blind, placebo-controlled phase II/III clinical trial (5) and one small phase I clinical trial (6), 26 observational vaccine effectiveness studies, and two postauthorization vaccine safety monitoring systems: 1) the Vaccine Adverse Events Reporting System (VAERS) and 2) the Vaccine Safety Datalink (VSD). VAERS, the national vaccine safety monitoring system managed by CDC and FDA, is based on passive reporting and covers

* <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

† <https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf>

§ <https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html>

¶ On August 30, 2021, ACIP voted unanimously in favor of the recommendation for use of Pfizer-BioNTech COVID-19 vaccine for persons aged ≥ 16 years under the FDA Biologics License Application.

** <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/07-COVID-Gargano-508.pdf>

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

On August 23, 2021, the Food and Drug Administration granted full approval of the Pfizer-BioNTech COVID-19 vaccine for persons aged ≥ 16 years.

What is added by this report?

On August 30, 2021, after a systematic review of the data, the Advisory Committee on Immunization Practices revised its interim recommendation to a standard recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years for the prevention of COVID-19.

What are the implications for public health practice?

Continued use of the Pfizer-BioNTech COVID-19 vaccine, now fully approved by the FDA in persons aged ≥ 16 years, is recommended based on increased certainty that its benefits (prevention of asymptomatic infection, COVID-19, and associated hospitalization and death) outweigh vaccine-associated risks.

the entire U.S. population. VSD covers nine participating integrated health care organizations serving approximately 12 million persons and identifies possible adverse events after vaccination as well as age, race, ethnicity, and other demographic information from electronic medical records. Updated findings from the ongoing phase II/III clinical trial were based on data from 44,165 enrolled participants contributing approximately 12,000 person-years, with more than one half of participants followed for ≥ 6 months (August 24, 2020–March 13, 2021). Pooled effectiveness estimates were calculated when multiple observational studies reported data on an outcome, the study periods for which ranged from 3 to 7 months (median = 5 months).

The estimated efficacy of the Pfizer-BioNTech COVID-19 vaccine in the phase II/III clinical trial was based on outcomes that occurred ≥ 7 days after receipt of the second dose. The demographic characteristics of participants, including age and race, published in December 2020 (5), have not changed substantially since initial enrollment. Efficacy in preventing symptomatic, laboratory-confirmed COVID-19 in persons aged ≥ 16 years without evidence of previous SARS-CoV-2 infection was 91.1% (Table 1). No hospitalizations were reported for confirmed COVID-19 in the vaccinated group and 31 confirmed COVID-19–associated hospitalizations in the placebo group, yielding an estimated vaccine efficacy of 100% against COVID-19 hospitalization. One death attributed to COVID-19 occurred in the vaccinated group and six in the placebo group, resulting in a vaccine efficacy of 83.3% against death attributed to COVID-19. The clinical trial did not routinely collect specimens to test for asymptomatic SARS-CoV-2 infection. Observational data were available for

all beneficial outcomes assessed. The pooled vaccine effectiveness estimates from observational studies were 92.4% for prevention of symptomatic, laboratory-confirmed COVID-19; 94.3% against COVID-19–related hospitalization; 96.1% against death attributed to COVID-19; and 89.3% against asymptomatic SARS-CoV-2 infection. Although some studies covered recent periods, most follow-up time occurred before widespread circulation of the SARS-CoV-2 B.1.617.2 (Delta) variant.

Severe local and systemic adverse reactions (i.e., reactogenicity) occurring in the 7 days after vaccination (grade 3 or higher, defined as interfering with daily activity) were more likely to be reported among vaccine recipients (10.7%) than placebo recipients (2.3%) (relative risk = 4.7) (Table 2). Among vaccine recipients, the most common grade 3 symptoms were fatigue, headache, chills, muscle pain, fever, and injection site pain. Overall, reactions consistent with grade 3 or higher were more likely after the second dose than after the first dose. The frequency of serious adverse events^{††} was 1.2% among both vaccine recipients and placebo recipients. Data on serious adverse events from VAERS and VSD demonstrated anaphylaxis and myocarditis/myopericarditis,^{§§} which were rare but occurred after vaccination. VAERS and VSD estimated 4.7 and 5.0 cases of anaphylaxis per million doses of Pfizer-BioNTech COVID-19 vaccine administered, respectively. Myocarditis and myopericarditis were more common among vaccine recipients who were younger, were male, and received the second dose of vaccine. The VSD evaluation included chart-reviewed confirmed myocarditis cases among persons aged 18–39 years after dose 2; the rates of myocarditis were 368 per 1 million person-years (9 of 24,432) in the 0–7-day risk interval compared with 48 per 1 million person-years (3 of 62,481) in the 22–42-day comparison interval among vaccinated persons (adjusted^{¶¶} rate ratio = 9.1). Although VAERS data are subject to the limitations inherent in a passive surveillance system,^{***} the elevated number of observed versus expected myocarditis cases in the 7-day interval after receipt

^{††} Serious adverse events are defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent disability or incapacity; suspected transmission of any infectious agent via a medicinal product; and a medically important event.

^{§§} Myocarditis is an adverse event defined as inflammation of the heart muscle. If it is accompanied by pericarditis, an inflammation of the thin tissue surrounding the heart (the pericardium), it is referred to as myopericarditis.

^{¶¶} Rate ratio adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date.

^{***} Because VAERS is a passive reporting system, limitations include possible bias in reporting, inconsistent data quality, and incomplete information; in addition, VAERS has no direct comparison group. The VAERS system was not designed to assess causality; therefore, VAERS data generally cannot be used to determine whether a causal association between an adverse event and a vaccine exists.

TABLE 1. Potential benefits of Pfizer-BioNTech COVID-19 vaccination: Grading of Recommendations, Assessment, Development and Evaluation — United States, September 2021

Potential benefit	Clinical trial evidence		Observational evidence		GRADE evidence type [†]
	No. of studies	Vaccine efficacy (95% CI)	No. of studies	Pooled vaccine effectiveness* (95% CI)	
Prevention of symptomatic laboratory-confirmed COVID-19 [§]	1	91.1 (88.8 to 93.1)	8	92.4 (87.5 to 95.3)	1
Prevention of COVID-19–associated hospitalization [§]	1	100 (87.6 to 100)	8	94.3 (87.9 to 97.3)	2
Prevention of COVID-19–associated death	1	83.3 (–38.6 to 98.0)	4	96.1 (91.5 to 98.2)	2
Prevention of asymptomatic SARS-CoV-2 infection	0	No data	2	89.3 (88.4 to 90.1)	4

Abbreviations: CI = confidence interval; GRADE = Grading of Recommendations, Assessment, Development and Evaluation.

* Vaccine effectiveness estimates were pooled for the purposes of GRADE review. <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine.html>

[†] GRADE evidence types: 1 = high certainty, 2 = moderate certainty, 3 = low certainty, 4 = very low certainty.

[§] Considered a critical outcome in GRADE. <https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html>

TABLE 2. Potential harms of Pfizer-BioNTech COVID-19 vaccination: Grading of Recommendations, Assessment, Development and Evaluation — United States, September 2021

Potential harms	Clinical trial evidence		Observational evidence		GRADE evidence type*
	No. of studies	RR (95% CI)	No. of studies	Cases per million doses; RR (95% CI); observed versus expected cases	
Reactogenicity	2	4.7 (3.8–5.7)	0	No data	1
Serious adverse events [†]	2	1.0 (0.8–1.2)	0	No data [§]	2
Anaphylaxis					
Persons aged ≥16 yrs, VAERS	NA	NA	1	4.7 cases per million doses [¶]	3
Persons aged ≥12 yrs, VSD	NA	NA	1	5.0 cases per million doses**	
Myocarditis					
Males and females aged 18–39 yrs, VSD	NA	NA	1	RR = 9.1 (95% CI = 2.1–48.6) ^{††}	3
Males aged 16–17 yrs, VAERS	NA	NA	1	120 cases observed versus 0–3 expected ^{§§}	
Females aged 16–17 yrs, VAERS	NA	NA	1	15 cases observed versus 2 expected ^{§§}	
Males aged 30–39 yrs, VAERS	NA	NA	1	40 cases observed versus 1–11 expected ^{¶¶}	
Females aged 30–39 yrs, VAERS	NA	NA	1	7 cases observed versus 1–13 expected ^{¶¶}	

Abbreviations: CI = confidence interval; GRADE = Grading of Recommendations, Assessment, Development and Evaluation; NA = not applicable; RR = relative risk; VAERS = Vaccine Adverse Event Reporting System; VSD = Vaccine Safety Datalink.

* GRADE evidence types: 1 = high certainty, 2 = moderate certainty, 3 = low certainty, 4 = very low certainty.

[†] Considered a critical outcome in GRADE. <https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html>

[§] Observational evidence did not include an aggregate measure of serious adverse events. Data on specific serious adverse events identified through post-authorization safety surveillance were reviewed. Increased risk for myocarditis and anaphylaxis were observed in VAERS and VSD.

[¶] Based on VAERS passively reported cases, in persons aged ≥16 years, occurring in a 0–1-day risk interval after vaccination.

** Based on VSD chart reviewed cases of anaphylaxis, in persons aged ≥12 years, occurring in a 0–1-day risk interval after vaccination (RR = 5.0; 95% CI = 3.5–6.9).

^{††} Based on VSD chart-reviewed cases of myocarditis occurring among persons aged 18–39 years after dose 2, occurring in a 7-day risk interval after vaccination (368 per million person-years) versus a 22–42 day comparison interval in vaccinated persons (48 per million person-years). Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date.

^{§§} Based on VAERS chart-reviewed cases of myocarditis among males and females aged 16–17 years compared with baseline expected cases in the absence of vaccination.

^{¶¶} Based on VAERS preliminary reports of myocarditis among males and females aged 30–39 years compared with baseline expected cases in the absence of vaccination.

of dose 2 of Pfizer-BioNTech vaccine is consistent with the findings from VSD (Table 2).

From the GRADE evidence assessment, the level of certainty for the benefits of Pfizer-BioNTech COVID-19 vaccination among persons aged ≥16 years was type 1 (high certainty) for the prevention of symptomatic COVID-19, type 2 (moderate certainty) for prevention of hospitalization and death attributed to COVID-19, and type 4 (very low certainty) for prevention of asymptomatic SARS-CoV-2 infection (Table 1). Regarding potential harms after vaccination, evidence was type 2 for serious adverse events and type 1 for reactogenicity (Table 2). Since the interim recommendations for Pfizer-BioNTech COVID-19 vaccine were issued in December 2020 (1), data have become available on all outcomes of interest, and the level of certainty

in the estimates of the vaccine benefits has increased for prevention of hospitalization and death. The GRADE evidence profile is available at <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine.html>.

Data reviewed within the EtR framework support the use of the Pfizer-BioNTech COVID-19 vaccine. The COVID-19 Vaccines Work Group concluded that COVID-19 remains an important public health problem and that the desirable effects of disease prevention via vaccination with Pfizer-BioNTech COVID-19 vaccine in persons aged ≥16 years are large and outweigh the potential harms. The Work Group determined that the vaccine is acceptable to vaccine providers and that implementation of vaccination is feasible. Moreover, full FDA approval might increase acceptability of the vaccine among

unvaccinated persons. The Work Group also acknowledged that vaccine-eligible persons aged ≥ 16 years probably considered the desirable effects of vaccination to be favorable compared with the undesirable effects; however, there is likely important variability in vaccine acceptance within this age group, especially among those who are currently unvaccinated. The Work Group had varying opinions regarding the impact that a standard ACIP recommendation for Pfizer-BioNTech COVID-19 vaccine would have on health equity; most felt the impact might vary by subpopulation. The evidence used to guide the EtR is available at <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-etr.html>.

In summary, after 8 months of use under an FDA EUA and ACIP interim recommendation, the Pfizer-BioNTech COVID-19 vaccine, Comirnaty, now has full FDA approval and is recommended by ACIP for use in persons aged ≥ 16 years in the United States. Comirnaty has the same formulation and can be used interchangeably with the Pfizer-BioNTech COVID-19 vaccine used under EUA without presenting any safety or effectiveness concerns. ACIP considered new information beyond what was available at the time of the interim recommendation: an additional 4 months of follow-up of phase II/III clinical trial participants, 26 observational vaccine effectiveness studies involving hundreds of thousands of vaccinated persons, and two postauthorization safety monitoring systems that encompassed millions of vaccinated persons in the United States. The additional information increased certainty that the benefits of Pfizer-BioNTech COVID-19 vaccine outweigh vaccine-associated risks. The Pfizer-BioNTech COVID-19 vaccine continues to have FDA authorization for emergency use and ACIP interim recommendation for use in adolescents aged 12–15 years (2), as well as an additional dose in persons aged ≥ 12 years who are moderately to severely immunocompromised (7).

Before vaccination, a Fact Sheet or Vaccine Information Sheet should be provided to recipients and parents or guardians. Providers should counsel Pfizer-BioNTech COVID-19 vaccine recipients and parents or guardians about expected systemic and local reactogenicity. Additional clinical considerations for COVID-19 vaccine administration are available at <https://www.cdc.gov/vaccines/covid-19/info-by-manufacturer/pfizer/clinical-considerations.html>.

Reporting of Vaccine Adverse Events

Providers are required to report adverse events (including administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death) that occur after receipt of any COVID-19 vaccine to VAERS (8). Information on how to submit a report to VAERS is available at

<https://vaers.hhs.gov/index.html> or 1-800-822-7967. Any person who administers or receives a COVID-19 vaccine is encouraged to report any clinically significant adverse event, regardless of whether it is clear that a vaccine caused the adverse event. In addition, CDC has developed a voluntary smartphone-based online tool (v-safe) that uses text messaging and online surveys to provide near real-time health check-ins after receipt of a COVID-19 vaccine. Adult vaccine recipients can register in v-safe, and parents or guardians can register their adolescent children in v-safe and complete the health surveys on their behalf. CDC's v-safe call center follows up on reports to v-safe that include possible medically significant health events to collect additional information for completion of a VAERS report. Information on v-safe is available at <https://www.cdc.gov/vsafe>.

Acknowledgments

Voting members of the Advisory Committee on Immunization Practices (in addition to listed authors): Kevin A. Ault, University of Kansas Medical Center; Lynn Bahta, Minnesota Department of Health; Beth Bell, University of Washington, Seattle, Washington; Wilbur Chen, University of Maryland School of Medicine; Sybil Cineas, The Warren Alpert Medical School of Brown University; Camille Kotton, Harvard Medical School; Sarah Long, Drexel University College of Medicine; Veronica V. McNally, Franny Strong Foundation; Katherine A. Poehling, Wake Forest School of Medicine; Pablo J. Sánchez, The Research Institute at Nationwide Children's Hospital. Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group: Edward Belongia, Center for Clinical Epidemiology & Population Health, Marshfield Clinic Research Institute; Henry Bernstein, Zucker School of Medicine at Hofstra/Northwell Cohen Children's Medical Center; Dayna Bowen Matthew, George Washington University Law School; Jillian Doss-Walker, Indian Health Service; Marci Drees, Society for Healthcare Epidemiology of America; Jeffrey Duchin, Infectious Diseases Society of America; Doran Fink, Food and Drug Administration; Sandra Fryhofer, American Medical Association; Jason M. Goldman, American College of Physicians; Michael Hogue, American Pharmacists Association; Denise Jamieson, American College of Obstetricians and Gynecologists; Jeffery Kelman, Centers for Medicare & Medicaid Services; David Kim, U.S. Department of Health and Human Services; Kathy Kinlaw, Center for Ethics, Emory University; Susan Lett, Council of State and Territorial Epidemiologists; Dayna Matthew, George Washington University Law School; Kendra McMillan, American Nurses Association; Kathleen Neuzil, Center for Vaccine Development and Global Health, University of Maryland School of Medicine; Sean O'Leary, American Academy of Pediatrics; Christine Oshansky, Biomedical Advanced Research and Development Authority; Stanley Perlman, Department of Microbiology and Immunology, University of Iowa; Marcus Plescia, Association of State and Territorial Health Officials; Chris Roberts, National Institutes of Health; Jose Romero, Arkansas Department of Health; William Schaffner, National Foundation for

Infectious Diseases; Rob Schechter, Association of Immunization Managers; Kenneth Schmader, American Geriatrics Society; Bryan Schumacher, Department of Defense; Peter Szilagyi, University of California, Los Angeles; Jonathan Temte, American Academy of Family Physicians; Matthew Tunis, National Advisory Committee on Immunization Secretariat, Public Health Agency of Canada; Thomas Weiser, Indian Health Service; Matt Zahn, National Association of County and City Health Officials; Rachel Zhang, Food and Drug Administration.

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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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Outbreak of SARS-CoV-2 B.1.617.2 (Delta) Variant Infections Among Incarcerated Persons in a Federal Prison — Texas, July–August 2021

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On September 21, 2021, this report was posted as an MMWR Early Release on the MMWR website (<https://www.cdc.gov/mmwr>).

Incarcerated populations have experienced disproportionately higher rates of COVID-19–related illness and death compared with the general U.S. population, due in part to congregate living environments that can facilitate rapid transmission of SARS-CoV-2, the virus that causes COVID-19, and the high prevalence of underlying medical conditions associated with severe COVID-19 (1,2). The SARS-CoV-2 B.1.617.2 (Delta) variant has caused outbreaks among vaccinated and unvaccinated persons in congregate settings and large public gatherings (3,4). During July 2021, a COVID-19 outbreak involving the Delta variant was identified in a federal prison in Texas, infecting 172 of 233 (74%) incarcerated persons in two housing units. The Federal Bureau of Prisons (BOP) partnered with CDC to investigate. CDC analyzed data on infection status, symptom onset date, hospitalizations, and deaths among incarcerated persons. The attack rate was higher among unvaccinated versus fully vaccinated persons (39 of 42, 93% versus 129 of 185, 70%; $p = 0.002$).[†] Four persons were hospitalized, three of whom were unvaccinated, and one person died, who was unvaccinated. Among a subset of 70 persons consenting to an embedded serial swabbing protocol, the median interval between symptom onset and last positive reverse transcription–polymerase chain reaction (RT-PCR) test result in fully vaccinated versus unvaccinated persons was similar (9 versus 11 days, $p = 0.37$). One or more specimens were culture-positive from five of 12 (42%) unvaccinated and 14 of 37 (38%) fully vaccinated persons for whom viral culture was attempted. In settings where physical distancing is challenging, including correctional and detention facilities, vaccination and implementation of multicomponent prevention strategies

(e.g., testing, medical isolation, quarantine, and masking) are critical to limiting SARS-CoV-2 transmission (5).

Investigation and Response

On July 12, 2021, 18 persons incarcerated in a federal prison in Texas reported COVID-19–like symptoms to BOP health services staff members. All 18 received positive SARS-CoV-2 test results using the Abbott BinaxNOW COVID-19 Ag Card (rapid antigen) test; 11 were fully vaccinated. Three of these persons had reported to the on-site clinic on July 8 with symptoms including coryza, cough, headache, myalgia, or rhinorrhea but did not receive SARS-CoV-2 testing at that time.[§] The 18 persons with positive test results lived in two interconnected units (unit A and unit B) that operated as a single cohort and housed 233 persons in 2- to 10-person cells without doors. Standard COVID-19 prevention protocols that were in place among incarcerated persons included mandatory masking in common areas, cohorting of housing units for daily activities, and head-to-toe sleeping arrangements. Among staff members, prevention protocols included mandatory masking and mandatory daily COVID-19 symptom screening and temperature checks (5).[¶] Before the outbreak, incarcerated persons moved freely between units A and B and were together for meals, recreation, and work; they did not have contact with incarcerated persons housed in other units. After initial identification of COVID-19 cases, unit A was designated as a quarantine unit for persons with negative test results, and unit B was designated as

[§] These persons were identified by a review of on-site clinic records. Clinic records and discussions with on-site staff members suggested that clinicians thought symptoms were likely due to other causes, given a lack of known cases in the prison since January 2021.

[¶] Alcohol-based hand sanitizer was provided in staff-only areas. Mitigation measures among incarcerated persons beyond mandatory masking in common areas included on-site voluntary vaccination provided by BOP; prompt medical isolation of persons testing positive for SARS-CoV-2 and quarantine of exposed persons testing negative; consistent cohorting of housing units for daily activities including meals, recreation, and work assignments; and head-to-toe sleeping arrangements. Signs encouraging frequent hand hygiene were posted throughout the prison, and soap was provided without cost to incarcerated persons. Environmental mitigation measures included regular disinfection of common areas and high-touch surfaces and provision of individual bottles of disinfectant to incarcerated persons for use in their personal spaces. Hard plastic barriers were installed in visitation areas to prevent physical contact between incarcerated persons and visitors.

* These authors contributed equally to the report.

[†] All persons included in the vaccine coverage calculation categorized as vaccinated were fully vaccinated. Persons were considered fully vaccinated if ≥ 14 days had elapsed since they completed all recommended doses of a Food and Drug Administration (FDA)-authorized COVID-19 vaccine series before symptom onset or date of first positive test. Persons were considered partially vaccinated if they had not completed all doses of an FDA-authorized COVID-19 vaccine series or if they had received the final vaccine dose < 14 days before symptom onset or date of first positive test. Partially vaccinated persons were excluded from statistical comparisons by vaccination status.

a medical isolation unit for COVID-19 patients. Staff members assigned to units A and B rotated between these two units and to other units on the basis of daily staffing needs.

During July 12–August 14, 2021, BOP staff members offered same-day SARS-CoV-2 rapid antigen testing to all 233 persons in units A and B reporting symptoms or known exposures; the entire quarantined cohort received testing from BOP during July 12–13 and again on July 14, July 19, July 22, August 2, and August 10 with a combination of rapid antigen and RT-PCR tests.** SARS-CoV-2 testing among staff members was voluntary and was performed off-site by staff members' health care providers. A subset of 70 incarcerated persons in units A and B consented to a secondary investigation for which they reported symptom data through a questionnaire and provided nasal midturbinate swabs daily for up to 20 days after symptom onset. Specimens were tested by RT-PCR.†† Viral culture was attempted for RT-PCR–positive specimens from a nonrandom subset of participants.§§ Genomic sequencing was attempted for one RT-PCR–positive specimen from each participant, when possible.

COVID-19 vaccination was voluntary for BOP staff and incarcerated persons. In 2020, BOP worked with CDC to develop a vaccine prioritization plan in which all staff members were offered vaccination first, followed by incarcerated persons. Among incarcerated persons, those aged ≥ 65 years and those with underlying medical conditions associated with severe COVID-19 were the first to receive a COVID-19 vaccine. In this prison, the Pfizer-BioNTech vaccine was the first available, with first doses administered to incarcerated persons in January 2021.¶¶ Staff vaccination coverage in this report includes only doses administered as part of the BOP occupational health program. BOP was unable to determine the number of staff members who were vaccinated through other providers.

Information on vaccination, demographic characteristics, and underlying medical conditions was extracted from BOP electronic medical records for all 233 persons living in units A and B. Demographic characteristics, underlying medical conditions, and COVID-19–associated hospitalizations and deaths were compared by vaccination status and, among vaccinated persons, by vaccine

product received. Attack rates were compared by demographic and medical characteristics, vaccination status and vaccine product, and time since vaccination. Descriptive statistics were calculated. Differences between groups were assessed using chi-square or Fisher's exact tests. P-values < 0.05 were considered statistically significant, adjusted for multiple comparisons using the Bonferroni correction method. Statistical analyses were performed using SAS (version 9.4; SAS Institute). This activity was reviewed and approved by the BOP Research Review Board and CDC and conducted consistent with applicable federal law and CDC policy.***

Among 233 incarcerated persons, 185 (79%) of whom were fully vaccinated, 172 (74%) received positive SARS-CoV-2 test results during July 12–August 14 (Supplementary Figure, <https://stacks.cdc.gov/view/cdc/109901>). Among a subset of 70 symptomatic persons providing swabs for serial testing, no significant difference was found in the median interval between reported symptom onset and last positive RT-PCR result in vaccinated versus unvaccinated persons (9 versus 11 days, respectively; $p = 0.37$) (Figure). Virus was cultured from one or more specimens from five of 12 (42%) unvaccinated and 14 of 37 (38%) fully vaccinated persons for whom viral culture was attempted. Genomic sequencing confirmed the AY.3 sublineage of the Delta variant in 58 specimens from 58 persons.

Vaccination coverage was 79% among incarcerated persons in units A and B. Among fully vaccinated persons, 93 of 122 (76%) Pfizer-BioNTech recipients and 0 of 50 (0%) Moderna recipients had been vaccinated ≥ 4 months before the outbreak ($p < 0.001$). A larger proportion of Pfizer-BioNTech recipients had diabetes ($p = 0.02$) or hypertension ($p < 0.001$) than Moderna or Janssen COVID-19 vaccine recipients, and a higher proportion of Pfizer-BioNTech and Janssen recipients had a history of smoking ($p < 0.001$) than Moderna recipients (Table 1).

Attack rates were higher among unvaccinated persons (39 of 42; 93%) than among fully vaccinated persons (129 of 185; 70%) ($p = 0.002$) and among persons vaccinated ≥ 4 months before the outbreak (83 of 93; 89%) than among those vaccinated 2 weeks to 2 months before the outbreak (19 of 31; 61%) ($p < 0.001$) (Table 2).

Among both persons with and without a previous SARS-CoV-2 infection, the attack rate was lower among fully vaccinated versus unvaccinated persons (1 of 21 [5%] versus 4 of 7 [57%], $p = 0.008$; 128 of 164 [78%] versus 35 of 35 [100%], $p < 0.001$) (Supplementary Table, <https://stacks.cdc.gov/view/cdc/109901>). Among fully vaccinated persons without a previous SARS-CoV-2 infection, the attack rate was

** Rapid antigen testing was used during the early and middle phases of the outbreak to identify cases quickly and facilitate timely separation of infected persons from those with negative test results. RT-PCR testing was used in the late phase of the outbreak to confirm no new cases had occurred before lifting quarantine precautions.

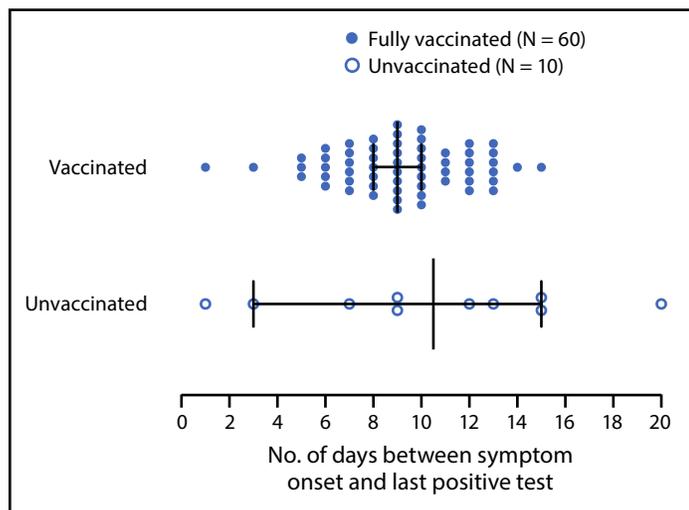
†† <https://www.fda.gov/media/139743/download>

§§ RT-PCR–positive specimens were chosen for viral culture to include both vaccinated and unvaccinated participants and to represent different points in time since first positive diagnostic test. All specimens chosen for culture from vaccinated and unvaccinated participants had a cycle threshold value of < 38 and were collected from 3 days before through 13 days after symptom onset.

¶¶ <https://www.sciencedirect.com/science/article/pii/S0264410X21010781?via%3Dihub>

*** 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.

FIGURE. Number of days* between COVID-19 symptom onset and last positive SARS-CoV-2 reverse transcription–polymerase chain reaction test result among incarcerated persons† in a federal prison, by vaccination status‡ — Texas, July 19–August 9, 2021



Abbreviation: FDA = Food and Drug Administration.

* Vertical lines indicate median number of days; horizontal lines indicate interquartile ranges.

† A subset of 70 persons who consented to an embedded serial swabbing protocol.

‡ Persons were considered fully vaccinated if ≥ 14 days had elapsed since they completed all recommended doses of an FDA-authorized COVID-19 vaccine series before symptom onset or date of first positive test.

higher among Pfizer-BioNTech recipients (99 of 117; 85%) than among Moderna recipients (19 of 35; 54%) ($p < 0.001$).

Among 172 infected persons, four (2%) were hospitalized for COVID-19, including three (8%) of 39 unvaccinated patients, and one (1%) of 129 fully vaccinated patients ($p = 0.04$). One (3%) of the unvaccinated hospitalized patients required endotracheal intubation and mechanical ventilation and died in the hospital (Table 1).^{†††}

Nine of 275 (3%) staff members, four of whom worked in units A or B, reported a positive SARS-CoV-2 test result during the outbreak and were restricted from work per BOP policy. BOP administered COVID-19 vaccine to 37% of staff members in the prison.

Discussion

This study demonstrates the potential for SARS-CoV-2 Delta variant outbreaks in congregate settings including correctional and detention facilities, even among resident populations with

^{†††} The unvaccinated hospitalized patient who died was aged 50–59 years and had obesity, hypertension, and a history of smoking. Among the remaining two hospitalized unvaccinated patients, one was aged 40–49 years and had obesity, and the other was aged 40–49 years and had overweight and moderate to severe asthma. The vaccinated hospitalized patient was aged 50–59 years and had obesity, type II diabetes, hypertension, and a history of smoking.

high vaccination coverage. In this outbreak involving almost three fourths of the incarcerated population in the affected housing units, fewer hospitalizations and deaths occurred among vaccinated than unvaccinated persons, highlighting vaccination as an important strategy to reduce serious COVID-19–related illness and death in congregate settings. In addition, the high number of infections in vaccinated persons, comparable duration of positive RT-PCR test results after symptom onset regardless of vaccination status, and presence of infectious virus in specimens from both unvaccinated and vaccinated infected persons underscore the importance of implementing and maintaining multiple COVID-19 prevention strategies in settings where physical distancing is challenging, even when vaccination coverage is high. Prevention strategies that were in place during this outbreak, including promptly separating infected and exposed persons and cohorting housing units for daily activities, might have prevented the outbreak from spreading to other areas of the prison.

Three of the four hospitalizations and the only death occurred in unvaccinated persons. These findings are consistent with a previous study in which vaccination with a COVID-19 mRNA vaccine (Pfizer-BioNTech or Moderna) reduced the risk for hospitalization associated with Delta variant infection (6). These findings reinforce the critical importance of vaccination in reducing risk for severe illness and death from SARS-CoV-2 Delta variant infections, particularly in congregate settings.

Natural infection with SARS-CoV-2 confers some degree of immunity, although the duration of protection is unknown (7). In this outbreak, the lowest attack rate occurred among fully vaccinated persons with previous infection, highlighting the importance of vaccination, even among persons with previous infection. In addition, attack rates in persons without previous infection were higher among Pfizer-BioNTech recipients than among Moderna recipients. In a recent study, the Moderna vaccine was found to be more effective at preventing COVID-19–related hospitalizations among U.S. adults without immunocompromising conditions (6). In this outbreak, attack rates were also higher in persons who were vaccinated ≥ 4 months before the outbreak compared with persons vaccinated more recently. Because all persons vaccinated ≥ 4 months before the outbreak received the Pfizer-BioNTech vaccine, determining the independent impact of vaccine product versus time since vaccination was not possible. Additional research is warranted to assess the duration of vaccine-induced and natural immunity, as well as the duration of infectious virus shedding by vaccinated and unvaccinated infected persons.

BOP records indicate that nearly two thirds of staff members in this prison were unvaccinated, and at least nine were infected during this outbreak. In addition, during the 2 weeks before the

TABLE 1. Vaccination status* among incarcerated persons in a federal prison, by demographic characteristics, underlying conditions, and COVID-19-associated hospitalizations and deaths — Texas, July 12–August 14, 2021

Characteristic	No. (%)			p-value [†]
	Total	Unvaccinated	Fully vaccinated	
Total	233 (100)	42 (18)	185 (79)	—
Sex				
Male	233 (100)	42 (18)	185 (79)	—
Age group, yrs				
18–29 (Ref.)	—	—	—	0.17
30–39	10 (4)	3 (33)	6 (67)	Ref.
40–49	63 (27)	16 (26)	46 (74)	0.69
50–59	68 (29)	11 (17)	53 (83)	0.36
≥60	65 (28)	10 (15)	55 (85)	0.19
	27 (12)	2 (7)	25 (93)	0.09
Race/Ethnicity				
American Indian/ Alaska Native	—	—	—	0.02
Asian	5 (2)	0 (—)	5 (100)	1.0
Black, non-Hispanic	3 (1)	0 (—)	2 (100)	1.0
Hispanic	47 (20)	16 (36)	29 (64)	<0.001 [§]
White, non-Hispanic	34 (15)	7 (22)	25 (78)	0.22
	144 (62)	19 (13)	124 (87)	Ref.
Country of birth				
Outside the United States	10 (4)	3 (33)	6 (67)	0.37
United States	223 (96)	39 (18)	179 (82)	
Vaccination status				
Fully vaccinated	185 (79)	—	185 (100)	—
Partially vaccinated	6 (3)	—	—	—
Unvaccinated	42 (18)	42 (100)	—	—
Vaccine product received (among fully vaccinated)				
Janssen (Johnson & Johnson)	—	—	13 (100)	—
Moderna	—	—	50 (100)	—
Pfizer-BioNTech	—	—	122 (100)	—
Time from full vaccination to outbreak (among fully vaccinated)				
≥2 wks to 2 mos	—	—	31 (100)	—
2–4 mos	—	—	61 (100)	—
4–6 mos	—	—	93 (100)	—
Documented previous SARS-CoV-2 infection				
No	204 (88)	35 (18)	164 (82)	0.34
Yes	29 (12)	7 (25)	21 (75)	
Housing unit before outbreak				
A	146 (63)	25 (18)	116 (82)	0.70
B	87 (37)	17 (20)	69 (80)	

outbreak, community transmission was high.^{§§§} SARS-CoV-2 can be introduced into correctional facility populations and back into the community through daily entry and exit of staff members and interfacility transfers of incarcerated persons, and the identification of a single viral lineage among all sequenced

^{§§§} <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>. CDC defines community transmission as high when ≥10.0% of nucleic acid amplification tests (NAATs) in the previous 7 days have been positive or when ≥100 new cases per 100,000 persons have occurred in the previous 7 days. In the 2 weeks before the outbreak described in this report, median NAAT test positivity was 17.8% (range = 5%–39.5%) in counties surrounding the affected federal prison.

TABLE 1. (Continued) Vaccination status* among incarcerated persons in a federal prison, by demographic characteristics, underlying conditions, and COVID-19-associated hospitalizations and deaths — Texas, July 12–August 14, 2021

Characteristic	No. (%)			p-value [†]
	Total	Unvaccinated	Fully vaccinated	
Underlying medical conditions[¶]				
History of smoking ^{**}	121 (52)	14 (12)	105 (88)	0.006 [§]
Overweight ^{††}	89 (38)	22 (25)	66 (75)	
Obesity ^{††}	101 (43)	13 (13)	84 (87)	0.07
Severe obesity ^{††}	19 (8)	1 (6)	17 (94)	
Hypertension	90 (39)	13 (15)	75 (85)	0.25
Diabetes	29 (12)	2 (7)	27 (93)	0.12
Moderate to severe asthma	25 (11)	3 (12)	21 (88)	0.58
Chronic obstructive pulmonary disease	16 (7)	1 (7)	14 (93)	0.32
Immunocompromised state	4 (2)	0 (—)	4 (100)	1.0
Chronic kidney disease	3 (1)	0 (—)	3 (100)	1.0
Cancer	2 (1)	0 (—)	2 (100)	1.0
Liver disease	2 (1)	1 (50)	1 (50)	0.34
Serious cardiac condition	1 (0)	1 (0)	0 (—)	0.19
HIV infection	1 (0)	0 (—)	1 (100)	1.0
COVID-19 outcomes				
Hospitalization	4 (2)	3 (75)	1 (25)	0.04 [§]
Death	1 (0)	1 (100)	0 (—)	0.23

Abbreviations: BMI = body mass index; FDA = Food and Drug Administration; Ref. = referent group.

* Descriptive statistics were not calculated for partially vaccinated persons. Partially vaccinated persons were excluded from statistical comparisons by vaccination status. Persons were considered fully vaccinated if ≥14 days had elapsed since they completed all recommended doses of an FDA-authorized COVID-19 vaccine series before symptom onset or date of first positive test. Persons were considered partially vaccinated if they had not completed all doses of an FDA-authorized COVID-19 vaccine series or if they had received the final vaccine dose <14 days before symptom onset or date of first positive test.

[†] P-values from chi-square test (when all cell sizes ≥5) or Fisher's exact test (when any cell size <5).

[§] Statistically significant difference; p-values <0.05 were considered statistically significant, adjusted for multiple comparisons using the Bonferroni correction method.

[¶] No persons had pulmonary fibrosis or history of solid organ or stem cell transplant.

** Information on the type of product smoked was not available.

^{††} Overweight: BMI >25 kg/m² but <30 kg/m²; obesity: BMI ≥30 kg/m² but <40 kg/m²; severe obesity: BMI ≥40 kg/m².

specimens in this outbreak suggests a single introduction of the virus into the prison (8). Bidirectional connections between correctional facilities and communities highlight the importance of high vaccination coverage among both staff members and incarcerated persons, early diagnostic testing, routine screening testing when community transmission is high, maintaining consistent assignments of staff members for each housing unit, and excluding staff members from work when they are symptomatic or have COVID-19 (5,9).

The findings in this report are subject to at least five limitations. First, although rapid antigen testing can identify cases

TABLE 2. SARS-CoV-2 attack rates among incarcerated persons in a federal prison, by demographic characteristics, vaccination status, COVID-19 vaccine product, and underlying conditions — Texas, July 12–August 14, 2021

Characteristic	Total (column %)	No. of cases	Attack rate, %	p-value*
Total	233 (100)	172	74	—
Vaccination status[†]	—	—	—	0.003[§]
Unvaccinated	42 (18)	39	93	0.002 [§]
Partially vaccinated	6 (3)	4	67	1.0
Fully vaccinated	185 (79)	129	70	Ref.
Vaccine product (among fully vaccinated)	—	—	—	<0.001[§]
Janssen (Johnson & Johnson)	13 (7)	10	77	0.03
Moderna	50 (27)	20	40	Ref.
Pfizer-BioNTech	122 (66)	99	81	<0.001 [§]
Time from full vaccination to outbreak (among fully vaccinated)	—	—	—	<0.001[§]
≥2 wks to 2 mos	31 (17)	19	61	Ref.
2–4 mos	61 (33)	27	44	0.12
4–6 mos	93 (50)	83	89	<0.001 [§]
Sex	—	—	—	—
Male	233 (100)	172	74	—
Age group, yrs	—	—	—	0.46
18–29	10 (4)	6	60	Ref.
30–39	63 (27)	43	68	0.72
40–49	68 (29)	50	74	0.46
50–59	65 (28)	52	80	0.22
≥60	27 (12)	21	78	0.41
Race/Ethnicity	—	—	—	0.16
American Indian/Alaska Native	5 (2)	3	60	0.31
Asian	3 (1)	3	100	1.0
Black, non-Hispanic	47 (20)	31	66	0.08
Hispanic	34 (15)	22	65	0.09
White, non-Hispanic	144 (62)	113	78	Ref.
Country of birth	—	—	—	0.46
Outside United States	10 (4)	9	90	0.46
United States	223 (96)	163	73	—
Housing unit before outbreak	—	—	—	0.81
Unit A	146 (63)	107	73	0.81
Unit B	87 (37)	65	75	—

quickly, its limited sensitivity for detecting infections in asymptomatic patients can underestimate attack rates (10). Second, transmission might have preceded initial identification of cases, resulting in an underestimation of total cases. Third, it is uncertain whether lower attack rates by vaccine product were caused by differences in waning vaccine-induced immunity, varying levels of protection among vaccine products, or differences in exposure level among persons who received different vaccine products. Fourth, testing was not mandatory for BOP staff members, limiting the ability to confirm the total numbers of COVID-19 cases. Finally, RT-PCR-positive specimens were not selected randomly for viral culture and thus are not representative of all vaccinated and unvaccinated participants.

TABLE 2. (Continued) SARS-CoV-2 attack rates among incarcerated persons in a federal prison, by demographic characteristics, vaccination status, COVID-19 vaccine product, and underlying conditions — Texas, July 12–August 14, 2021

Characteristic	Total (column %)	No. of cases	Attack rate, %	p-value*
Underlying medical conditions				
History of smoking [¶]	121 (52)	88	73	0.69
Hypertension	90 (39)	73	81	0.05
Overweight**	89 (38)	64	72	0.55
Obesity**	101 (43)	76	75	—
Severe obesity**	19 (8)	16	84	—
Moderate to severe asthma	25 (11)	21	84	0.34
Diabetes	29 (12)	26	90	0.04 [§]
Chronic obstructive pulmonary disease	16 (7)	15	94	0.08
Chronic kidney disease	3 (1)	3	100	0.57
Immunocompromised state	4 (2)	3	75	1.0
Liver disease	2 (1)	2	100	1.0
Cancer	2 (1)	1	50	0.46
Serious cardiac condition	1 (0.4)	1	100	1.0
HIV infection	1 (0.4)	1	100	1.0

Abbreviations: BMI = body mass index; FDA = Food and Drug Administration; Ref. = referent group.

* P-values from chi-square test (when all cell sizes ≥5) or Fisher's exact test (when any cell size <5).

[†] Persons were considered fully vaccinated if ≥14 days had elapsed since they completed all recommended doses of an FDA-authorized COVID-19 vaccine series before symptom onset or date of first positive test. Persons were considered partially vaccinated if they had not completed all doses of an FDA-authorized COVID-19 vaccine series or if they had received the final vaccine dose <14 days before symptom onset or date of first positive test.

[§] Statistically significant difference; p-values <0.05 were considered statistically significant, adjusted for multiple comparisons using the Bonferroni correction method.

[¶] Information on type of product smoked was not available.

** Overweight: BMI >25 kg/m² but <30 kg/m²; obesity: BMI ≥30 kg/m² but <40 kg/m²; severe obesity: BMI ≥40 kg/m².

During a COVID-19 outbreak in a federal prison involving the highly transmissible SARS-CoV-2 Delta variant, transmission was high among vaccinated and unvaccinated persons. Although hospitalizations, deaths, and attack rates were higher among unvaccinated than vaccinated persons, the duration of positive serial test results was similar between these two groups, and infectious virus was cultured from both vaccinated and unvaccinated participants. Widespread vaccination among incarcerated persons and staff members in coordination with other prevention strategies, including early diagnostic testing for all persons with any COVID-19–like symptoms, screening testing, medical isolation, quarantine, masking, and physical distancing where possible, remain critical to limiting SARS-CoV-2 transmission and COVID-19–related illness and death in congregate settings, including correctional and detention facilities (5).

References

Summary

What is already known about this topic?

Incarcerated populations have experienced disproportionately higher rates of COVID-19–related illness and death.

What is added by this report?

During a COVID-19 outbreak involving the Delta variant in a highly vaccinated incarcerated population, transmission rates were high, even among vaccinated persons. Although attack rates, hospitalizations, and deaths were higher among unvaccinated than among vaccinated persons, duration of positive serial test results was similar for both groups. Infectious virus was cultured from vaccinated and unvaccinated infected persons.

What are the implications for public health practice?

Even with high vaccination rates, maintaining multicomponent prevention strategies (e.g., testing and masking for all persons and prompt medical isolation and quarantine for incarcerated persons) remains critical to limiting SARS-CoV-2 transmission in congregate settings where physical distancing is challenging.

Acknowledgments

Mario Cordova, Torrey Haskins, Jennifer Jackson, Joshua Jett, Barbara Swopes, Tammy Winbush, Federal Bureau of Prisons; Raydel Anderson, Adam K. Wharton, Kay W. Radford, Gimin Kim, Dexter Thompson, Benton Lawson, Congrong Miao, Bettina Bankamp, Suganthi Suppiah, Michael Bowen, Baoming Jiang, Jan Vinjé, Amy Hopkins, Kenny Nguyen, Leslie Barclay, Sung-Sil Moon, Leeann Smart, Courtnee Wright, Mary Casey-Moore, Boris Relja, Michelle Honeywood, Rashi Gautam, Theresa Bessey, Jennifer M. Folster, Shannon Rogers, Nhien T. Wynn, John Michael Metz, Ebenezer David, Madina Jumabaeva, Justin Runac, Min-shin Chen, Maria Solano, Joyce Peterson, Diagnostics Testing Laboratories, CDC COVID-19 Response Team; Dhvani Batra, Andrew Beck, Jason Caravas, Victoria Caban-Figueroa, Eric Chirtel, Roxana Cintron-Moret, Peter W. Cook, Jonathan Gerhart, Christopher Gulvik, Norman Hassell, Dakota Howard, Yunho Jang, Tymeckia Kendall, Rebecca J. Kondor, Nicholas Kovacs, Kristine Lacek, Brian R. Mann, Laura K. McMullan, Kara Moser, Roopa Nagilla, Clinton R. Paden, Benjamin Rambo-Martin, Adam Retchless, Matthew Schmerer, Sandra Seby, Samuel Shepard, Phillip Shirk, Catherine Smith, Richard Stanton, Thomas Stark, Erisa Sula, Yvette Unoarumhi, Xiao-yu Zheng, Jonathan Zhong, CDC Strain Surveillance and Emerging Variant Work Group.

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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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Errata

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In the report “Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 years — United States, August 2020–August 2021,” on page 1252, in the Table, the second footnote should have read, “† ED visit data are from the National Syndromic Surveillance Program (NSSP). Data are limited to ED visits with a discharge diagnosis. Data from Hawaii and Ohio are not included. Fewer than 50% of facilities in California, Iowa, Minnesota, and **Oklahoma** report to NSSP. In HHS Region 7, fewer than 50% of all ED visits have a discharge diagnosis.” On page 1253, the title for Figure 2 should have read, “Number of **COVID-19 hospitalizations** and percentage of COVID-19 hospitalizations resulting in intensive care unit admission or invasive mechanical ventilation among persons aged 0–17 years, by age group — United States, August 1, 2020–August 21, 2021.”

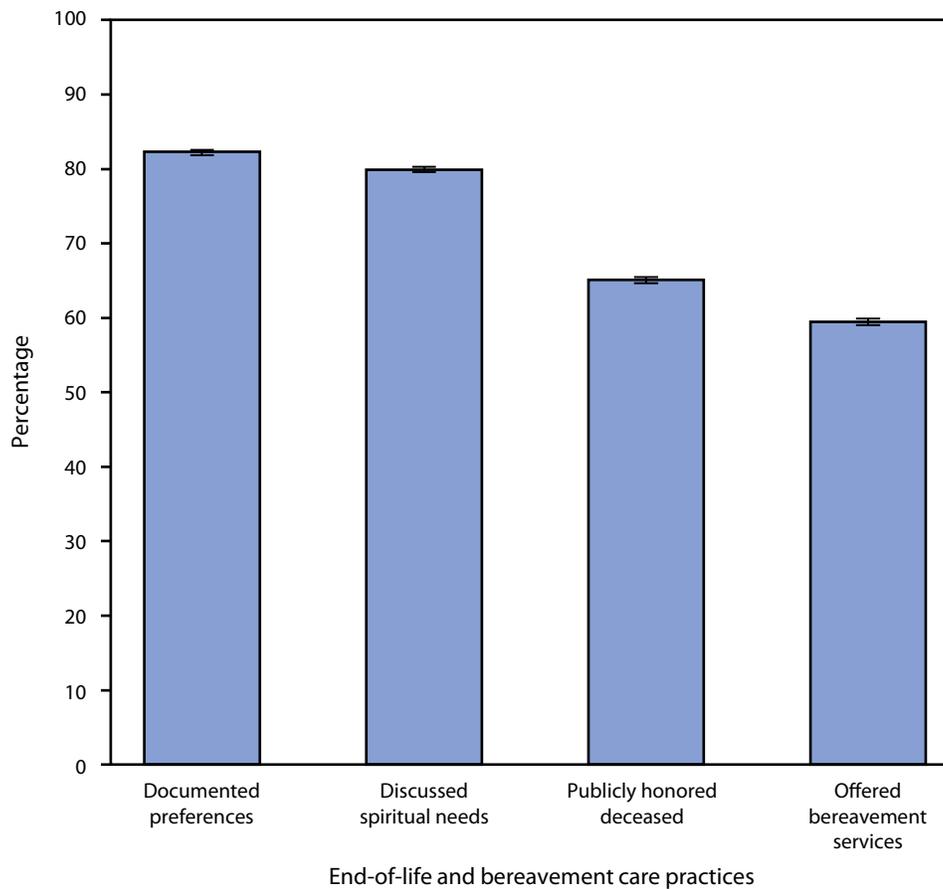
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In the report “Longitudinal Trends in Body Mass Index Before and During the COVID-19 Pandemic Among Persons Aged 2–19 Years — United States, 2018–2020,” on page 1279, the third sentence of the first full paragraph should have read, “Based on initial BMI, obesity prevalence was **16.0%**, including 4.8% with severe obesity.” On page 1280, the last sentence should have read, “Weight gain at this rate over 6 months is estimated to result in 6.1 and **7.3** pounds, respectively, compared with 2.7 pounds in a person with healthy weight.” On page 1281, the figure title should have read, “Estimated body mass index before and during the COVID-19 pandemic, by initial body mass index category, stratified by age group — IQVIA Ambulatory Electronic Medical Records Database, United States, **January 2018–November 2020.**”

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Residential Care Communities[†] Engaged in Selected End-of-Life and Bereavement Care Practices[§] — National Study of Long-Term Care Providers, United States, 2018



Abbreviation: RCC = residential care community.

* 95% confidence intervals indicated with error bars.

[†] RCCs and similar assisted living communities are state-regulated, provide services in noninstitutional home-like settings, and are staffed around the clock to provide supervision and assistance with personal care to adults.

[§] Based on RCCs that answered "often" or "almost always" to the question, "How often do you engage in the following practices when a resident is dying or has died: rarely, sometimes, often, or almost always?"

In 2018, when a resident was dying or died, 82% of RCCs documented residents' family, religious, or cultural preferences in their care plans, 79.9% discussed residents' spiritual needs with them, 65.1% publicly honored deceased residents in the RCC, and 59.5% offered bereavement services to staff members and residents.

Source: National Study of Long-Term Care Providers, 2018. <https://www.cdc.gov/nchs/npals/index.htm>

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For more information about this topic, CDC recommends the following link: <https://www.cdc.gov/aging/advancecareplanning>.

Morbidity and Mortality Weekly Report

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ISSN: 0149-2195 (Print)