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Health Status and Health Care Use Among Adolescents Identified With and Without Autism in Early Childhood — Four U.S. Sites, 2018–2020

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Persons identified in early childhood as having autism spectrum disorder (autism) often have co-occurring health problems that extend into adolescence (*1–3*). Although only limited data exist on their health and use of health care services as they transition to adolescence, emerging data suggest that a minority of these persons receive recommended guidance* from their primary care providers (PCPs) starting at age 12 years to ensure a planned transition from pediatric to adult health care (*4,5*). To address this gap in data, researchers analyzed preliminary data from a follow-up survey of parents and guardians of adolescents aged 12–16 years who previously participated in the Study to Explore Early Development (https://www.cdc.gov/ncbddd/autism/seed.html). The adolescents were originally studied at ages 2–5 years and identified at that age as having autism (autism group) or as general population controls (control group). Adjusted prevalence ratios (aPRs) that accounted for differences in demographic characteristics were used to compare outcomes between groups. Adolescents in the autism group were more likely than were those in the control group to have physical difficulties (21.2% versus 1.6%; aPR = 11.6; 95% confidence interval [CI] = 4.2–31.9), and to have additional mental health or other conditions†

* Recommended guidance on health care transition is defined in the context of three transition elements included in the National Performance Measure of the Health Resources and Services Administration (HRSA) Maternal and Child Health Bureau (MCHB) (https://mchb.tvisdata.hrsa.gov/PrioritiesAndMeasures/NationalPerformanceMeasures). The three elements are 1) time alone, without a parent present, with PCP at last preventive visit; 2) PCP actively worked with child; and 3) parent knows how child will be insured as he or she becomes an adult. Adolescents met the health care transition measure if all three elements were endorsed by the adolescent's parent. https://doi.org/10.1007/s10995-019-02858-6

† Mental health and other conditions included attention-deficit/hyperactivity disorder, anxiety, intellectual disability, depression, obsessive-compulsive disorder, epilepsy/seizure disorder, bipolar disorder, substance abuse disorders, Tourette syndrome, fragile X syndrome, and Down syndrome.

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(one or more condition: 63.0% versus 28.9%; aPR = 1.9; 95% CI = 1.5–2.5). Adolescents in the autism group were more likely to receive mental health services (41.8% versus 22.1%; aPR = 1.8, 95% CI = 1.3–2.6) but were also more likely to have an unmet medical or mental health service need[§] (11.0% versus 3.2%; aPR = 3.1; 95% CI = 1.1–8.8). In both groups, a small percentage of adolescents (autism, 7.5%; control, 14.1%) received recommended health care transition (transition) guidance. These findings are consistent with previous research (*4,5*) indicating that few adolescents receive the recommended transition guidance and suggest that adolescents identified with autism in early childhood are more likely than adolescents in the general population to have unmet health care service needs. Improved provider training on the heath care needs of adolescents with autism and coordination of comprehensive programs[¶] to meet their needs can improve delivery of services and adherence to recommended guidance for transitioning from pediatric to adult health care.

Data were collected during July 2018–December 2020 from parents and guardians (parents) of adolescents aged 12–16 years (born September 2003–August 2006) who took part in a multisite study during 2007–2011 at ages 2–5 years (*6*). To assess the feasibility of conducting a larger follow-up study of all participants who took part in the multisite study, researchers at four sites (located in Georgia, Maryland, North Carolina, and Pennsylvania) conducted this preliminary follow-up study. Participants had completed key study components and received a final study classification in the autism or control group during the original study, and parents had consented to future follow-up. Participants identified in a second control arm of the original study as having a developmental disability

Summary

What is already known about this topic?

Mental health and other conditions are more frequent among children with autism; these conditions often persist into adolescence and require more services and coordination of care.

What is added by this report?

Compared with a general population control group, adolescents with autism were 90% more likely to have additional mental health or other conditions and three times more likely to have unmet health care service needs.

What are the implications for public health practice?

Improved provider training on the heath care needs of adolescents with autism and coordination of comprehensive programs to meet their needs can improve delivery of services and adherence to guidance for transitioning from pediatric to adult health care.

[§] Affirmative response to the question, "During the past 12 months, was there any time when this child needed health care, but it was not received? By health care, we mean medical care as well as other kinds of care like dental care, vision care, and mental health services."

[¶] For example, HRSA MCHB's adolescent and young adult programs. https://mchb.hrsa.gov/maternal-child-health-topics/adolescent-and-young-adult-health

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other than autism were excluded from the current analyses due to substantial heterogeneity of conditions. During the original study, classification of adolescents in the autism group was based on a comprehensive in-person evaluation (*7*).

For the current follow-up study, parents completed survey questions and standardized scales related to the adolescent's daily living skills (*8*), current severity of autism symptoms, overall health status, physical difficulties (e.g., difficulty walking, using hands to write or eat, hearing, or seeing), gastrointestinal symptoms, sleep problems, mental health or other conditions, and use of health and mental health services during the previous 12 months.** Parents were also asked about transition planning in the context of the three elements included in the Health Resources and Services Administration Maternal and Child Health Bureau (MCHB) National Performance Measure. Adolescents were considered to have received the recommended guidance on transition planning if they met all three elements, which include 1) time alone, without a parent present, with PCP at last preventive visit; 2) PCP actively worked with child; and 3) parent knows how child will be insured as he or she becomes an adult.

Categorical sociodemographic variables were compared using a modified Poisson regression with robust error variance to estimate unadjusted prevalence ratios (PRs) and 95% CIs; PRs were considered significant when the 95% CI did not include 1. For all other categorical variables, PRs and 95% CIs were adjusted for demographics (aPR)†† to examine differences between the autism and control groups. Continuous variables (e.g., mother's and adolescent's age, difficulty carrying out daily living tasks, and autism symptoms) were examined via linear regression. Because between-group differences could be influenced by the higher percentage of co-occurring intellectual disability among adolescents in the autism group, sensitivity analyses were conducted that excluded participants with a current diagnosis of intellectual disability. Additionally, to assess the potential impact of the COVID-19 pandemic, investigators compared use of health care services and transition planning among participants who completed the survey during July 2018–February 2020 to those who completed the survey during March 2020–December 2020. All analyses were conducted using R (version 3.6.1; The R Foundation).

As of December 2020, the survey had been completed by 146 parents of adolescents in the autism group and 249 in the control group.§§,¶¶ Mean age of adolescents was 14.7 years (interquartile range = 14.3–15.0). Compared with the control group, the following percentages were higher among the autism group: mother born outside the United States (17.1% versus 6.0%), household income below the federal poverty level (26.7% versus 11.2%), and use of public insurance only (24.0% versus 6.0%) or both public and private insurance (23.3% versus 3.2%). A higher percentage of adolescents in the autism group were male (80.1% versus 49.0%) and non-Hispanic Black (21.2% versus 9.2%). Adolescents in the autism group demonstrated greater difficulty carrying out daily tasks independently and had higher autism symptom severity scores (Table 1).

Compared with the control group, the percentage of adolescents in the autism group whose overall health was reported as excellent was lower (40.4% versus 65.1%), whereas percentages in the autism group were higher for physical difficulties (21.2% versus 1.6%), sleep problems (54.8% versus 40.2%), and additional mental health or other conditions (one or more condition: 63.0% versus 28.9%, and two or more conditions: 41.8% versus 10.8%). The two most common conditions in both groups were more prevalent in the autism group: attention-deficit/hyperactivity disorder (ADHD) (39.7% versus 15.7%) and anxiety (36.3% versus 16.1%). Intellectual

** Measures used to assess health-related outcomes and use of services included 1) daily living skills: Waisman Activities of Daily Living (https://doi.org/10.1016/j.dhjo.2012.08.005); 2) autism symptoms: Social Responsiveness Scale 2nd edition parent-report for school-aged children form (https://www.carautismroadmap.org/social-responsiveness-scale/) wherein total standard scores <60 were considered not clinically significant symptoms of autism spectrum disorder; 3) overall health: parents rated child's health as excellent, very good, good, fair, or poor; 4) physical difficulties: parents indicated if child had any difficulty with walking or climbing stairs, using his or her hands (e.g., for writing or eating), hearing or deafness, or seeing or blindness; 5) gastrointestinal symptoms: parents indicated if child had any frequent or chronic difficulty in the previous 12 months with digesting food, including stomach or intestinal problems, constipation, or diarrhea; 6) sleep problems: parents indicated that their child experienced one or more of the following sleep problems at least two or more times per week: teeth grinding, restlessness, bed-wetting, sleep talking, sleep walking, nightmares, and night terrors; and 7) health and mental health services, which included preventive check-ups (including well-child visits), medical care of any type (including seeing a doctor, nurse, or other health care professional for sick-child care, physical exams, or hospitalizations), and mental health care (including seeing a psychiatrist, psychologist, psychiatric nurse, or clinical social worker).

†† PRs adjusted for mother's level of education, mother's country of birth, adolescent's sex, adolescent's race and ethnicity, income relative to the federal poverty level, and insurance type. Additional details on demographics are provided (Table 1).

§§ A total of 1,007 adolescents met the eligibility criteria for the follow-up study. As of December 2020, approximately 82% (824) had been invited to participate, 70% (581) of those invited were enrolled, and 68% (395) of those enrolled completed the follow-up study. Participation rates for the autism versus control group did not differ for either the percentage of those invited who enrolled (67% versus 73%; p = 0.3) or the percentage completing the study (61% versus 73%; p = 0.1).

¶¶ Demographic data from the original study indicated that parents who participated in the follow-up study, compared with those who did not, were more likely to have a bachelor's degree or higher degree (71.8% versus 56.0%; PR = 1.6; 95% CI = 1.3–1.9) and have an annual income of $70,000 or more (63.6% versus 53.7%; PR = 1.3; 95% CI = 1.1–1.5). Adolescents in the current study were more likely to be non-Hispanic White (69.1% versus 56.3%; PR = 1.2; 95% CI = 1.1–1.4). Mother's primary language and country of birth did not differ between those who did and did not participate in the current study.

TABLE 1. Sociodemographic characteristics of mothers and their adolescent children in the autism spectrum disorder and the general population control groups — Study to Explore Early Development, four U.S. sites, 2018–2020*

Adolescent/Maternal characteristic	Autism, % (n = 146)	Control, % (n = 249)	Autism vs. control, PR† (95% CI)§
Maternal age, yrs, mean (SD)	45.8 (6.7)	46.4 (4.6)	p = 0.3¶
Adolescent's age, yrs, mean (SD)	14.7 (0.6)	14.7 (0.4)	p = 0.4¶
Maternal education			
≤High school diploma	7.5	5.6	1.3 (0.6–2.9)
Some college or technical degree	23.3	16.1	1.5 (1.0–2.2)
Bachelor's degree	33.6	41.4	0.8 (0.6–1.1)
Advanced degree	35.6	36.9	1.0 (0.8–1.2)
Mother born outside United States**	17.1	6.0	2.8 (1.6–5.2)
Adolescent's sex**			
Female	19.9	51.0	0.4 (0.3–0.6)
Male	80.1	49.0	1.6 (1.4–1.9)
Adolescent's race/ethnicity,††**			
White, non-Hispanic	56.2	76.7	0.7 (0.6–0.9)
Black, non-Hispanic	21.2	9.2	2.3 (1.4–3.8)
Other, non-Hispanic	14.4	7.6	1.9 (1.1–3.4)
Hispanic	8.2	6.4	1.3 (0.6–2.6)
Primary language spoken in home**			
English	93.2	96.8	1.0 (0.9–1.0)
Other	6.8	3.2	2.1 (0.9–5.3)
Current household income, % FPL§§			
<100	26.7	11.2	2.4 (1.6–3.8)
100–199	16.4	10.8	1.6 (0.9–2.6)
200–299	39.7	58.2	0.7 (0.6–0.9)
≥300	11.6	16.5	0.7 (0.4–1.2)
Insurance¶¶			
Private only	51.4	90.0	0.6 (0.5–0.7)
Public only	24.0	6.0	4.0 (2.3–7.0)
Both public and private	23.3	3.2	7.3 (3.5–15.2)
Daily living skills,* mean (SD)**	22.7 (7.1)	31.5 (2.6)	p≤0.001
Autism symptom severity,††† mean (SD)	70.7 (12.9)	46.8 (8.1)	p≤0.001

Abbreviations: CI = confidence interval; FPL = federal poverty level; PR = prevalence ratio; SD = standard deviation.

* Survey data were collected from four sites in Georgia, Maryland, North Carolina, and Pennsylvania as part of a preliminary follow-up study of parents or guardians of adolescents aged 12–16 years who were enrolled in the Study to Explore Early Development (https://www.cdc.gov/ncbddd/autism/seed.html) at ages 2–5 years and initially identified as having autism (autism group) or as general population controls (control group).

† For categorical variables, unadjusted PRs were estimated using a modified Poisson regression with robust standard error (https://doi.org/10.1093/aje/kwh090) and study group (autism or control) as the only predictor variable.

§ PRs were considered significant when the 95% CI did not include the null value of 1.

¶ For continuous variables (e.g., maternal age, child age, daily living skills, and autism symptom severity), linear regression was conducted using study group (autism or control) as the only predictor variable.

** Data collected as part of original Study to Explore Early Development when child was aged 2–5 years.

†† Maternal and paternal race/ethnicity used in combination to assign adolescent race/ethnicity.

§§ Data missing for 16 participants (autism: n = 8; control: n = 8).

¶¶ Uninsured participants not reported because of small sample size (autism: n = 2; control: n = 2).

*** Current daily living skills measured by Waisman Activities of Daily Living, which contains 17 items; each item is rated as 0 = does not do, 1 = does with help, 2 = does on own. Item scores are summed to produce an overall score; a maximum score of 34 indicates complete independence. https://doi.org/10.1016/j.dhjo.2012.08.005

††† Current autism symptoms measured by Social Responsiveness Scale, 2nd edition parent-report for school-aged children (https://www.carautismroadmap.org/social-responsiveness-scale/). Scores <60 were considered not clinically significant symptoms of autism; scores of 60–65, 66–75, or >76 indicated mild, moderate, or severe deficiencies in reciprocal social behavior associated with autism, respectively.

disability was more prevalent in the autism group (27.4% versus 0.8%) (Table 2).

The percentage of participants receiving a preventive health check-up within the previous 12 months was 89.7% for the autism group and 96.0% for the control group. Compared with the control group, a higher percentage of participants in the autism group received mental health services (41.8% versus 22.1%) and had an unmet medical or mental health care service need (11.0% versus 3.2%). In both groups, a small percentage of adolescents met all three elements of the health care transition measure (i.e., the child spent time alone with the PCP, without a parent present at last preventive visit; the PCP actively worked with child; and the parent knows how child will be insured as he or she reaches adulthood) (autism, 7.5%; control, 14.1%). The percentage of those receiving a limited number of transition planning elements (i.e., none or one of three) was higher in the autism group (69.2% versus 43.0%), whereas the percentage who spoke with their doctor or PCP privately, without a parent present, was lower (38.4% versus 66.3%) (Table 3).

Results were similar when adolescents with a current intellectual disability diagnosis were excluded. Adolescents in the autism group had more physical difficulties and additional mental health or other conditions than did those in the control group (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/105176) and completed fewer transition planning components (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/105177). Comparing participants who completed the survey before and after the onset of the COVID-19 pandemic, investigators noted no significant declines in the receipt of services or health care transition planning elements.

Discussion

This study confirms previous research indicating that physical difficulties and co-occurring mental health or other conditions are prevalent among adolescents identified with autism in early childhood (*1–3,9*). Approximately one in five had physical difficulties, and approximately three in five had additional mental health or other conditions, such as ADHD

TABLE 2. Overall health, physical difficulties, and co-occurring mental health or other conditions among adolescent children in the autism spectrum disorder and the general population control groups — Study to Explore Early Development, four U.S. sites, 2018–2020*

Current health-related outcomes	Autism, % (n = 146)	Control, % (n = 249)	Autism vs. control, aPR† (95% CI)§
Overall health	N/A	N/A	p<0.001¶
Excellent	40.4	65.1	0.7 (0.5–0.9)
Very good	41.1	24.9	1.7 (1.2–2.4)
Good	15.1	7.6	2.0 (1.1–3.5)
Fair or poor	3.4	2.4	—**
Physical difficulties, one or more	21.2	1.6	11.6 (4.2–31.9)
Difficulty using hands	13.7	0.4	20.8 (3.0–143.4)
Difficulty hearing or deafness	5.5	0.4	—**
Difficulty seeing or blindness	5.5	0.4	—**
Difficulty walking or climbing stairs	3.4	1.2	—**
Gastrointestinal symptoms/ difficulties††	19.9	11.6	1.4 (0.7–2.6)
At least one sleep problem occurring ≥2 times/week§§	54.8	40.2	1.5 (1.2–1.9)
Current mental health or other conditions			
Attention-deficit/ Hyperactivity disorder	39.7	15.7	1.7 (1.2–2.6)
Anxiety	36.3	16.1	2.4 (1.6–3.5)
Intellectual disability	27.4	0.8	30.6 (7.4–127.4)
Depression	6.8	6.8	1.0 (0.4–2.2)
Obsessive-compulsive disorder	8.9	2.0	3.5 (1.1–10.8)
Epilepsy or seizure disorder	7.5	0.4	1.8 (0.5–6.2)
Other conditions¶¶	4.1	0.4	—**
One or more conditions	63.0	28.9	1.9 (1.5–2.5)
Two or more conditions	41.8	10.8	3.4 (2.2–5.3)

Abbreviations: aPR = adjusted prevalence ratio; CI = confidence interval; N/A = not applicable.

* Survey data were collected from four sites in Georgia, Maryland, North Carolina, and Pennsylvania as part of a preliminary follow-up study of parents or guardians of adolescents aged 12–16 years who were enrolled in the Study to Explore Early Development (https://www.cdc.gov/ncbddd/autism/seed.html) at ages 2–5 years and initially identified as having autism (autism group) or as general population controls (control group).

† aPRs were estimated using a modified Poisson regression with robust standard error (https://doi.org/10.1093/aje/kwh090) and study group (autism or control) as the predictor, adjusted for maternal education, maternal country of birth (born inside or outside the United States), adolescent sex (male or female), adolescent race/ethnicity (non-Hispanic White, non-Hispanic Black, non-Hispanic other, or Hispanic), household income as a percentage of federal poverty level, and insurance type (private, public, both, or neither); data on maternal and paternal race/ethnicity that were collected during the original Study to Explore Early Development were used in combination to assign adolescent race/ethnicity.

§ aPRs were considered significant when the 95% CI did not include the null value of 1.

¶ Significance testing conducted using ordinal logistic regression; p-values indicate significant between group variation.

** aPR suppressed because of small cell size (n<10) and low estimated stability.

†† Parents who indicated that during the previous 12 months their child had frequent or chronic difficulty with any digesting food, including stomach or intestinal problems, constipation, or diarrhea.

§§ Sleep problems included teeth grinding, restlessness, bed-wetting, sleep talking, sleep walking, nightmares, and night terrors.

¶¶ Other conditions included substance abuse, bipolar disorder, Tourette syndrome, fragile X syndrome, or Down syndrome; adolescents with more than one of these specific conditions are represented only once.

or anxiety. Compared with adolescents in the control group, those with autism were 90% more likely to have additional mental health or other conditions, yet three times more likely to have an unmet health care service need. Consistent with other studies (*4*,*5*,*10*), a small percentage of adolescents in both groups (7.5% versus 14.1%) received the recommended guidance on health care transition planning from their doctors or health care providers. However, the percentage of adolescents receiving little to no transition guidance from their PCPs (i.e., none or one of three transition recommendations) was higher in the autism group. Taken together with other studies (*1*–*3*,*9*,*10*), these results not only add to the growing body of evidence indicating a gap in transition guidance for adolescents in the general population but also suggest that adolescents with autism are even less likely to receive this guidance.

The findings in this report are subject to at least five limitations. First, autism was reported but not re-confirmed in adolescents, so some adolescents who were identified with autism in early childhood might no longer meet the criteria applied in the original study (*7*). Second, not all eligible participants responded, which might have led to selection bias. Third, the small sample size limited statistical power. Fourth, data are based on parent-report and might be subject to recall or social desirability bias. Finally, although relevant demographic characteristics were adjusted for when computing aPRs, residual confounding possibly remained.

The findings provided in this report indicate that adolescents with autism had greater physical difficulties, had poorer physical and mental health, and experienced greater gaps in health care use and transition planning than did adolescents from the population control group. Potential strategies for improving health outcomes and reducing gaps in use of services for adolescents with autism include offering interdisciplinary training to professionals that promotes use of evidence-based interventions and increases provider comfort in treating adolescents with autism and other developmental disorders;*** improving delivery of care to be timely, coordinated, and family-centered;††† and promoting programs that facilitate successful health care transition for adolescents, including those with autism and other developmental disorders.§§§

*** For example, HRSA MCHB's Autism Initiatives. https://mchb.hrsa.gov/maternal-child-health-initiatives/autism

††† For example, the Association of University Centers on Disabilities Children's Mental Health Champions program: https://www.aucd.org/template/news.cfm?news_id=14854&parent=16

§§§ For example, HRSA MCHB's Center for Health Care Transition. https://www.hrsa.gov/library/got-transition

TABLE 3. Health care use, need, and transition planning among adolescent children in the autism spectrum disorder and general population control groups — Study to Explore Early Development, four U.S. sites, 2018–2020*

Health care use and need	Autism, % (n = 146)	Control, % (n = 249)	Autism vs. control, aPR† (95% CI)§
Received health care services in previous 12 mos			
Preventive check-ups¶	89.7	96.0	0.9 (0.8–1.0)
Medical care of any type**	93.2	98.0	0.9 (0.9–1.0)
Mental health††	41.8	22.1	1.8 (1.3–2.6)
Needed health care services at any time in previous 12 mos but did not receive			
Health care of any type§§	11.0	3.2	3.1 (1.1–8.8)
Medical care of any type¶¶	7.5	2.0	3.4 (1.0–11.8)
Mental health***,†††	7.5	3.2	2.2 (0.7–6.6)
Health care transition components§§§			
Actively worked with doctor or health care provider¶¶¶	23.3	28.1	0.8 (0.5–1.2)
Parents know how child will be insured as an adult	47.7	63.5	0.8 (0.6–1.0)
Child sees doctor or health care provider privately	38.4	66.3	0.6 (0.5–0.8)
Health care transition components met§§§			
Met all three components	7.5	14.1	0.7 (0.3–1.5)
Met two or more components	30.8	57.0	0.6 (0.4–0.8)
Met zero or one component	69.2	43.0	1.5 (1.2–1.9)

Abbreviations: aPR = adjusted prevalence ratio; CI = confidence interval.

* Survey data were collected from four sites in Georgia, Maryland, North Carolina, and Pennsylvania as part of a preliminary follow-up study of parents or guardians of adolescents aged 12–16 years who were enrolled in the Study to Explore Early Development (https://www.cdc.gov/ncbddd/autism/seed.html) at ages 2–5 years and initially identified as having autism (autism group) or as general population controls (control group).

† aPRs were estimated using a modified Poisson regression with robust standard error (https://doi.org/10.1093/aje/kwh090) and study group (autism or control) as the predictor, adjusted for maternal education, maternal country of birth (born inside or outside the United States), adolescent sex (male or female), adolescent race/ethnicity (non-Hispanic White, non-Hispanic Black, non-Hispanic other, or Hispanic), household income as a percentage of federal poverty level, and insurance type (private, public, both, or neither); data on maternal and paternal race/ethnicity that were collected during the original Study to Explore Early Development were used in combination to assign adolescent race/ethnicity.

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TABLE 3. (*Continued*) Health care use, need, and transition planning among adolescent children in the autism spectrum disorder and general population control groups — Study to Explore Early Development, four U.S. sites, 2018–2020*

§ aPRs were considered significant when the 95% CI did not include the null value of 1.

¶ One or more preventative check-ups in the previous 12 months.

** Includes any visit to a doctor, nurse or other health care provider for sick-child care, preventive check-ups, physical exams, hospitalizations, or any other medical care.

†† Includes adolescents whose parents affirmed that they had received treatment or counseling from a mental health professional in the previous 12 months.

§§ Includes adolescents whose parents reported that they needed health care of any type in the previous 12 months but did not receive it. Health care of any type includes medical, dental, vision, hearing, and mental health care.

¶¶ Includes adolescents whose parents affirmed the types of care that they specifically needed (i.e., medical, dental, vision, or hearing care) in the previous 12 months but did not receive it.

*** Includes adolescents whose parents indicated that they needed treatment or counseling from a mental health professional but did not receive it.

††† Data missing from one participant in the autism group.

§§§ Adolescents met the National Performance Measure of the Health Resources and Services Administration Maternal and Child Health Bureau (https://mchb.tvisdata.hrsa.gov/PrioritiesAndMeasures/NationalPerformanceMeasures) if all three elements of the health care transition measure (https://doi.org/10.1007/s10995-019-02858-6) were met.

¶¶¶ This element comprised four indicators. Parents were asked whether their child's doctors or primary care providers actively worked with the child to 1) think about and plan for his/her future; 2) make positive choices about his/her health; 3) gain skills to manage his/her health and health care; and 4) understand the changes in health care that happen at age 18 years. To meet criteria for this component, the adolescent's parent had to endorse at least three of four indicators.

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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Emergency Department Visits for Tick Bites — United States, January 2017–December 2019

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The incidence of tickborne diseases in the United States is increasing; reported cases more than doubled from >22,000 in 2004 to >48,000 in 2016 (*1*). Ticks are responsible for approximately 95% of all locally acquired vectorborne diseases reported by states and the District of Columbia, with Lyme disease accounting for >80% of those cases (*2*). After a tick bite, persons might seek care at an emergency department (ED) for tick removal and to receive postexposure prophylaxis, which has been shown to effectively prevent Lyme disease when taken within 72 hours of a high-risk bite (*3*). Using data from CDC's National Syndromic Surveillance Program (NSSP), investigators examined ED tick bite visits during January 2017–December 2019 by sex, age group, U.S. region, and seasonality. During this 36-month period, 149,364 ED tick bite visits were identified. Mean cumulative incidence was 49 ED tick bite visits per 100,000 ED visits overall; incidence was highest in the Northeast (110 per 100,000 ED visits). The seasonal distribution of ED tick bite visits was bimodal: the larger peak occurred during the spring and early summer, and the smaller peak occurred in the fall. This pattern aligns with the seasonality of a known and abundant human-biter, the blacklegged tick, *Ixodes scapularis* (*4*). Compared with other age groups, pediatric patients aged 0–9 years accounted for the highest number and incidence of ED tick bite visits; incidence was higher among male patients than among females. Tick bites are not monitored by current surveillance systems because a tick bite is an event that in and of itself is not a reportable condition to health departments. Syndromic surveillance of ED tick bite visits can provide timely information that might predict temporal and geographic risk for exposure to tickborne diseases and guide actionable public health messaging such as avoiding tick habitats, wearing repellent consistently when outdoors, and performing regular tick checks during times of increased tick bite risk.

Health care visits were identified using CDC's NSSP BioSense Platform, which hosts a national public health surveillance system that aggregates data by U.S. Department of Health and Human Services (HHS) geographic regions.* By the end of calendar year 2019, NSSP included data from an estimated 71% of all ED visits in the United States, with 3,206 ED facilities actively contributing data.† Health care visits at facilities categorized as EDs were included in this analysis; other visit categories such as inpatient hospitalizations, urgent care, or outpatient clinic visits were excluded. Data were extracted using the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE),§ a tool in the BioSense Platform. In collaboration with syndromic surveillance and vectorborne disease epidemiologists from states with high incidences of tickborne diseases, a query was developed to identify ED visits by patients with a chief complaint for ticks or tick bites. The query used Boolean operators (e.g., tick or tick and bite) and included common misspellings. Diagnostic codes specific to tick bites were not available in any of the diagnostic code classification systems, including the ninth and tenth revisions of the *International Classification of Diseases* and so were not included in the query.

The tick bite query was applied to all ED visits during January 1, 2017–December 31, 2019, available in ESSENCE to identify ED tick bite visits. Absolute counts and incidence of ED tick bite visits were computed by sex, age group, month, and geographic region.¶ Incidence was calculated by dividing the number of ED tick bite visits by the total number of ED visits in ESSENCE in that category, multiplied by 100,000. These data were also used to create a public-facing, interactive visualization tool** to allow the public to explore the data for ED tick bite visits by region, month, and basic patient demographic characteristics.

* https://www.hhs.gov/about/agencies/iea/regional-offices/index.html

† https://www.cdc.gov/nssp/overview.html

§ ESSENCE is a secure, integrated web-based application that allows application of custom and standardized analytic queries to identify, evaluate, share, and store syndromic surveillance data.

¶ The *Northeast* region includes HHS Region 1 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), HHS Region 2 (New Jersey and New York), and HHS Region 3 (District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia); the *Southeast* region includes HHS Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee); the *South Central* region includes HHS Region 6 (Arkansas, Louisiana, New Mexico, and Texas); the *Midwest* region includes HHS Region 5 (Indiana, Illinois, Michigan, Minnesota, Ohio, and Wisconsin) and HHS Region 7 (Iowa, Kansas, Missouri, and Nebraska); the *West* region includes HHS Region 8 (Colorado, Montana, North Dakota, and Utah), HHS Region 9 (Arizona, California, and Nevada), and HHS Region 10 (Alaska, Idaho, Oregon, and Washington).

** https://www.cdc.gov/ticks/tickedvisits/index.html

During 2017–2019, the mean annual number of ED tick bite visits was 49,788 (mean incidence = 49 per 100,000 ED visits) (Table); the mean annual number (31,340) and incidence (110 per 100,000 ED visits) were highest in the Northeast region. Males accounted for the majority (57%) of ED tick bite visits. The mean number (10,142) and incidence (86 per 100,000 ED visits) of ED visits for tick bites were highest among pediatric patients aged 0–9 years; a second peak occurred among patients aged 70–79 years (64 per 100,000 ED visits). Seasonality was bimodal, with the first and larger peak during April through July and a second smaller peak in October through November (Figure).

Discussion

Syndromic surveillance using NSSP data indicates high numbers and incidence of ED tick bite visits in the United States particularly during the late spring and early summer months, when nymphal blacklegged ticks are most active (*4*). The number and rate of ED tick bite visits were highest in the Northeast, where Lyme disease is highly endemic and where tickborne disease risk might be well recognized (*5*). Male patients, as well as very young (aged <10 years) and older patients (aged 50–79 years) were most likely to seek care at an ED for tick bites.

This analysis demonstrates that many patients are sufficiently concerned about tickborne diseases to seek care at an ED after a tick bite. However, ED visits likely represent only a fraction of the total health care impact of patients seeking care after a tick bite; a study in the United Kingdom showed that ED visits accounted only for approximately 12% of all health care visits by patients for arthropod bites, with most patients (67%) seeking care at outpatient clinics (*6*). The bimodal seasonal distribution of ED tick bite visits is consistent with a New Hampshire study of ED encounters for Lyme disease (*7*). In a prospective study, tick encounters were a strong predictor of tickborne diseases in the northeastern United States (*8*). Findings from the current study closely parallel patterns seen in Lyme disease surveillance (*5*) that show that Lyme disease is reported more frequently among males and among very young and older persons, supporting the application of syndromic surveillance for tick bites as a harbinger for tickborne disease.

Syndromic surveillance represents the only national system currently available to track tick bites in humans and is a powerful complementary tool to traditional surveillance for tickborne diseases, particularly in areas with high incidence of Lyme disease, the most common U.S. tickborne disease. A major benefit of syndromic surveillance is its timeliness because most data are available within days of the health care visit. These data can guide actionable public health messaging.

Summary

What is already known about this topic?

Tickborne diseases are spread by the bites of infected ticks; approximately 50,000 cases of tickborne diseases are reported in the United States each year. National surveillance for tick bites is not currently available.

What is added by this report?

A novel query of National Syndromic Surveillance Program data indicated that one out of every 2,000 emergency department visits are for tick bites, with higher incidence during the spring and early summer and in the Northeast.

What are the implications for public health practice?

Syndromic surveillance data for tick bites can guide timely, actionable public health messaging such as avoiding tick habitats, wearing repellent consistently when outdoors, and performing regular tick checks during times of increased tick bite risk.

Tickborne disease prevention practices include avoiding tick habitats, wearing repellent consistently when outdoors, and performing regular tick checks during times of increased tick bite risk. After a high-risk tick bite, a timely single dose of doxycycline might be effective in preventing Lyme disease and is considered safe for all ages, including pediatric and geriatric populations.[††] Another benefit of syndromic surveillance is its efficiency; because it relies on automated systems, it represents a lower cost in fiscal and human resources.

The findings in this report are subject to at least four limitations. First, the geographic granularity of these data is limited to HHS regions, which can comprise states and territories with heterogenous risks for tick exposure, ED data-sharing coverage with NSSP, and health care–seeking behavior. Given that most ED tick bite visits occurred in the Northeast, these trends might reflect primarily patient health care–seeking behavior in areas where Lyme disease is a major concern. County or state level data would reveal a more precise picture of tick bite risk and might be more informative for local public health action. Second, the query was limited to select combinations of words in patients' chief complaints and did not include any specific diagnostic or laboratory test codes. This might have led to misclassification that could have under- or overestimated the actual impact of ED tick bite visits. Medical record reviews of ED visits identified by the query could more thoroughly characterize this surveillance system by evaluating the sensitivity, specificity, and negative and positive predictive value of the syndromic surveillance query. Third, this analysis was limited

[††] https://www.cdc.gov/lyme/resources/FS-Guidance-for-Clinicians-Patients-after-TickBite-508.pdf

TABLE. Cumulative number and incidence of emergency department (ED) visits for tick bites, by demographic factors, region, and month — National Syndromic Surveillance Program, United States, 2017–2019

Characteristic	2017			2018			2019			Cumulative average, 2017–2019		
	No. of tick bite ED visits*	Total no. of ED visits†	Incidence§ of tick bite visits	No. of tick bite ED visits*	Total no. of ED visits†	Incidence§ of tick bite visits	No. of tick bite ED visits*	Total no. of ED visits†	Incidence§ of tick bite visits	No. of tick bite ED visits*	Total no. of ED visits†	Incidence§ of tick bite visits
Total	**50,158**	**90,940,257**	**55**	**44,561**	**104,527,637**	**43**	**54,645**	**110,980,103**	**49**	**49,788**	**102,149,332**	**49**
Sex												
Male	28,678	39,785,212	72	24,917	46,382,359	54	30,846	49,519,825	62	28,147	45,229,132	63
Female	21,480	49,777,365	43	19,644	57,805,649	34	23,799	61,273,383	39	21,641	56,285,466	39
Age group, yrs												
0–9	10,720	10,704,916	100	9,196	12,057,058	76	10,511	12,886,736	82	10,142	11,882,903	86
10–19	4,143	8,243,147	50	3,527	9,246,155	38	4,135	9,865,868	42	3,935	9,118,390	43
20–29	4,691	13,764,651	34	4,118	15,512,091	27	4,822	16,163,531	30	4,544	15,146,758	30
30–39	5,216	12,357,259	42	4,752	14,274,053	33	5,542	15,206,138	36	5,170	13,945,817	37
40–49	5,010	10,539,127	48	4,508	12,111,360	37	5,641	12,792,555	44	5,053	11,814,347	43
50–59	6,780	11,356,661	60	6,005	13,044,008	46	7,407	13,686,328	54	6,731	12,695,666	53
60–69	6,634	9,315,019	71	5,797	11,100,812	52	7,888	12,097,594	65	6,773	10,837,808	63
70–79	5,043	7,101,448	71	4,764	8,604,464	55	6,251	9,499,166	66	5,353	8,401,693	64
≥80	1,921	6,406,677	30	1,894	7,552,911	25	2,448	8,158,639	30	2,088	7,372,742	28
HHS region¶												
1	12,347	4,067,333	304	10,419	6,237,317	167	15,930	6,941,317	229	12,899	5,748,656	233
2	10,279	10,941,507	94	7,358	11,634,469	63	9,524	12,004,088	79	9,054	11,526,688	79
3	10,634	10,992,838	97	8,309	11,403,157	73	9,220	12,055,553	76	9,388	11,483,849	82
4	7,825	27,908,048	28	8,047	30,030,851	27	8,294	30,692,825	27	8,055	29,543,908	27
5	5,174	15,998,559	32	5,977	20,329,466	29	7,029	20,833,532	34	6,060	19,053,852	32
6	934	6,064,208	15	899	8,297,951	11	942	10,087,091	9	925	8,149,750	12
7	1,852	4,029,845	46	1,742	4,070,726	43	1,722	4,225,766	41	1,772	4,108,779	43
8	294	2,217,989	13	290	2,309,572	13	334	2,517,931	13	306	2,348,497	13
9	693	5,569,146	12	733	6,418,490	11	869	6,789,059	13	765	6,258,898	12
10	126	1,773,107	7	787	3,795,681	21	781	4,833,260	16	565	3,467,349	15
Region**												
Northeast	33,260	26,001,678	128	26,086	29,274,943	89	34,674	31,000,958	112	31,340	28,759,193	110
Midwest	7,825	20,028,404	39	8,047	24,400,192	33	8,751	25,059,298	35	8,208	23,162,631	36
Southeast	7,026	27,908,048	25	7,719	30,030,851	26	8,294	30,692,825	27	7,680	29,543,908	26
South Central	934	6,064,208	15	899	8,297,951	11	942	10,087,091	9	925	8,149,750	12
West	1,113	9,560,242	12	1,810	12,523,743	14	1,984	14,140,250	14	1,636	12,074,745	13
Month												
January	545	7,492,932	7	373	9,270,005	4	481	9,046,380	5	466	8,603,106	6
February	983	6,829,363	14	961	8,446,446	11	463	8,506,546	5	802	7,927,452	10
March	1,428	7,441,914	19	1,266	8,662,761	15	1,334	9,457,533	14	1,343	8,520,736	16
April	6,678	7,134,015	94	4,344	8,427,314	52	7,824	9,045,045	87	6,282	8,202,125	77
May	10,934	7,421,685	147	12,889	8,835,952	146	12,965	9,439,181	137	12,263	8,565,606	144
June	9,476	7,017,227	135	9,413	8,376,279	112	11,027	8,897,334	124	9,972	8,096,947	124
July	5,849	7,238,783	81	5,353	8,711,041	61	6,316	9,305,038	68	5,839	8,418,287	70
August	2,471	7,838,505	32	2,812	8,834,930	32	2,903	9,278,326	31	2,729	8,650,587	32
September	1,293	7,944,542	16	1,640	8,770,367	19	1,879	9,390,582	20	1,604	8,701,830	18
October	5,252	8,199,536	64	2,753	8,913,738	31	5,424	9,343,509	58	4,476	8,818,928	51
November	4,195	7,961,834	53	2,113	8,341,256	25	3,101	9,166,370	34	3,136	8,489,820	37
December	1,054	8,419,921	13	644	8,937,591	7	928	10,104,817	9	875	9,154,110	10

Abbreviation: HHS = U.S. Department of Health and Human Services.

* Tick ED visits were identified by the CDC Tick Bite syndrome query (https://knowledgerepository.syndromicsurveillance.org/tick-bites-centers-disease-control-and-prevention).

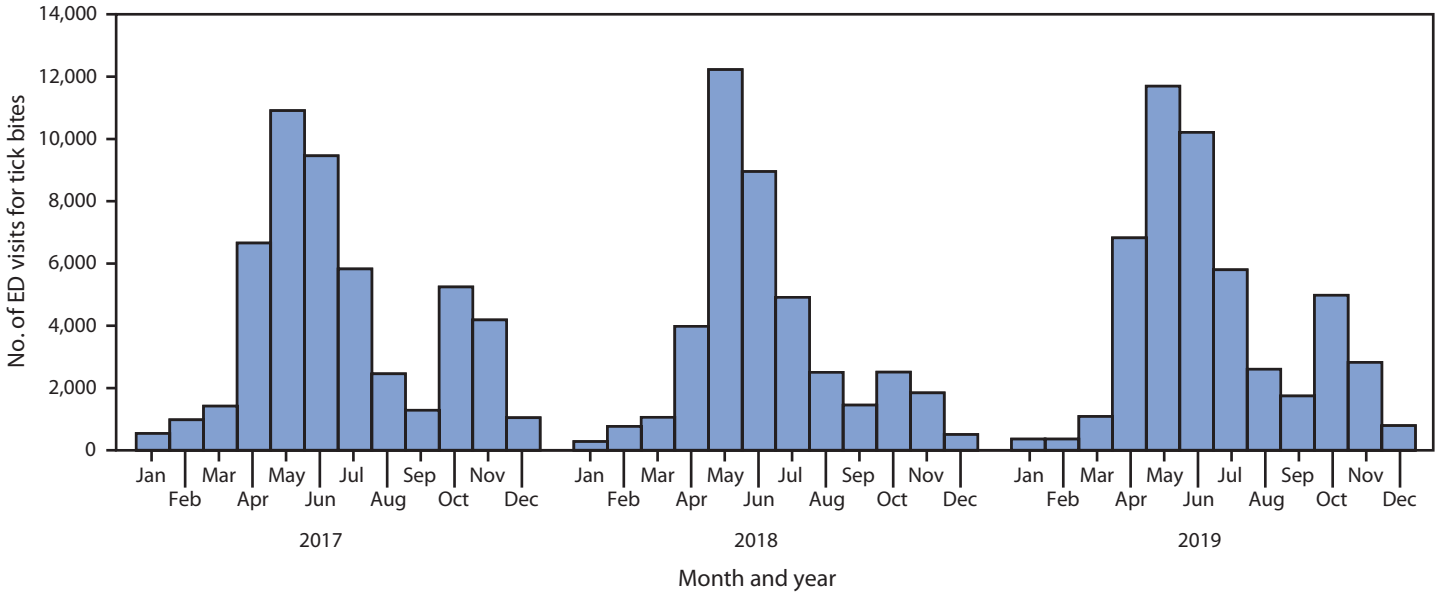
† Totals by category might not sum to overall total counts because of missing data in some categories.

§ Per 100,000 total ED visits.

¶ HHS Region 1 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), HHS Region 2 (New Jersey and New York), HHS Region 3 (District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia), HHS Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee), HHS Region 6 (Arkansas, Louisiana, New Mexico, and Texas), HHS Region 5 (Indiana, Illinois, Michigan, Minnesota, Ohio, and Wisconsin), HHS Region 7 (Iowa, Kansas, Missouri, and Nebraska), HHS Region 8 (Colorado, Montana, North Dakota, and Utah), HHS Region 9 (Arizona, California, and Nevada), and HHS Region 10 (Alaska, Idaho, Oregon, and Washington).

** The *Northeast* region includes HHS Region 1 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), HHS Region 2 (New Jersey and New York), and HHS Region 3 (District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia); the *Southeast* region includes HHS Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee); the *South Central* region includes HHS Region 6 (Arkansas, Louisiana, New Mexico, and Texas); the *Midwest* region includes HHS Region 5 (Indiana, Illinois, Michigan, Minnesota, Ohio, and Wisconsin) and HHS Region 7 (Iowa, Kansas, Missouri, and Nebraska); the *West* region includes HHS Region 8 (Colorado, Montana, North Dakota, and Utah), HHS Region 9 (Arizona, California, and Nevada), and HHS Region 10 (Alaska, Idaho, Oregon, and Washington).

FIGURE. Emergency department (ED) visits for tick bites, by month — National Syndromic Surveillance Program, United States, 2017–2019



to patients seeking care at an ED and does not represent all health care visits by patients seeking care after tick bites. The analysis was restricted to ED data because data available in NSSP are most complete for ED visits. Patients who are young, single, and employed might be more likely to visit an ED than an outpatient clinic (*9*) and might be overrepresented in this analysis. Finally, this analysis is based only on data from facilities that participate in NSSP and therefore is not generalizable to patients at nonparticipating facilities.

Syndromic surveillance for tick bites is valuable as a novel and efficient method to understand past trends and current risk for tick bites by region. By accessing these data through CDC's tick bite data tracker, a public-facing dashboard (https://www.cdc.gov/ticks/tickedvisits/index.html), public health practitioners and communities have access to immediately actionable data to guide public health messaging and individual tick bite prevention efforts (e.g., avoiding tick habitats, wearing repellent consistently when outdoors, and performing regular tick checks during times of increased tick bite risk). Educational campaigns that provide information to the public about how to safely remove ticks at home and when prophylactic antibiotics are indicated might be beneficial to reduce the impact on health care, associated health care costs, and personal risk for exposure to tickborne diseases.[§§]

[§§] https://www.cdc.gov/ticks/removing_a_tick.html

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COVID-19 Outbreak Among Farmworkers — Okanogan County, Washington, May–August 2020

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Okanogan County, Washington, experienced increased community transmission of SARS-CoV-2, the virus that causes COVID-19, during summer 2020 (*1*). Multiple COVID-19 outbreaks occurred in agricultural settings, including a large outbreak among employees of a fruit grower during May–August. Because of this outbreak, Okanogan County Public Health and the Washington State Department of Health initiated one-time, on-site screening testing (*2*) of all orchard and warehouse employees in August 2020 and assessed risk factors for SARS-CoV-2 infection. Among 3,708 known orchard employees, a valid SARS-CoV-2 test result or information on COVID-19–like symptoms in the absence of a test was available for 3,013 (81%). Cumulative incidence of SARS-CoV-2 infection during approximately 3 months among tested orchard employees was 6%. Cumulative incidence was 12% in employees residing in the community, compared with 4% in employees residing in farmworker housing (p<0.001); point prevalence during the single screening testing event was 1% in both groups. Among 1,247 known warehouse employees, a valid result was available for 726 (58%). Cumulative incidence over approximately 3 months among tested warehouse employees was 23%, with substantial variation across job roles. Positive test results were received by 28% of employees who worked packing and sorting fruit, 24% of those in other roles in the packing and sorting area, 10% of forklift operators, 7% of employees in other warehouse roles, and 6% of office employees. Point prevalence among all warehouse workers was 1% at the screening testing event. Collaboration among employers, community groups, and public health authorities can reveal risk factors and help decrease farmworkers' risk for SARS-CoV-2 infection in the community and the workplace. Creation of a COVID-19 assessment and control plan by agricultural employers, with particular focus on indoor workers whose jobs limit physical distancing, could reduce workplace transmission.

The Okanogan County fruit grower began referring symptomatic employees for SARS-CoV-2 testing in late May 2020. One-time SARS-CoV-2 screening testing of all employees was conducted on-site in late August.* Before then, asymptomatic employees were not systematically tested. Employees were eligible for inclusion in this investigation if they received at least one SARS-CoV-2 nucleic acid amplification test (NAAT) or antigen test with a positive or negative result, or if they were symptomatic but declined testing. A confirmed case was defined as the first positive SARS-CoV-2 NAAT or antigen test result received by an employee. A suspected case was defined as the presence of symptoms compatible with COVID-19 identified during work site symptom screening in an employee who declined testing.

Employees were classified by job site: orchard or warehouse. Orchard employees were further classified by housing location: congregate temporary farmworker housing (provided by the grower) or personally obtained housing in the community. All warehouse employees resided in the community. Warehouse employees were further classified into the following job roles: 1) sorting and packing fruit, 2) other roles supporting the fruit packing line, 3) forklift operation, 4) administrative (office setting), and 5) other warehouse roles (e.g., cleaning, maintenance, and transportation). Orchard employees worked predominantly outdoors. Warehouse employees generally worked indoors, although some warehouse roles involved some outdoor work. Warehouse employees performed similar work at three separate locations of differing size.

Descriptive analyses included cumulative incidence during approximately 3 months, stratified by housing category, job role, and work site. Chi-square tests and log-binomial regression models with robust error variance were used to evaluate differences in relative risk for SARS-CoV-2 infection across job roles and housing locations, with adjustment for work site among warehouse employees. Data were analyzed using Stata (version 15; StataCorp).† This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.§

During the 2020 harvest season, the fruit grower's 4,955 employees included 3,708 orchard employees and 1,247 warehouse employees. Overall, 3,739 (75%) employees were included in this analysis, including 348 (9%) who received a positive SARS-CoV-2 test result (i.e., confirmed cases) and

* Employees who previously received a positive test result were not retested during the screening testing. Although 16 tests had a reported test date of September 1, 2020, these tests were likely collected in late August at the screening testing event and occurred, or were reported to the fruit grower, on September 1.

† Section 27.9 of the Stata User's Guide reviews the various approaches to generalized linear models available in Stata. https://www.stata.com/manuals/u.pdf

§ 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.

71 (2%) suspected of having COVID-19. Among the 3,013 (81%) included orchard employees, 628 (21%) resided in the community and 2,385 (79%) in farmworker housing (Table 1). Among included orchard employees, 178 (6%) confirmed cases were identified, including 158 during symptomatic testing (May–August) and 20 during screening testing (August), along with 71 (2%) suspected cases. Among 196 symptomatic orchard employees tested, 158 (81%) received positive SARS-CoV-2 test results; 72 of 100 (72%) resided in the community, and 86 of 96 (90%) resided in farmworker housing. Over a period of approximately 3 months, the cumulative incidence of SARS-CoV-2 infection in orchard employees was 6%. Incidence was significantly higher among those residing in the community (12%) than among those residing in farmworker housing (4%) (p<0.001). Among orchard employees, the point prevalence during screening testing was similar across housing locations (1% in both groups; p = 0.950).

Among 726 (58%) included warehouse employees, 170 confirmed cases occurred, including 162 identified during symptomatic testing and eight during screening testing; no suspected cases were identified in these employees (Table 2). The percentage of tests that returned positive results during symptomatic testing could not be ascertained.¶ Cumulative SARS-CoV-2 incidence during approximately 3 months among warehouse employees was 23%, with substantial variation across job roles (ranging from 28% in employees packing and sorting fruit to 6% in office employees) and across work sites. Point prevalence during screening testing of warehouse workers was 1%. Information on employees' use of face masks while working was not available.

The first multivariate regression model used a binary outcome of confirmed SARS-CoV-2 infection among warehouse workers, with forklift operators and work site A as reference categories. The model identified a relative risk for infection of 2.7 for employees packing and sorting fruit (p = 0.002) and 2.4 for other packing roles (p = 0.015). The relative risk for office workers and other warehouse workers did not significantly differ from that of forklift operators (Table 3). The relative risk for infection was 6.8 (p<0.001) for employees at work site B and 5.8 for employees at work site C (p<0.001), compared with those at work site A. The second model examined SARS-CoV-2 infection in relation to job role and housing location for all employees. Results for warehouse job roles were similar, with significant associations between the packer and sorter role and other packing line roles and risk for SARS-CoV-2 infection. Orchard employees did not have a significant relative risk compared with forklift operators (relative risk = 1.2; p = 0.663). The relative risk for infection among those living in the community compared with those living in farmworker housing was 2.8 (p<0.001).

Discussion

Known risk factors for SARS-CoV-2 transmission and findings from previous outbreak investigations in other congregate housing and workplace settings suggest that farmworkers living in congregate housing and those working in larger groups indoors might be at elevated risk for SARS-CoV-2

¶ For some warehouse employees tested during screening testing, records of previous negative tests during symptomatic testing were incomplete.

TABLE 1. SARS-CoV-2 test status and cumulative incidence of SARS-CoV-2 infection, by housing location among orchard employees at a fruit grower (N = 3,013) — Okanogan County, Washington, May–August 2020

Measure	Residence no./total no. (%)			p-value
	Community housing	Farmworker housing	Total	
All testing				
Total employees with positive SARS-CoV-2 test results	76/628 (12)	102/2,385 (4)	178/3,013 (6)	<0.001
Total employees with positive SARS-CoV-2 test results or suspected COVID-19	88/628 (14)	161/2,385 (7)	249/3,013 (8)	<0.001
Symptomatic testing (May–August 2020)				
Employees with positive test results during symptomatic testing (among all employees completing symptomatic testing)*	72/100 (72)	86/96 (90)	158/196 (81)	0.002
Employees with positive test results during symptomatic testing (among total included employees)	72/628 (11)	86/2,385 (4)	158/3,013 (5)	<0.001
Employees with suspected COVID-19†	12/628 (2)	59/2,385 (2)	71/3,013 (2)	0.408
Screening testing (August 2020)				
Employees with positive test results during screening testing§	4/552 (1)	16/2,287 (1)	20/2,839 (1)	0.950

* An additional 16 employees were recorded as having been tested during symptomatic testing but did not have a test result recorded and were not listed as having a suspected case of COVID-19. Among these 16 employees, 14 were tested during screening testing. The other two employees, who never had a test result recorded, were excluded from analysis. All 16 employees were excluded from the calculation of percentage of positive test results during symptomatic testing.

† A suspected case was defined as the presence of symptoms compatible with COVID-19 in an employee who declined testing.

§ Employees who received negative test results during symptomatic testing or were considered to have suspected COVID-19 were tested during the screening testing. Employees who received positive test results during previous symptomatic testing were intended to be excluded from screening testing; however, five such employees were inadvertently retested and are excluded from this measure.

TABLE 2. Characteristics, SARS-CoV-2 test status, and cumulative incidence of SARS-CoV-2 infection among warehouse employees (N = 726) at a fruit grower — Okanogan County, Washington, May–August 2020

Measure	No./Total no. (%)
Symptomatic testing (May–August 2020)	
Employees with positive test results during symptomatic testing (among total included employees)*	162/726 (22)
Screening testing (August 2020)	
Employees with positive test results during screening testing	8/548 (1)
All testing	
Total employees with positive SARS-CoV-2 test results†	170/726 (23)
Work site A	5/125 (4)
Work site B	44/118 (37)
Work site C	121/483 (25)
All testing, by job role	
Forklift operator	9/86 (10)
Packing and sorting fruit	84/304 (28)
Fruit packing support	30/126 (24)
Office	3/49 (6)
Other warehouse (e.g., maintenance, cleaning, transportation)	8/110 (7)
Unknown job role	36/51 (71)

* Full records of warehouse employees who received negative test results during symptomatic testing were not available, so the percentage of positive test results for symptomatic testing could not be determined.

† Twelve new employees were tested at the screening testing event before starting work; they are excluded from analysis because they did not have any exposure to the work site before being tested. Seven employees had indeterminate results at the screening testing; five were retested and found to be negative, two were not retested and are excluded from analysis.

TABLE 3. Multivariate log-binomial regression models comparing risk for SARS-CoV-2 infection, by job role among employees at a fruit grower — Okanogan County, Washington, May–August 2020

Measure	Relative risk (95% CI)	p-value
Model for warehouse employees, assessing job role and work site*		
Forklift operator	Reference	—
Packing and sorting fruit	2.7 (1.4–5.2)	0.002
Fruit packing support	2.4 (1.2–4.7)	0.015
Office	0.6 (0.2–1.9)	0.347
Other warehouse (e.g., maintenance, cleaning, transportation)	0.8 (0.3–1.9)	0.552
Work site A	Reference	—
Work site B	6.8 (2.8–16.7)	<0.001
Work site C	5.8 (2.5–13.9)	<0.001
Model for all employees, assessing job role and housing location†		
Forklift operator	Reference	—
Packing and sorting fruit	2.6 (1.4–5.0)	0.003
Fruit packing support	2.3 (1.1–4.5)	0.020
Office	0.6 (0.2–2.1)	0.404
Other warehouse (e.g., maintenance, cleaning, transportation)	0.7 (0.3–1.7)	0.433
Orchard work	1.2 (0.6–2.2)	0.663
Lives in community	2.8 (2.1–3.8)	<0.001

Abbreviation: CI = confidence interval.

* Housing location was not included in this model because all warehouse workers resided in the community.

† Work site was not included in this model because of collinearity for orchard workers.

infection (*3*–*5*). In other settings, farmworkers residing in the community were more likely to live in larger households with multiple adults working outside the home (*6*), which might also increase the risk for infection. In this investigation, cumulative incidence of SARS-CoV-2 infection was higher in orchard employees living in the community (12%) than among those residing in congregate temporary farmworker housing (4%). The point prevalence at the time of screening testing was equivalent in both groups. The difference in cumulative incidence could be explained by successful infection prevention efforts at farmworker housing facilities, differences in community exposures or behaviors between employees living in temporary farmworker housing and those living in the community, or more effective isolation of infected persons living in temporary farmworker housing. Alternatively, employees living in temporary farmworker housing might be less able or willing to seek SARS-CoV-2 testing. During the same period, cumulative incidence of SARS-CoV-2 infection in Okanogan County was approximately 2% (*1*). Incidence in both groups of orchard workers was higher than that in the overall community, although this comparison could be affected by differences in testing.

This investigation also demonstrated high cumulative incidence of SARS-CoV-2 infection among employees packing and sorting fruit or in other packing roles (24%–28%), who work primarily indoors in a large group, compared with that among forklift operators (10%), who work alone and partially outdoors, or among employees in other primarily indoor roles who tend to work alone or in small groups (6%–7%). Although this investigation could not directly assess transmission patterns, the significant differences in cumulative incidence of infection across job roles suggest that workplace transmission contributed to this outbreak. Differences in workplace prevention measures or differences in localized community transmission could explain the lower incidence at work site A, which is in a different town. Point prevalence among warehouse workers at the time of screening testing was 1%, which might reflect more widespread use of prevention measures, decreased community transmission, or decreased transmission as a result of the increased proportion of employees with immunity by that time. Early and improved access to testing for farmworkers and screening testing early in an outbreak might help to control transmission in future outbreaks. Focused efforts to maximize COVID-19 vaccination uptake among farmworkers also can help in preventing outbreaks, although such vaccines were not yet available at the time of this outbreak.

The findings in this report are subject to at least three limitations. First, the lack of individual exposure information, combined with a potentially high level of underascertainment

of cases during symptomatic testing (i.e., cases in asymptomatic persons or persons who did not report their symptoms), might result in unmeasured confounding. Some employees might also have sought testing independently and not reported the results to their employer. Second, missing job role information for some employees could bias the comparison of cumulative incidence and regression models. Finally, the available employee records from the grower did not include employees' race, ethnicity, preferred language, or other demographic information. Nationally, 83% of farmworkers identify as Hispanic (*7*). Hispanic or Latino, non-Hispanic Black, and non-Hispanic Asian/Pacific Islander farmworkers have been reported to experience increased incidence of COVID-19 (*8*). Collection of demographic information before or during an outbreak can help to identify potential exposures and disproportionately affected populations and guide prevention and messaging strategies.

Public health authorities and community organizations should prioritize culturally and linguistically tailored communication and interventions, including COVID-19 vaccination, to address farmworkers' risk for acquiring COVID-19 in the community and in different work and living settings.** Creation of a COVID-19 assessment and control plan by agricultural employers, with particular focus on creating safer work environments for indoor workers whose job roles limit their ability to practice physical distancing, might help to reduce transmission in this group of disproportionately affected workers†† (*9*,*10*).

** Potential community interventions include 1) dedicated vaccination outreach efforts; 2) increased access to SARS-CoV-2 testing and, more broadly, to high quality and culturally competent health care; 3) improved housing access to decrease the risks for household transmission in crowded housing situations; and 4) policies that enable persons to isolate or quarantine if needed without fear of financial hardship or job loss.

†† Workplace prevention measures could include providing linguistically tailored education and training, promoting vaccination, cohorting employees, developing supportive policies for employees who need to isolate or quarantine, implementing engineering and administrative controls, and providing appropriate face masks or other personal protective equipment.

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Summary

What is already known about this topic?

SARS-CoV-2 can spread rapidly in congregate housing and workplaces with limited physical distancing.

What is added by this report?

Among farmworkers employed by a fruit grower in Washington, SARS-CoV-2 incidence was higher among those living in the community (12%) than among those living in congregate temporary housing (4%). Incidence was higher among farmworkers packing and sorting fruit indoors (28%) than among those working alone or in small groups indoors or working outdoors (6%–10%).

What are the implications for public health practice?

Collaboration among employers, community groups, and public health authorities can help decrease farmworkers' risk for COVID-19 in the community and the workplace, with particular focus on indoor workers whose jobs limit physical distancing.

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COVID-19 Among Workers in the Seafood Processing Industry: Implications for Prevention Measures — Alaska, March–October 2020

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Large COVID-19 outbreaks have occurred in high-density workplaces, such as food processing facilities (*1*). Alaska's seafood processing industry attracts approximately 18,000 out-of-state workers annually (*2*). Many of the state's seafood processing facilities are located in remote areas with limited health care capacity. On March 23, 2020, the governor of Alaska issued a COVID-19 health mandate (HM10) to address health concerns related to the impending influx of workers amid the COVID-19 pandemic (*3*). HM10 required employers bringing critical infrastructure (essential) workers into Alaska to submit a Community Workforce Protective Plan.* On May 15, 2020, Appendix 1 was added to the mandate, which outlined specific requirements for seafood processors, to reduce the risk for transmission of SARS-CoV-2, the virus that causes COVID-19, in these high-density workplaces (*4*). These requirements included measures to prevent introduction of SARS-CoV-2 into the workplace, including testing of incoming workers and a 14-day entry quarantine before workers could enter nonquarantine residences. After 13 COVID-19 outbreaks in Alaska seafood processing facilities and on processing vessels during summer and early fall 2020, State of Alaska personnel and CDC field assignees reviewed the state's seafood processing–associated cases. Requirements were amended in November 2020 to address gaps in COVID-19 prevention. These revised requirements included restricting quarantine groups to ≤10 persons, pretransfer testing, and serial testing (*5*). Vaccination of this essential workforce is important (*6*); until high vaccination coverage rates are achieved, other mitigation strategies are needed in this high-risk setting. Updating industry guidance will be important as more information becomes available.

On May 15, 2020, the state issued HM10 Appendix 1, detailing three entry quarantine options for onshore seafood processors: 1) quarantine workers for 14 days before travel to Alaska (pretravel quarantine), 2) quarantine workers in an Alaskan community with a general acute care or critical access hospital (midtravel quarantine), or 3) quarantine workers at the destination community after arrival (posttravel quarantine) (Table 1). These options also included requirements for safe transit† (e.g., chartered air travel) and for each worker to receive one or more (depending on the quarantine option selected) negative reverse transcription–polymerase chain reaction (RT-PCR) tests for SARS-CoV-2. A separate but similar set of options was available for workers boarding processing vessels (*4*). HM10 Appendix 1 also included a requirement for using safe transit during transfer of workers between facilities (*4*).

After 13 COVID-19 outbreaks occurred in seafood processing facilities and on processing vessels through early fall 2020, Alaska-based CDC field assignees assisted State of Alaska personnel with revising HM10 Appendix 1 by reviewing data from investigations of the state's laboratory-confirmed SARS-CoV-2§ cases that occurred during March 1–October 13, 2020. Seafood processing–associated cases were identified by querying the state's reportable disease database and searching records obtained during outbreak investigations. In addition, the number of cases identified under certain circumstances (e.g., cases identified during entry quarantine or after workers were transferred from one facility to another) was evaluated using detailed notes from public health investigations. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶

During the period reviewed, 677 cases of SARS-CoV-2 infection were identified among seafood processing industry workers (Figure). Among these, 132 cases were either independent cases (i.e., did not result in transmission to another person) during entry quarantine or were part of a cluster of infections within an entry quarantine group (i.e., a group of workers living and working solely with each other). Among the remaining cases, 539 were either part of outbreaks that spread beyond an entry quarantine group or included persons outside of entry quarantine, including local workers; six cases were not classified because of insufficient information.

* https://covid19.alaska.gov/unified-command/protective-plans/

† Safe transit is a mode of transportation in which all employees have completed quarantine and testing requirements, are not interacting with any populations whose quarantine and testing status is unknown, and are physical distancing, using appropriate personal protective equipment to isolate the travelers from the vehicle crew, or both.

§ Laboratory confirmation requires detection of SARS-CoV-2 RNA in a clinical specimen using a molecular amplification detection test (https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/).

¶ 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 1. Entry quarantine options for onshore seafood processors under initial Alaska COVID-19 health mandate 10, appendix 1*

Option	Quarantine	Testing	Transit	Destination community
Pretravel quarantine	Workers observed a 14-day monitored quarantine period outside of Alaska.	RT-PCR† test was done within 48 hours before beginning travel to Alaska.	Safe transit§ was used for all travel to the processing facility in the destination community on a chartered aircraft, ground vehicle, or vessel.	Workers entered the nonquarantine quarters upon arrival and started work alongside workers who had completed quarantine.
Midtravel quarantine	Workers traveled to Alaska to observe a 14-day monitored quarantine period in temporary lodging in a large community with a general acute care or critical access hospital.	RT-PCR test was done within 48 hours before beginning onward travel to the destination community.	All travel from the quarantine location to the processing facility in the destination community was accomplished via safe transit.	Workers entered the nonquarantine quarters upon arrival and started work alongside workers who had completed quarantine.
Posttravel quarantine	Workers traveled to their final destination community in Alaska to observe a 14-day quarantine, housed individually or in a quarantine group (workers living or working in close proximity were assigned to a quarantine group and completed quarantine together).	RT-PCR test was done before entering monitored quarantine lodging. (Another test was done at day 6 and within 48 hours of completion of quarantine as supplies allowed.)	Travel to the destination community was done via commercial transit.	Workers were permitted to work during their 14-day quarantine period under specific circumstances.¶

Abbreviation: RT-PCR = reverse transcription–polymerase chain reaction.
* Issued on May 15, 2020 (https://covid19.alaska.gov/wp-content/uploads/2020/05/COVID-MANDATE-10-Appendix-01.pdf).
† Using a Food and Drug Administration–authorized test.
§ Safe transit is a mode of transportation in which all employees have completed quarantine and testing requirements, are not interacting with any populations whose quarantine and testing status is unknown, and are physical distancing, using appropriate personal protective equipment to isolate the travelers from the vehicle crew, or both.
¶ Specific circumstances refers to a situation in which tasks can be conducted while maintaining 6-ft physical distancing measures, or using physical barriers and personal protective equipment to separate workers from all other workers outside of their quarantine group.

Among the 132 cases that were independent or part of a cluster within an entry quarantine group, 81 cases (61%) occurred in workers quarantined at an onshore processing facility; 72 (89%) of these cases were part of a cluster. Twelve distinct clusters of 2–23 cases (median = 3 cases), were identified at facilities conducting entry quarantine in the destination community (Figure). Persons completing entry quarantine at the processing facility in the destination community were usually housed in groups and allowed to work if they were able to maintain a distance of 6 ft or use physical barriers and personal protective equipment to separate themselves from other workers outside of their quarantine group. Although persons with positive SARS-CoV-2 RT-PCR test results were removed from these groups for isolation once they were identified, transmission within the entry quarantine group occurred. The remaining 51 (39%) cases occurred in workers quarantined off-site in Alaska; 37 (73%) of these were independent cases with no known onward transmission.

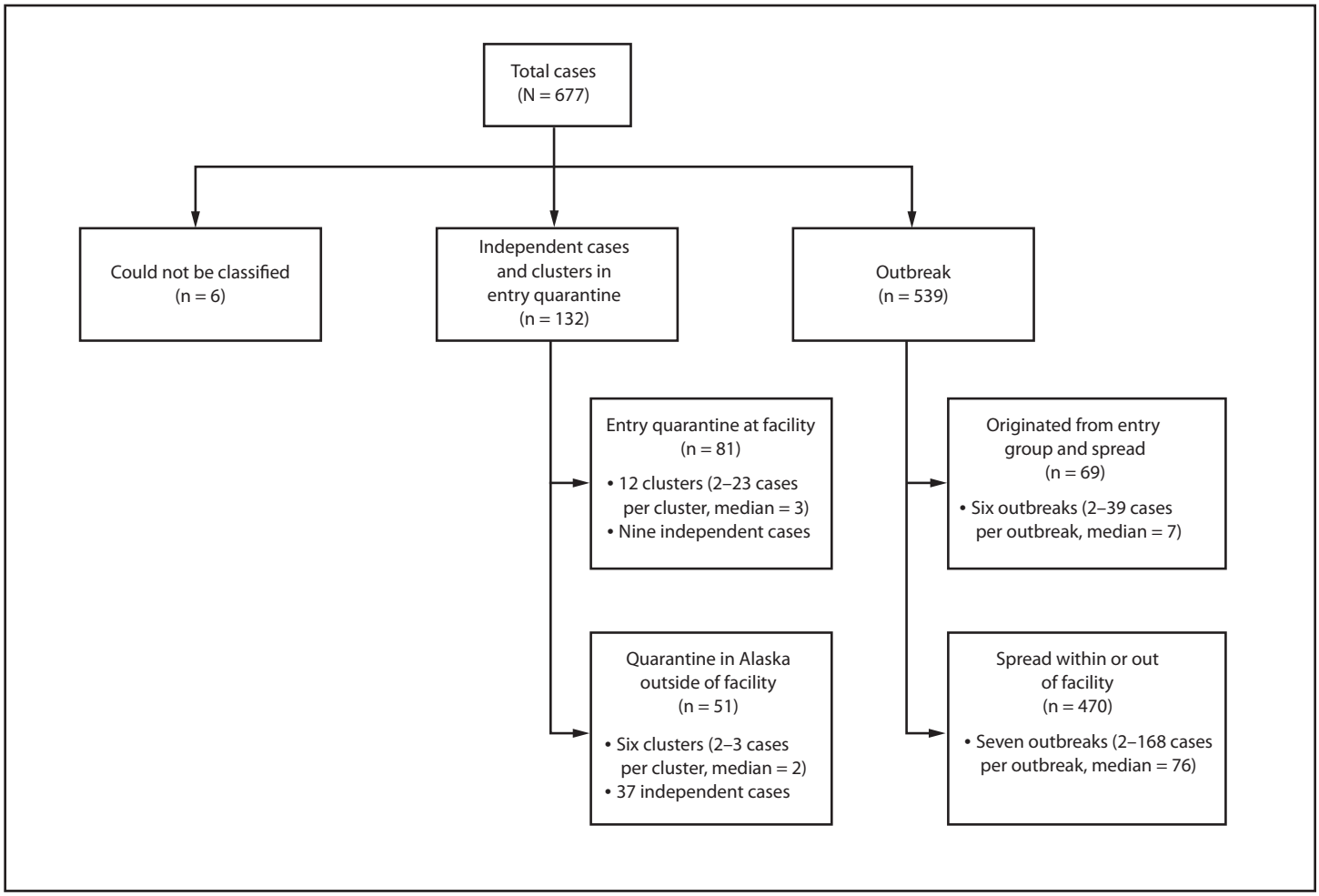
Thirteen distinct outbreaks identified in onshore facilities or on vessels involved persons who had either completed entry quarantine, were in a different entry quarantine group, or who were local workers. Attack rates in onshore facilities and vessels ranged from <5%–75%. Six outbreaks (range = 2–39 cases, median = 7 cases) appeared to have originated in an entry quarantine group and then spread (Figure). The remaining seven outbreaks (range = 2–168 cases, median = 76 cases) were of unknown origin; these outbreaks were responsible for 470 (87%) of the 539 outbreak-associated cases. One outbreak of 39 cases was the result of a midseason crew transfer in which persons previously not known to be infected were moved via safe transit from a facility that had experienced an outbreak to a closed campus (i.e., a facility with no or limited interaction with local persons) where the workers had previously received negative test results. A separate outbreak of 168 cases was identified only after an employee sought care for a non–COVID-19 medical issue and was screened as part of that visit.

As a result of the large number of cases that occurred among workers outside entry quarantine, additional prevention measures were developed to further reduce risk (Table 2). These were reflected in revised requirements implemented in November 2020 (*5*).

Discussion

After review of the state's seafood processing–associated cases, a revision of the required measures went into effect on November 16, 2020 to address gaps in COVID-19 prevention (*5*). Introduction of the virus into remote areas was likely reduced when the 51 persons with positive SARS-CoV-2 test results were identified during entry quarantine outside of the facility and thus completed isolation off-site. Entry quarantine at a processing facility in the destination community was less effective and led to clusters within entry quarantine groups.

FIGURE. Laboratory-confirmed cases*,† of COVID-19 associated with the seafood processing industry§ — Alaska, March 1–October 13, 2020



* Clusters include those determined to include person-to-person transmission within an entry quarantine group.
† Independent cases were not known to have transmitted SARS-CoV-2 to others.
§ The source of the spread within or outside of facility was unknown.

The revised requirements restricted the size of quarantine groups to ≤10 persons; HM10 Appendix 1 had included guidance to keep the groups "as small as possible." The revision also eliminated the option for working during entry quarantine.

Expanding the scope of the required measures was also necessary. The outbreak that occurred after a transfer of crew from one processing facility to another indicated that recommending safe transit for midseason crew changes was inadequate for eliminating the risk for interfacility transmission. A pretransfer testing requirement was included in the revised measures to reduce the risk of unintentional movement of infected persons. Another outbreak was identified only after a worker who was seeking non–COVID-19-related health care was tested, indicating that identification of outbreaks was not always timely. Because serial testing of all workers throughout the season might be a more effective strategy to identify outbreaks earlier, a requirement for serial testing was included in the revised measures.

The findings in this report are subject to at least four limitations. First, case counts were based on surveillance data and might be subject to small discrepancies. Second, a comparison before and after implementation of the revised requirements was not possible because the initial set of required measures was issued early in the seafood processing season that took place during the summer months. Third, the lack of precise denominators restricted analysis of the overall rate of disease among seafood processing workers. Finally, quantifying the size of outbreaks was often challenging because testing strategies conducted after cases were identified varied considerably among facilities, which likely affected case finding. For example, in response to an outbreak identified at one facility, the company elected to conduct multiple rounds of mass testing and

TABLE 2. Selected requirements from Alaska COVID-19 health mandate 10, appendix 1* and Alaska health order 5 (revised appendix 1)†

Protective measure	Original requirements	Revised requirements
Posttravel entry quarantine	Entry quarantine groups were kept "as small as possible" and allowed to work during quarantine under specific circumstances.§	Entry quarantine groups were ≤10 persons and prohibited from working during quarantine.
Midseason transfers	Safe transit¶ was used for all travel from one location to another; if not available and transferring workers had to travel within 6 ft for >10 min with persons whose quarantine status was not known, transferring workers had to repeat their quarantine period at the new location, with RT-PCR** testing on day 6 and within 48 hours before being released from quarantine.	Pretransfer testing was also required if leaving a vessel or onshore facility that had experienced an outbreak.
Serial testing	Not included	Serial testing was required. Guidance for the frequency of testing was based on risk category†† and facility type (e.g., open or closed campuses).
Response to a positive worker	Not included	Notifying public health, isolating confirmed cases, and quarantining close contacts explicitly required (with detailed instructions provided), as was a requirement to develop an outbreak contingency plan.
Daily symptom screening	Only required during the entry quarantine	Daily symptom screening of workers required throughout the season.

Abbreviation: RT-PCR = reverse transcription–polymerase chain reaction.
* Issued on May 15, 2020 (https://covid19.alaska.gov/wp-content/uploads/2020/05/COVID-MANDATE-10-Appendix-01.pdf).
† Issued on November 16, 2020 (https://covid19.alaska.gov/wp-content/uploads/2020/12/Outbreak-Health-Order-No-5-Appendix-01-Enhanced-Protective-Measures-for-Seafood-Processing-Workers-DD3.pdf).
§ Specific circumstances refers to a situation in which tasks can be conducted while maintaining 6-ft physical distancing measures, or using physical barriers and personal protective equipment (PPE) to separate workers from all other workers outside of their quarantine group.
¶ Safe transit is a mode of transportation in which all employees have completed quarantine and testing requirements, are not interacting with any populations whose quarantine and testing status is unknown, and are physical distancing, using appropriate PPE to isolate the travelers from the vehicle crew, or both.
** Using a Food and Drug Administration–authorized test.
†† Risk categories were based on the local alert level (if available) or the alert level at the community school. The community-level indicators used by local jurisdictions and schools to assign their alert level varied by locality. Companies were asked to use the alert level in combination with the timing of the arrival of new workers to determine their risk category.

ultimately determined that 168 (61%) workers were infected. Another company that identified cases conducted little additional testing, and fewer than 10 cases among approximately 500 workers were ultimately identified.

These findings suggest that requiring entry testing and quarantine might have reduced importations of SARS-CoV-2 into remote seafood processing facilities and vessels. Incorporating additional measures, such as serial testing and restricting work during quarantine, might further reduce the risk to seafood processing workers and the communities in which they work. Vaccination of this essential workforce is important (*6*) and underway. Updated guidance for the industry will be needed as more is learned about how mitigation strategies might change in high-density workplaces when high vaccination coverage levels are achieved.

Summary

What is already known about this topic?

Large outbreaks of COVID-19 have occurred in high-density workplaces. In May 2020, Alaska mandated prevention measures in the seafood processing industry.

What is added by this report?

A review of COVID-19 cases and outbreaks in this industry found that entry quarantine and testing might have reduced introduction of the virus to seafood processing facilities and vessels. The review also identified gaps in the required COVID-19 prevention strategies. Findings were used to revise requirements, which included the addition of serial testing.

What are the implications for public health practice?

Until high vaccination coverage rates are achieved among the seafood processing workforce, rigorous mitigation strategies are needed to prevent and control outbreaks in this high-risk setting.

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Linked Clusters of SARS-CoV-2 Variant B.1.351 — Maryland, January–February 2021

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In late January 2021, a clinical laboratory notified the Maryland Department of Health (MDH) that the SARS-CoV-2 variant of concern B.1.351 had been identified in a specimen collected from a Maryland resident with COVID-19 (*1*). The SARS-CoV-2 B.1.351 lineage was first identified in South Africa (*2*) and might be neutralized less effectively by antibodies produced after vaccination or natural infection with other strains (*3*–*6*). To limit SARS-CoV-2 chains of transmission associated with this index patient, MDH used contact tracing to identify the source of infection and any linked infections among other persons. The investigation identified two linked clusters of SARS-CoV-2 infection that included 17 patients. Three additional specimens from these clusters were sequenced; all three had the B.1.351 variant and all sequences were closely related to the sequence from the index patient's specimen. Among the 17 patients identified, none reported recent international travel or contact with international travelers. Two patients, including the index patient, had received the first of a 2-dose COVID-19 vaccination series in the 2 weeks before their likely exposure; one additional patient had a confirmed SARS-CoV-2 infection 5 months before exposure. Two patients were hospitalized with COVID-19, and one died. These first identified linked clusters of B.1.351 infections in the United States with no apparent link to international travel highlight the importance of expanding the scope and volume of genetic surveillance programs to identify variants, completing contact investigations for SARS-CoV-2 infections, and using universal prevention strategies, including vaccination, masking, and physical distancing, to control the spread of variants of concern.

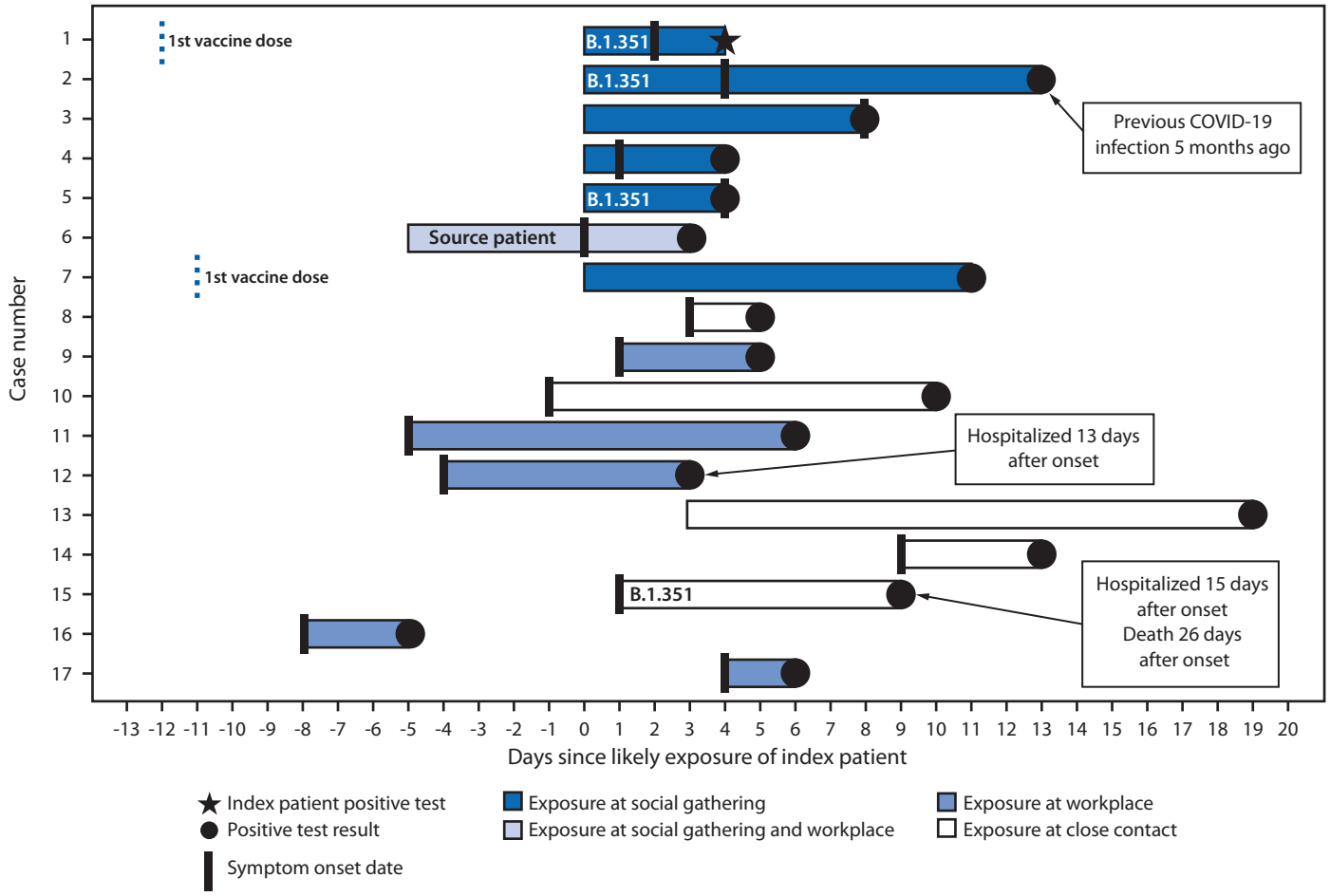
Case investigation, contact elicitation (following CDC guidelines for defining close contacts) (*7*,*8*), and contact tracing were conducted for the index patient immediately after the initial diagnostic test result before the sequencing results were available; in Maryland, this is standard procedure for all persons with COVID-19 diagnosed by a SARS-CoV-2 antigen test or nucleic acid amplification test (NAAT) (including reverse transcription–polymerase chain reaction [RT-PCR]). This process was conducted for all COVID-19 cases identified from among the index patient's contacts until no additional cases in the transmission chain could be identified. Interviews of persons with positive test results and their contacts were documented in a central data management system via a scripted electronic form and as audio recordings. For this investigation, electronic forms and recordings were reviewed, and available specimens from associated patients were sequenced by the Maryland Public Health Laboratory. This activity was reviewed by CDC and conducted consistent with applicable federal law and policy.*

The index patient reported two potential exposure settings that might have led to SARS-CoV-2 infection, including a workplace (3 days before symptom onset) and an indoor social gathering (2 days before symptom onset). The patient's workplace was excluded as the source of infection: investigation of the workplace identified no close contacts or high-risk exposures and no additional employees with SARS-CoV-2 infections. The index patient also attended an indoor social gathering with six other persons 2 days before symptom onset; the event lasted several hours, and attendees removed masks while eating. Review of contact tracing records for the six other attendees found that all six received positive SARS-CoV-2 antigen or NAAT test results, with specimen collection dates ranging from 3 to 13 days after the gathering. Five of the six attendees had symptomatic COVID-19; symptom onsets ranged from the day of the gathering through 8 days afterward (Figure 1). One attendee named two additional close contacts, both of whom received negative NAAT test results. The index patient identified one additional close contact during the infectious period. The final close contact named by the index patient never experienced symptoms of COVID-19 and received a negative SARS-CoV-2 NAAT test result as well as a negative SARS-CoV-2 immunoglobulin G antibody test result.

Among attendees at the social gathering reported by the index patient, the earliest self-reported illness onset was on the date of the social gathering. That person was identified as a possible source of infection for the other persons who attended the gathering. Retrospective review of this source patient's interview revealed that the patient's workplace was a business that had been reported through an anonymous tip line established for reporting COVID-19 safety concerns; several

* 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.

FIGURE 1. Timelines of exposures, symptom onsets, and SARS-CoV-2–positive test results,* including characteristics of cases associated with a B.1.351 variant investigation† — Maryland, January–February 2021



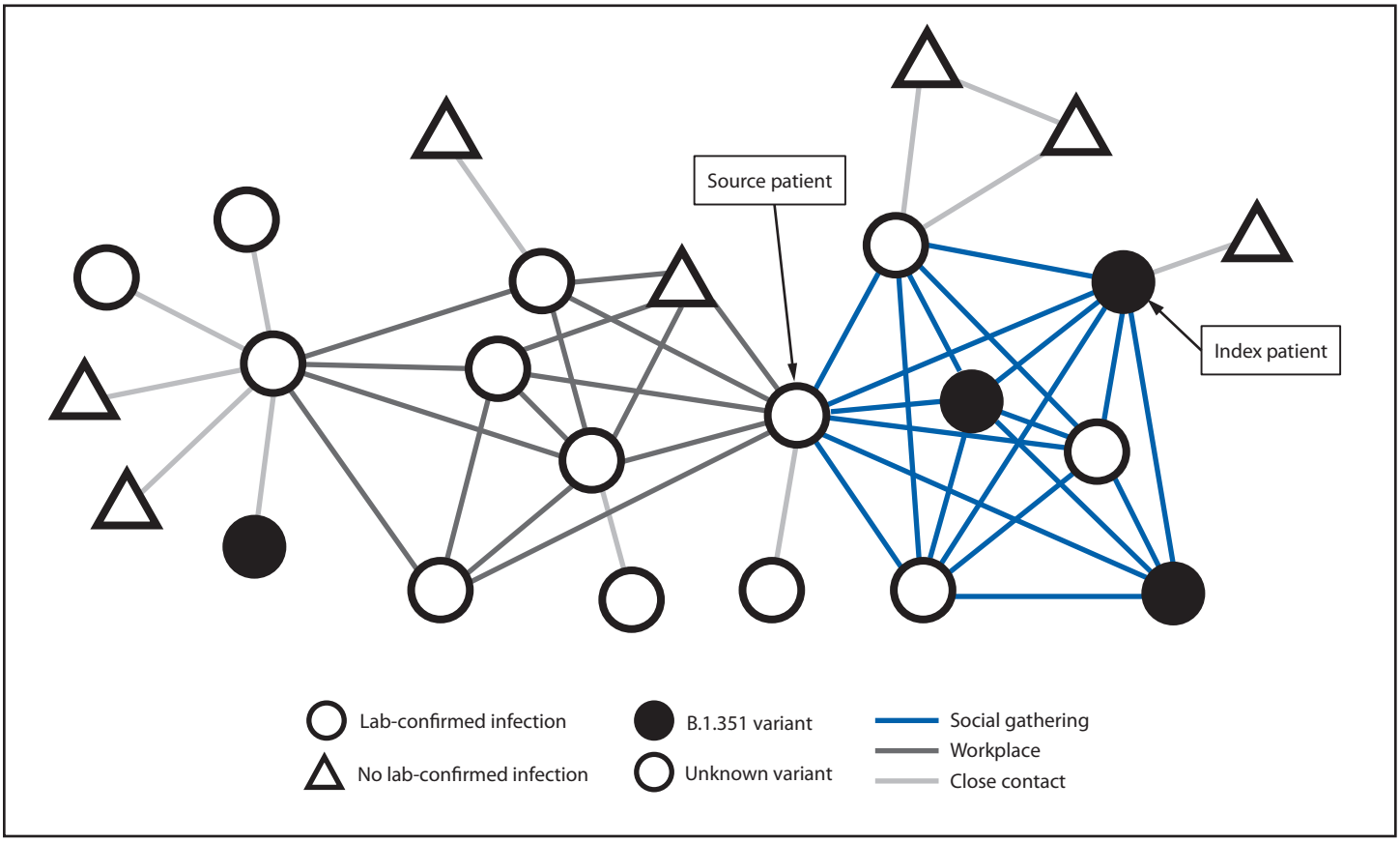
* Bars represent the number of days from either the individual patient's exposure date or symptom onset date to the date of positive test result. Exposure dates and onset dates are missing for some patients. Among patients with both exposure and onset dates available, the earlier date is used in this calculation.

† The index patient represented the first case identified during this investigation. The source patient had the earliest self-reported onset date among attendees of the social gathering and was identified as a possible source of infection at the gathering.

employees working while displaying symptoms consistent with COVID-19 were reported. The local health department initiated an outbreak investigation at the source patient's workplace, which found that employees worked in close quarters where physical distancing was not possible and that some employees had attended work while experiencing COVID-19–like symptoms. This workplace had seven employees (including the source patient), six of whom were symptomatic and received positive SARS-CoV-2 antigen or NAAT test results. Symptom onset dates occurred over a period of 12 days; symptom onset in three patients preceded that of the source patient, and two occurred later. The seventh employee never experienced symptoms and received two negative test results during this period. The six employees who received positive SARS-CoV-2 test results, including the source patient, named eight nonwork close contacts (in addition to those already identified from the indoor social gathering), five of whom received positive SARS-CoV-2 RT-PCR test results. The three other close contacts never experienced symptoms; NAAT test results were negative for one contact and inconclusive for another, and the third contact was not tested.

These two linked clusters resulted in a total of 17 laboratory-confirmed SARS-CoV-2 infections, including all seven attendees of the social gathering; six of seven employees of the source patient's workplace (with the source patient counted in both clusters); and five of 11 close contacts of persons with laboratory-confirmed infection in either setting (Figure 2). No patient reported a history of international travel or close contact with anyone with a history of recent international travel.

FIGURE 2. Persons with laboratory-confirmed SARS-CoV-2 infection and asymptomatic contacts without positive SARS-CoV-2 tests* associated with an investigation of B.1.351 variant SARS-CoV-2 infection,† by link type§ (N = 24) — Maryland, January–February 2021



* No laboratory-confirmed infection indicates persons named in the case interview who were within 6 ft of the patient for a total of ≥15 minutes over a 24-hour period starting from 2 days before illness or test specimen collection and who did not receive a positive SARS-CoV-2 test result (n = 7).
† Four specimens were sequenced and confirmed to be the B.1.351 variant, including that from the index patient; other specimens were not available for sequencing.
§ Before symptom onset, the index patient and six persons attended a social gathering; one of those persons was also connected to a workplace along with six other persons. Close contacts are persons for whom a household or other close connection with a patient was determined. The source patient had the earliest self-reported onset date for an attendee of the social gathering and was identified as a possible source of infection at the gathering.

Four total specimens from these clusters were sequenced, and all were of the B.1.351 lineage, including the index patient's specimen, two specimens from patients also exclusively associated with the social gathering cluster, and one specimen from a patient exclusively associated with the source patient's workplace cluster (Figure 3). Two sequences were identical to that of the index specimen. One differed from the index specimen by a single nucleotide polymorphism.

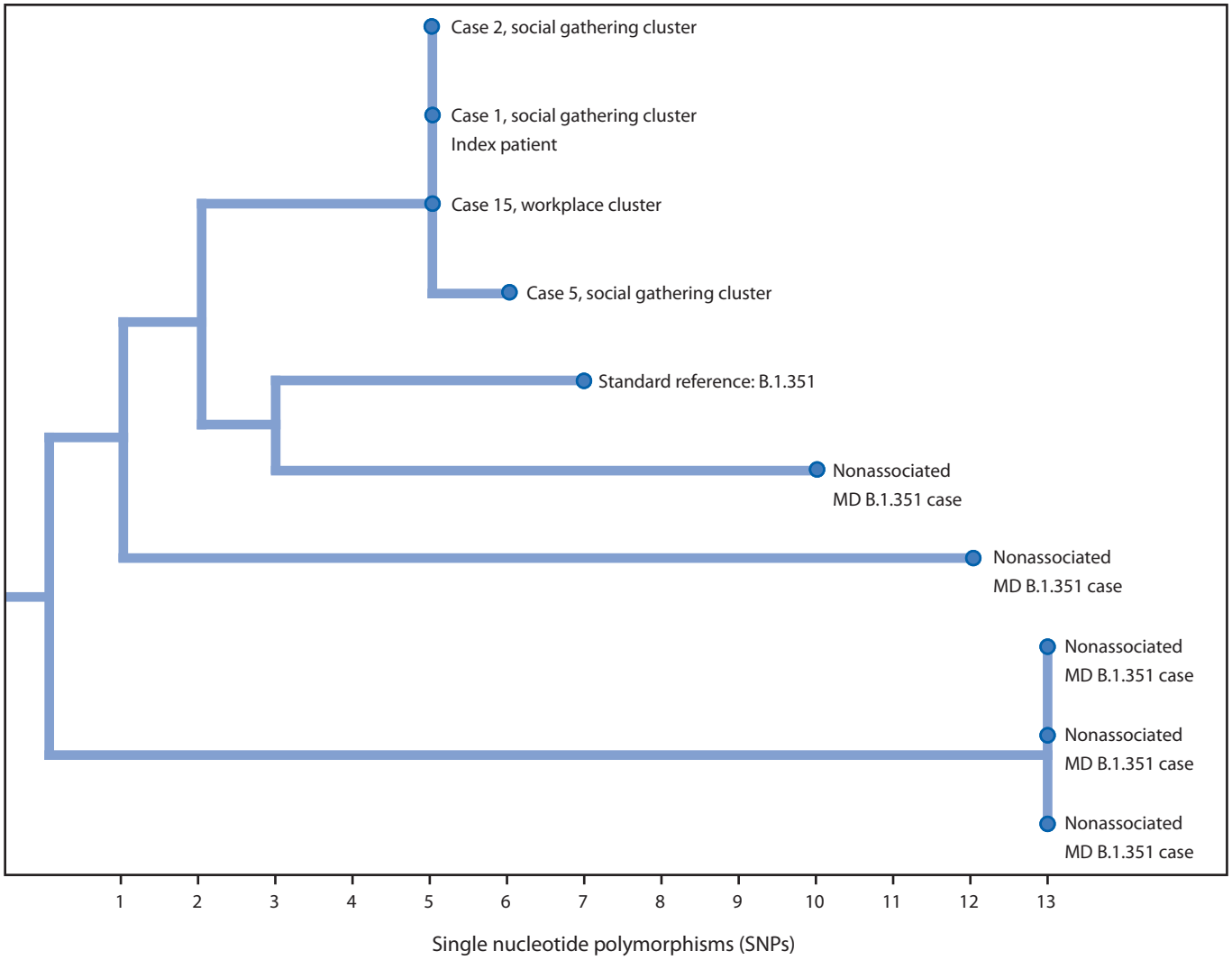
Two patients (aged 42 and 74 years) were hospitalized, including one employee of the source patient's workplace and one close contact of an employee in that workplace; one of these patients (aged 74 years) died. Neither had a history of vaccination or previous infection. Two symptomatic infections occurred in persons who had received the first of a 2-dose COVID-19 vaccination series 11 and 12 days before exposure, and one symptomatic infection occurred in a person with NAAT-confirmed symptomatic SARS-CoV-2 infection diagnosed approximately 5 months before symptom onset (Figure 1).

Discussion

This report documents the first identified linked clusters of B.1.351 infections in the United States with no identified link to international travel. Given the rapid spread of B.1.351 and the possible reduced susceptibility to neutralizing antibodies produced after vaccination or infection with other strains (*3*–*6*), this investigation highlights several important points for public health agencies responding to the B.1.351 SARS-CoV-2 variant and other variants of concern.

First, most of the case investigations took place before persons in case clusters were identified as having been infected by the B.1.351 SARS-CoV-2 variant. Genetic sequencing of SARS-CoV-2 specimens usually takes several days beyond the time needed for NAAT testing. Consequently, most

FIGURE 3. Phylogenetic tree of four investigation-associated B.1.351 lineage specimens* and five other non–investigation-associated B.1.351 specimens sequenced from Maryland resident patients — Maryland, January–February 2021



* Patient case numbers correspond to four of the 17 cases identified in the investigation. X-axis denotes the SNP distance of specimens from the nearest common ancestor of all sequenced Maryland B.1.351 specimens at the time of analysis.

successful variant case investigations and contact tracing are conducted before the variant case is identified by sequencing (*9*). Therefore, consistent implementation of best practices for case investigation and contact tracing as well as universal application of prevention strategies, including consistent and correct use of masks, physical distancing, and hand hygiene, are critical to controlling the spread of all SARS-CoV-2 variants, including B.1.351 (*9*).

Second, the index infection was identified in a person whose specimen was sequenced even though no history of international travel was reported. To maximize identification of variants of concern, prioritization of cases with factors that could indicate infection with a variant of concern (e.g., possible reinfection, vaccine failure, travel, and unusual clinical presentations) is important, as is random sequencing of specimens with low NAAT cycle threshold values, which might be more likely to produce a viable sequence; this is the approach currently used by Maryland's Public Health Laboratory.

Third, practices used by MDH and its local health department counterparts could be particularly useful for other health departments investigating clusters of SARS-CoV-2. These practices include audio recording interviews of persons with cases and their contacts for preservation of information and reinvestigation if needed; searching for the potential source of infection for confirmed cases, in addition to eliciting their

Summary

What is already known about this topic?

In January 2021, a SARS-CoV-2 specimen from a Maryland resident was determined to be the B.1.351 variant, first identified in South Africa. The SARS-CoV-2 B.1.351 variant might elicit a reduced neutralizing antibody response.

What is added by this report?

Investigation identified two linked clusters of SARS-CoV-2 infection, comprising 17 total patients (two were hospitalized and one died) who did not report recent travel. Four patients' specimens were sequenced; all were the B.1.351 variant.

What are the implications for public health practice?

These were the first identified clusters of B.1.351 in the United States with no link to travel. Completed contact investigations, expanded genetic sequencing, and universal prevention strategies, including vaccination, masking, and distance, might prevent the spread of SARS-CoV-2 variants of concern, including B.1.351.

exposed contacts to contain the spread (*6*); and establishing an anonymous tip line for COVID-19 safety concerns.

The findings in this report are subject to at least two limitations. First, because not all patients had specimens available for sequencing, some infections could have been associated with a separate SARS-CoV-2 introduction. Second, disclosure of close contacts might have been unreliable, and additional instances of transmission might have been missed.

This investigation identified multiple instances of transmission of the B.1.351 SARS-CoV-2 lineage in Maryland with no identified link to international travel. These findings have implications for public health agencies responding to SARS-CoV-2 variants of concern. Programs might improve detection and tracking of variant cases by expanding the scope and volume of genetic surveillance programs' sequencing. More generally, the findings highlight the importance of completing contact investigations for SARS-CoV-2 infections and using universal prevention strategies, including vaccination, masking, and physical distancing, to control the spread of variants of concern.

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Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021

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

Early studies suggest that COVID-19 vaccines protect against severe illness (*1*); however, postvaccination SARS-CoV-2 infections (i.e., breakthrough infections) can occur because COVID-19 vaccines do not offer 100% protection (*2*,*3*). Data evaluating the occurrence of breakthrough infections and impact of vaccination in decreasing transmission in congregate settings are limited. Skilled nursing facility (SNF) residents and staff members have been disproportionately affected by SARS-CoV-2, the virus that causes COVID-19 (*4*,*5*), and were prioritized for COVID-19 vaccination (*6*,*7*). Starting December 28, 2020, all 78 Chicago-based SNFs began COVID-19 vaccination clinics over several weeks through the federal Pharmacy Partnership for Long-Term Care Program (PPP).† In February 2021, through routine screening, the Chicago Department of Public Health (CDPH) identified a SARS-CoV-2 infection in a SNF resident >14 days after receipt of the second dose of a two-dose COVID-19 vaccination series. SARS-CoV-2 cases, vaccination status, and possible vaccine breakthrough infections were identified by matching facility reports with state case and vaccination registries. Among 627 persons with SARS-CoV-2 infection across 75 SNFs since vaccination clinics began, 22 SARS-CoV-2 infections were identified among 12 residents and 10 staff members across 15 facilities ≥14 days after receiving their second vaccine dose (i.e., breakthrough infections in fully vaccinated persons). Nearly two thirds (14 of 22; 64%) of persons with breakthrough infections were asymptomatic; two residents were hospitalized because of COVID-19, and one died. No facility-associated secondary transmission occurred. Although few SARS-CoV-2 infections in fully vaccinated persons were observed, these cases demonstrate the need for SNFs to follow recommended routine infection prevention and control practices and promote high vaccination coverage among SNF residents and staff members.

CDPH monitors SNF SARS-CoV-2 infections using a data triangulation method that matches the SARS-CoV-2 test results from nucleic acid amplification tests (NAATs, such as reverse transcription–polymerase chain reaction [RT-PCR]) and antigen tests reported to the Illinois' National Electronic Disease Surveillance System with facility-reported line lists of SARS-CoV-2 test results from routine screening testing.§ In February 2021, CDPH began matching records to Illinois' Comprehensive Automated Immunization Registry Exchange to identify breakthrough infections. After identifying SARS-CoV-2 infection in a SNF resident 16 days after receipt of a second vaccine dose, CDPH initiated an investigation to quantify breakthrough infections across all facilities, evaluate symptoms and clinical outcomes, and assess potential secondary transmission. Vaccine effectiveness was not evaluated.

A facility's investigation period started on its first vaccination clinic date and ended March 31, 2021.¶ A confirmed case of SARS-CoV-2 infection was defined as a positive SARS-CoV-2 NAAT or antigen test result from a respiratory specimen collected from a resident or staff member during the investigation period. Consistent with CDC guidance, a vaccine breakthrough infection in a resident or staff member was defined as a receipt of a positive SARS-CoV-2 NAAT or antigen test result from a respiratory specimen collected ≥14 days after completing the two-dose COVID-19 vaccination series.** Infection

* These authors contributed equally to this report.

† A public-private partnership among CDC; CVS Pharmacy; Managed Health Care Associates, Inc.; and Walgreens to provide on-site COVID-19 vaccination of residents and staff members at enrolled long-term care facilities, including SNFs. https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html

§ CDPH advises facilities to routinely test residents at least monthly. Staff members were also required to receive testing routinely, with frequency determined based on community positivity rate and other metrics of interest. Staff members at all Chicago-based SNFs were tested at least twice weekly (until February 4, 2021), then weekly (during February 4–March 18, 2021), then biweekly (from March 18, 2021 through the end of investigation period). In response to a facility outbreak (i.e., a resident or staff member with a case within the past 14 days), all staff members and residents (excluding those who received a positive SARS-CoV-2 test <90 days previously) are required to receive testing at least every 3–7 days until no new cases occur for at least 14 days. At the time a breakthrough infection was identified, frequency of resident testing at the 15 SNFs ranged from monthly to twice per week; frequency of staff member testing ranged from weekly to twice weekly.

¶ First round vaccination clinics occurred during December 28, 2020–January 18, 2021. Persons were included in the study if infection occurred between the first clinic date at their respective facility and March 31, 2021. Moderna COVID-19 vaccination was exclusively administered at Chicago-based SNFs through the federal PPP. Six residents and two staff members received Pfizer-BioNTech COVID-19 vaccine through Chicago-based vaccine providers not participating in the federal PPP or facilities outside the city of Chicago.

** CDC breakthrough infection guidance: https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html. Residents and staff members were excluded from the investigation if they had received 1) a positive SARS-CoV-2 test result from December 28 through the date of their facility's first vaccination clinic or 2) a known initial positive SARS-CoV-2 test result <90 days before their most recent SARS-CoV-2 test result.

Summary

What is already known about this topic?

Residents and staff members of skilled nursing facilities (SNFs) are recommended to receive COVID-19 vaccine as a priority group.

What is added by this report?

Twenty-two possible breakthrough SARS-CoV-2 infections occurred among fully vaccinated persons ≥14 days after their second dose of COVID-19 vaccine. Two thirds of persons were asymptomatic. A minority of persons with breakthrough infection experienced mild to moderate COVID-19–like symptoms; two COVID-19–related hospitalizations and one death occurred. No facility-associated secondary transmission was identified.

What are the implications for public health practice?

SNFs should prioritize vaccination and follow recommended COVID-19 infection prevention and control practices, including following work restrictions, isolation, quarantine, testing of residents and staff members, and use of personal protective equipment.

prevention specialists conducted case investigations to assess symptoms, clinical outcomes, and close contact information.

SARS-CoV-2 incidence during the investigation period was assessed across four groups based on vaccination status at the time a positive respiratory specimen was collected: 1) unvaccinated (never received a COVID-19 vaccine dose); 2) partially vaccinated (received one dose of a two-dose series); 3) vaccinated but not immune (received two doses of a two-dose series but <14 days had elapsed since the second dose); and 4) fully vaccinated (received two doses of a two-dose series and ≥14 days had elapsed since the second dose). In addition to routine facility follow-up, CDPH actively monitored facilities with breakthrough infections for 28 days to identify whether any new cases occurred in close contacts of the person with breakthrough infection.[††] Analyses were completed using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[§§]

During the investigation period, an estimated 7,931 SNF residents and 6,834 staff members received two doses of COVID-19 vaccine. A total of 627 confirmed SARS-CoV-2 infections were identified across 75 of the 78 Chicago-based SNFs, including 353 (56%) among residents and 274 (44%) among staff members during the investigation period (Table 1). Three facilities had no confirmed SARS-CoV-2 infections after their first vaccination clinic. Approximately one half (47%) of resident cases occurred in men, 42% were in non-Hispanic Black persons, and the median age was 71 years. More than two thirds (72%) of staff member cases were in women, 38% were in non-Hispanic Black persons, and the median age was 42 years. Among the 627 cases, 447 (71%) occurred in unvaccinated persons, 145 (23%) in partially vaccinated persons, 13 (2%) in vaccinated but not immune persons, and 22 (4%) in fully vaccinated persons (Figure). These breakthrough infections occurred in 12 residents and 10 staff members and accounted for 16% (22 of 136) of SNF-associated cases occurring across all facilities ≥14 days after the second vaccination clinic at the respective facilities. No demographic or clinical differences were observed by vaccination status.

Among the 22 breakthrough infections, 18 (82%) were detected in persons who received testing as part of routine screening, and four (18%) occurred in residents who received testing before a hospital admission or procedure. Among the 18 breakthrough infections identified during routine screening, 14 were detected (across 10 facilities) while residents were receiving weekly testing from the facilities; staff members at all facilities were receiving testing at least weekly. The median interval from second dose to collection of a positive SARS-CoV-2 specimen was 29 days (interquartile range [IQR] = 23–42 days). The median interval between most recent positive NAAT result and last known negative test result was 7 days (IQR = 7–14 days). Two-dose vaccination coverage among residents and staff members at facilities with breakthrough infections ranged from 62% to 96% and 18% to 85%, respectively. Among the 15 facilities with breakthrough cases, attack rates[¶¶] for unvaccinated and vaccinated residents were 15% (89 of 604) and 0.8% (15 of 1,781), respectively. Among staff members, attack rates for unvaccinated and vaccinated persons were 6% (62 of 992) and 1% (12 of 1,135), respectively. Eleven facilities reported a total of 41 confirmed cases within 28 days

[††] For residents, close contact was defined as being within 6 ft of a person for ≥15 minutes over a 24-hour period, regardless of personal protective equipment used. For staff members, close contact was defined as being within 6 ft of a person for ≥15 minutes over a 24-hour period when one or both persons were unmasked.

[§§] 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.

[¶¶] To calculate attack rates, residents and staff members who had never received COVID-19 vaccine (i.e., unvaccinated persons) and those who had received one COVID-19 vaccine dose of a two-dose series (i.e., partially vaccinated persons) were categorized as unvaccinated. Residents and staff members who had received two COVID-19 vaccine doses of a two-dose series and <14 days or ≥14 days had elapsed (i.e., vaccinated but not immune and fully vaccinated persons, respectively) were categorized as vaccinated. Aggregate vaccination data were only available for residents and staff members who received two doses of COVID-19 vaccine and did not have a SARS-CoV-2 infection. In the denominator, differentiation between persons who received two doses <14 days or ≥14 days was not possible.

TABLE 1. Number and percentage of skilled nursing facility residents and staff members with a positive confirmed SARS-CoV-2 test result, by demographic and clinical characteristics and vaccination status — Chicago, Illinois, December 2020–March 2021

Characteristic	Vaccination status of residents and staff members with SARS-CoV-2 infections, no. (column %)				
	Total (n = 627)	Unvaccinated* (n = 447)	Partially vaccinated* (n = 145)	Vaccinated but not immune* (n = 13)	Fully vaccinated with breakthrough infection* (n = 22)
Median age (IQR)	60.0 (43.0–73.0)	57.0 (39.0–71.0)	65.0 (50.0–79.0)	66.0 (58.0–79.0)	61.5 (41.0–73.0)
Sex					
Female	376 (60.0)	265 (59.3)	89 (61.4)	7 (53.9)	15 (68.2)
Male	237 (37.8)	168 (37.6)	56 (38.6)	6 (46.2)	7 (31.8)
Unknown	14 (2.2)	14 (3.1)	0 (—)	0 (—)	0 (—)
Race/Ethnicity					
Hispanic/Latino	58 (9.3)	37 (8.3)	16 (11.0)	1 (7.7)	4 (18.2)
Asian, non-Hispanic	24 (3.8)	11 (2.5)	9 (6.2)	1 (7.7)	3 (13.6)
Black, non-Hispanic	252 (40.2)	193 (43.2)	44 (30.3)	7 (53.9)	8 (36.4)
White, non-Hispanic	144 (23.0)	79 (17.7)	55 (37.9)	3 (23.1)	7 (31.8)
Other,† non-Hispanic	16 (2.6)	12 (2.7)	4 (2.8)	0 (—)	0 (—)
Unknown	133 (21.2)	115 (25.7)	17 (11.7)	1 (7.7)	0 (—)
Role					
Resident	353 (56.3)	235 (52.6)	97 (66.9)	9 (69.2)	12 (54.6)
Staff member	274 (43.7)	212 (47.4)	48 (33.1)	4 (30.8)	10 (45.5)
Symptoms§					
Yes	92 (14.7)	62 (13.9)	21 (14.5)	1 (7.7)	8 (36.4)
No	34 (5.4)	15 (3.4)	5 (3.5)	0 (—)	14 (63.6)
Unknown	501 (79.9)	370 (82.8)	119 (82.1)	12 (92.3)	0 (—)
Hospitalizations					
Yes	123 (19.6)	90 (20.1)	27 (18.6)	2 (15.4)	4 (18.2)¶
No	504 (80.4)	357 (79.9)	118 (81.4)	11 (84.6)	18 (81.8)
Deaths					
Yes	21 (3.4)	14 (3.1)	6 (4.1)	0 (—)	1 (4.6)
No	606 (96.7)	433 (96.9)	139 (95.9)	13 (100.0)	21 (95.5)
Previous positive SARS-CoV-2 result					
Yes	41 (6.5)	22 (4.9)	9 (6.2)	4 (30.8)	6 (27.3)
No	586 (93.5)	425 (95.1)	136 (93.8)	9 (69.2)	16 (72.7)

Abbreviations: I-NEDSS = Illinois' National Electronic Disease Surveillance System; IQR = interquartile range.

* Unvaccinated: received no COVID-19 vaccine doses; partially vaccinated: received one dose; vaccinated but not immune: received two doses but <14 days had elapsed since receipt of second dose; and fully vaccinated with breakthrough infection: received two doses and then received a positive SARS-CoV-2 test result ≥14 days after receipt of the second dose.

† Persons with the following races listed in I-NEDSS as American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, other, or multiracial were categorized as non-Hispanic other.

§ Data on symptoms were extracted from I-NEDSS for unvaccinated, partially vaccinated, and vaccinated but not immune persons. Most COVID-19 case reports are entered into I-NEDSS through electronic laboratory reporting and provide minimal information (e.g., name, date of birth, and laboratory test and results) needed to meet reporting requirements. Data on symptoms in persons with breakthrough infections were supplemented with details from case investigations, which were not completed for nonbreakthrough cases. Symptom status for many persons with nonbreakthrough infection cases is unknown.

¶ Two residents were hospitalized for COVID-19–related reasons. Two additional residents were hospitalized for non-COVID-19–related reasons.

after initial breakthrough infection at a facility (Table 2).*** No facility-associated secondary transmission was determined to have occurred because the new cases that occurred after the initial breakthrough infection were not close contacts of the persons with breakthrough infections.

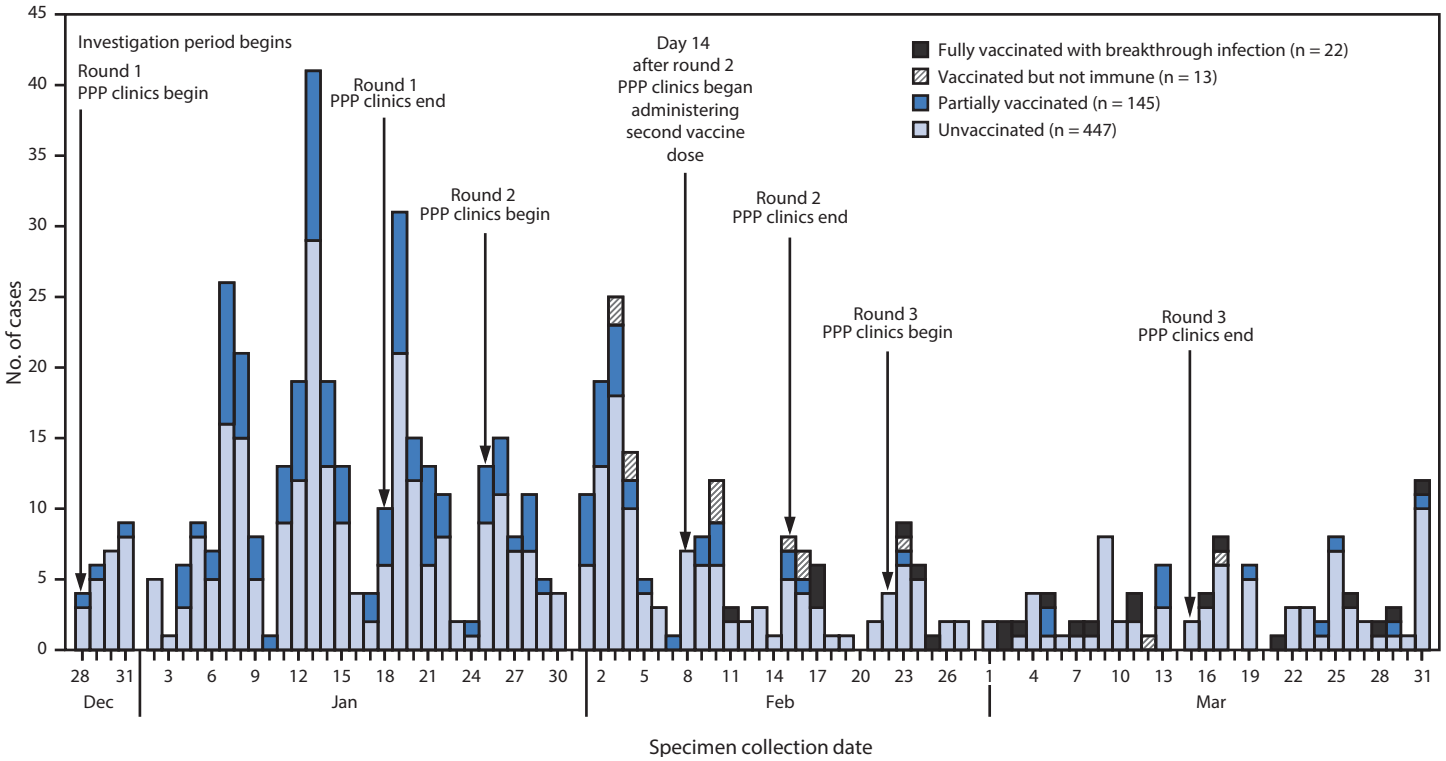
Among the 22 persons with breakthrough infections, 14 (64%; eight residents and six staff members) were asymptomatic (Table 2). Three symptomatic persons (B3, E10, and G13) had mild, nonspecific symptoms; two (E8 and G12) had mild, specific symptoms; and three (A1, D6, and O22) had diagnosed pneumonia.††† Four residents were hospitalized: two (D6 and O22) for COVID-19–related reasons and two (A1 and D5) for reasons unrelated to COVID-19; one resident (O22) died.

Resident A1 received a diagnosis of pneumonia 9 days after receiving the second COVID-19 vaccine dose and 7 days before receiving a positive SARS-CoV-2 test result (Table 2). Although the timing of the patient's positive SARS-CoV-2 test result met the definition of a breakthrough infection, the clinical history

*** Cases identified within a 28-day monitoring window from the date of specimen collection for the breakthrough infection. For facilities with multiple breakthrough infections, 28-day monitoring windows might overlap, and new facility cases might be listed multiple times. As of April 12, 2021, nine of the 41 cases were breakthrough infections; seven of which are listed (see Table 2) and occurred during the investigation period.

††† Symptoms were categorized as nonspecific, mild, or moderate based on the National Notifiable Diseases Surveillance System and Council of State and Territorial Epidemiologists definition of symptomatic COVID-19. https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/08/05/

FIGURE. Confirmed SARS-CoV-2 infections (n = 627) among residents and staff members at 75* skilled nursing facilities, by specimen collection date and vaccination status† — Chicago, Illinois, December 2020–March 2021



Abbreviation: PPP = Federal Pharmacy Partnership for Long-Term Care Program.

* Among 78 Chicago-based facilities. Three facilities had no confirmed SARS-CoV-2 infections.

† Unvaccinated: received no COVID-19 vaccine doses; partially vaccinated: received one dose; vaccinated but not immune: received two doses but <14 days had elapsed since receipt of second dose; fully vaccinated with breakthrough infection: received two doses and then received a positive SARS-CoV-2 test result ≥14 days after receipt of the second dose.

indicated that the infection likely occurred <14 days after the second dose. Resident D6 was hospitalized for weakness and loss of appetite in association with pneumonia. Resident O22 experienced fatigue and respiratory symptoms and received a diagnosis of pneumonia. This patient had a positive SARS-CoV-2 test result on hospital admission and had concomitant group B β-hemolytic streptococcal bacteremia and a *Pseudomonas* urinary tract infection and died 7 days after hospital admission. The death certificate listed complications of COVID-19 infection as primary cause of death; underlying conditions were hypertension, diabetes mellitus, and chronic kidney disease.

Among 12 available specimens from seven patients with breakthrough infections, RT-PCR cycle threshold values were >28, indicating low levels of detectable virus. Six persons with breakthrough infections had a previous positive SARS-CoV-2 test result >90 days before the most recent test, including five persons who had negative test results (range = 1–43 tests) between the positive results (Supplementary Figure, https://stacks.cdc.gov/view/cdc/105130) and at least one negative NAAT result <14 days before the postvaccination positive test result. Five persons were asymptomatic during the second infection. Paired specimens for sequence comparison were unavailable.

Discussion

Twelve SNF residents and 10 staff members had positive SARS-CoV-2 test results ≥14 days after receiving a second COVID-19 vaccine dose (breakthrough infections). Fourteen (64%) were asymptomatic, available RT-PCR cycle threshold values suggest low viral loads, and no facility-associated secondary transmission was detected. Two residents with breakthrough infections experienced COVID-related hospitalizations, one of whom died because of multiple concurrent infections. Although rare, postvaccination breakthrough infection can occur because COVID-19 vaccines do not offer 100% protection (*2*,*3*). Early studies suggest that COVID-19 vaccines protect against severe illness and might be effective at preventing infection (*1*); however, data on the impact of vaccination on transmission in congregate settings are limited. In addition, some persons whose infections met the case definition of a breakthrough infection might have had persistently positive NAAT results after initial infection; however, most had multiple confirmed negative interim test results. Additional data are needed to differentiate breakthrough infections from sequelae of previous infections and to determine whether persons with breakthrough infections can transmit virus.

TABLE 2. Skilled nursing facility residents and staff members with SARS-CoV-2 breakthrough infections,* by facility and clinical characteristics — Chicago, Illinois, December 2020–March 2021

		Residents and staff members with breakthrough infection										Facilities	
Facility	Patient	Sex, age (yrs)	Role	Symptoms	Hospitalized	Death	No. of days between second vaccine dose and positive specimen collection	Ct value†	Previous positive SARS-CoV-2 test result	No. of days between initial and most recent positive test result	No. of days between last negative SARS-CoV-2 test result and postvaccination positive test	No. of facility cases occurring after breakthrough infection§	No. of cases considered close contacts¶
A	1	F, 75	Resident	Pneumonia, seizure	Yes, not COVID-19 related**	No	16	—	No	—	23	3	0
B	2	F, 63	Staff	None	No	No	21	—	No	—	6	3	0
	3	F, 36	Staff	HA, fatigue	No	No	29	—	No	—	7	2	0
C	4	F, 83	Resident	None	No	No	18	26.2	No	—	7	2	0
D	5	M, 64	Resident	None	Yes, not COVID-19 related††	No	15	—	Yes	96	106	2	0
	6	M, 73	Resident	Pneumonia, weakness	Yes, COVID-19 related§§	No	21	—	No	—	112	2	0
	7	F, 70	Resident	None	No	No	42	28.8	No	—	7	4	0
E	8	F, 82	Resident	Fatigue, cough	No	No	19	26.9	No	—	29	9	0
	9	F, 95	Resident	None	No	No	28	—	Yes	303	9	5	0
	10	F, 29	Staff	HA	No	No	34	50.0¶¶	No	—	7	1	0
F	11	F, 46	Resident	None	No	No	29	—	Yes	112	8	0	NA
G	12	F, 36	Staff	Chills, myalgia, HA, sore throat, fatigue, cough, loss of taste or smell	No	No	27	29.9	No	—	4	2	0
	13	F, 46	Staff	Sore throat, nausea, diarrhea	No	No	51	27.7	No	—	10	2	0
H	14	M, 41	Staff	None	No	No	29	32.6	Yes	214	7	1	0
I	15	F, 37	Staff	None	No	No	39	28.6	No	—	5	1	0
J	16	M, 60	Resident	None	No	No	31	38.5	No	—	7	1	0
	17	M, 26	Staff	None	No	No	53	—	No	—	14	1	0
K	18	F, 57	Staff	None	No	No	27	28.3	No	—	7	7	0
L	19	F, 49	Staff	None	No	No	42	16.9	No	—	7	0	NA
M	20	M, 77	Resident	None	No	No	45	20.5	No	—	220	0	NA
N	21	F, 70	Resident	None	No	No	56	—	Yes	137	7	4	0
O	22	M, 66	Resident	Pneumonia, fatigue, cough, SOB, difficulty breathing	Yes, COVID-19 related***	Yes***	46	—	Yes	152	13	0	NA

See table footnotes on the next page.

The results in this report highlight the importance of COVID-19 vaccination in high-risk congregate settings such as SNFs; most fully vaccinated persons were not infected, did not have COVID-19–like symptoms, and did not have severe illness. Despite the identification of positive NAAT results during the investigation period, breakthrough infections did not lead to secondary transmission at these facilities.

Expanded testing of residents and staff members in these settings in response to clusters or outbreak investigations is also important, regardless of vaccination status, because these persons might have asymptomatic infections.§§§ A previous study found that vaccination has an estimated effectiveness of 63% against SARS-CoV-2 infection among SNF residents >14 days after the first dose through 7 days after the second dose (*8*). Additional studies are needed to assess the impact of full vaccination in SNFs and to understand how vaccination in settings that include

§§§ https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html

TABLE 2. (*Continued*) Skilled nursing facility residents and staff members with SARS-CoV-2 breakthrough infections,* by facility and clinical characteristics — Chicago, Illinois, December 2020–March 2021

Abbreviations: Ct = cycle threshold; F = female; HA = headache; M = male; NA = not applicable; NAAT = nucleic acid amplification test; SOB = shortness of breath.

* Receipt of a positive SARS-CoV-2 NAAT (e.g., reverse transcription–polymerase chain reaction) or antigen test result from a respiratory specimen collected ≥14 days after completing the two-dose COVID-19 vaccination series.

† Missing Ct values are for specimens that were discarded by the laboratory and unavailable for sequencing.

§ Cases identified within a 28-day monitoring window from the date of specimen collection for the breakthrough infection. For facilities with multiple breakthrough infections, 28-day monitoring windows might overlap, and new facility cases might be listed multiple times.

¶ When a new case in a facility was identified, infection prevention specialists determined whether the person with the case met criteria to be considered a close contact of the person with the breakthrough infection. Data in this column represent the number of cases in persons that met the definition of a close contact and occurred after identification of the breakthrough infection as of April 12, 2021.

** Resident A1 had a positive SARS-CoV-2 test result 16 days after receiving the second dose of COVID-19 vaccine, which was an incidental finding when admitted to the hospital for new onset of seizures. The positive result might have been related to an episode of pneumonia diagnosed 9 days after the second dose. COVID-19 testing was not associated with compatible symptoms, and this resident was included because the resident's case met the laboratory-based breakthrough infection definition. This resident likely did not experience a breakthrough infection because previous pneumonia onset is suggestive of SARS-CoV-2 infection before full immunization.

†† Resident D5 had a positive preprocedural SARS-CoV-2 test result and was subsequently hospitalized for non-COVID-19–related reasons, including multiple falls and a bloodstream infection related to a midline catheter.

§§ Resident D6 was hospitalized for COVID-19-related reasons because of weakness and loss of appetite in association with pneumonia diagnosed at hospital admission.

¶¶ Based on the symptomatic disease case definition outlined by the Council of State and Territorial Epidemiologists, patient E10 had nonspecific COVID-19 symptoms. Previous testing history was examined using the Illinois' National Electronic Disease Surveillance System. No known previous positive SARS-CoV-2 were identified for this patient.

*** Resident O22 was hospitalized for COVID-19-related reasons because of fatigue, cough, SOB, and difficulty breathing. SARS-CoV-2 test result was positive, and resident received a diagnosis of pneumonia requiring hospital admission and intubation in the intensive care unit for hypoxic respiratory failure. Concomitant infections including group B streptococcal bacteremia and *Pseudomonas* urinary tract infection were also identified. The resident died 7 days after hospital admission.

older adults, immunocompromised persons, and persons with known history of SARS-CoV-2 infection compares with clinical trial efficacy data. Whether vaccinated asymptomatic persons can transmit SARS-CoV-2 is also unknown; therefore, facilities should continue to require residents to quarantine after close contact with an infected person.¶¶¶

Vaccine effectiveness estimates for prevention of SARS-CoV-2 infection and COVID-19 were not calculated because CDPH does not have access to SNF electronic medical records, limiting the ability to obtain individual-level data from facilities on all residents and staff members and to calculate person-time among vaccinated and unvaccinated persons who were not infected. Facilities did not have the capacity to provide line lists and vaccination information for noninfected residents and staff members.

The findings in this report are subject to at least four limitations. First, confirming whether patients with a breakthrough infection and a previous positive SARS-CoV-2 test result had a true reinfection or represented persons with prolonged shedding from previous infection was not possible. Intermittent prolonged SARS-CoV-2 shedding is well described (*9*). In addition to two SARS-CoV-2 tests ≥90 days apart, paired respiratory specimens are needed so that their genetic sequences can be compared.**** Data such as epidemiologic links to confirmed cases and clinical course can provide supporting evidence for reinfection but do not definitively identify reinfection events. Second, vaccination data in this report are limited to Chicago residents and persons vaccinated in Chicago; data were unavailable for staff members who were not Chicago residents and were vaccinated outside Chicago. Third, data entry errors or delayed surveillance reporting might prevent record matching, leading to an underestimate of breakthrough infections. Finally, although some specimens were submitted for genotyping to evaluate possible variant strains, results are pending and not yet available.

SNFs should continue to follow recommended infection prevention and control practices,†††† including work restrictions, isolation of persons with confirmed cases, quarantine of residents who have had close contact with persons with confirmed cases, routine and outbreak testing of residents and staff members, and use of personal protective equipment, regardless of vaccination status. Maintaining high vaccination coverage among residents and staff members is also important to reduce opportunities for transmission within facilities and exposure among persons who might not have achieved protective immunity after vaccination.

¶¶¶ https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

**** https://www.cdc.gov/coronavirus/2019-ncov/php/invest-criteria.html

†††† https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

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COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021

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

Although COVID-19 mRNA vaccines demonstrated high efficacy in clinical trials (*1*), they were not 100% efficacious. Thus, some infections postvaccination are expected. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants. The Kentucky Department for Public Health (KDPH) and a local health department investigated a COVID-19 outbreak in a SNF that occurred after all residents and health care personnel (HCP) had been offered vaccination. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received 2 vaccine doses. Twenty-six residents and 20 HCP received positive test results for SARS-CoV-2, the virus that causes COVID-19, including 18 residents and four HCP who had received their second vaccine dose >14 days before the outbreak began. An R.1 lineage variant was detected with whole genome sequencing (WGS). Although the R.1 variant has multiple spike protein mutations, vaccinated residents and HCP were 87% less likely to have symptomatic COVID-19 compared with those who were unvaccinated. Vaccination of SNF populations, including HCP, is critical to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also essential.

Investigation and Epidemiologic Findings

The SNF conducted vaccination clinics using Pfizer-BioNTech mRNA vaccine on January 10, January 31, and February 21, 2021. Among 83 residents and 116 HCP, 75 (90.4%) and 61 (52.6%), respectively, received two vaccine doses. All vaccinated residents and HCP were vaccinated on-site, the majority on January 10 and 31. Four residents and five HCP received their second dose during the third clinic, which was <14 days before the outbreak onset.

Before and during the outbreak, SARS-CoV-2 testing was used for evaluating symptomatic illness in residents and HCP. Symptom screening of residents and HCP had been ongoing since March 2020, and twice-weekly screening testing of all HCP had been occurring since November 2020. A COVID-19 case was defined as a positive SARS-CoV-2 antigen or reverse transcription–polymerase chain reaction (RT-PCR) test result. Possible reinfection was defined as a positive SARS-CoV-2 test result >90 days after a previous laboratory-confirmed infection.

The outbreak was identified during routine HCP antigen testing on March 1.* This was 8 days after the third vaccination clinic. The index case occurred in an unvaccinated, symptomatic HCP. Once the outbreak was identified, daily rapid point-of-care antigen testing of all residents, regardless of symptoms, was added to the twice-weekly HCP testing. Additional specimens were collected the same day for RT-PCR confirmation of positive antigen test results. One week after the outbreak was identified, resident antigen testing was reduced to three times weekly, then to twice weekly after no additional cases were identified for 1 week.

The local health department interviewed HCP and facility staff members to collect information about the cases. Vaccination status was ascertained through immunization registry review and facility interviews. COVID-19–related hospitalizations and deaths were confirmed by medical records reviews. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.†

Relative risks (RRs) were calculated comparing unvaccinated and vaccinated residents and HCP; vaccine effectiveness (VE [1–RR of vaccinated versus unvaccinated x 100]) was calculated for the following outcomes: SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death. Persons who received their second vaccine dose ≥14 days before the outbreak began were considered vaccinated, consistent with CDC postvaccination guidance§ and breakthrough case definition. Ten persons who had received at least 1 dose but had not received a second vaccine dose ≥14 days before the outbreak were excluded from analyses.

A sensitivity analysis was conducted using a 7-day threshold to classify persons as vaccinated, consistent with the Pfizer-BioNTech vaccine clinical trials (*1*). Four residents and five HCP who received their second vaccine dose 8 days before outbreak identification were classified as vaccinated in this sensitivity analysis. One HCP who received a single vaccine

* https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
† 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. 241(d); 5 U.S.C. 552a; 44 U.S.C. 3501 et seq.
§ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

dose remained excluded (Supplementary Table https://stacks.cdc.gov/view/cdc/105235).

KDPH Division of Laboratory Services performed WGS (*2*). Genomes were assembled using the StaPH-B Monroe pipeline,[¶] followed by Nextclade[**] for clade assignment and mutation calling, Pangolin[††] for lineage assignment, and Nextstrain for phylogenetic analysis (*3*).

During the outbreak, 46 COVID-19 cases were identified, including cases in 26 residents (18 fully vaccinated) and 20 HCP (four vaccinated) (Figure) (Table). Two cases occurred in residents who had received their second vaccine dose within 14 days; these two cases were excluded from the primary analysis. Vaccinated residents and HCP were less likely to be infected than were unvaccinated persons. Attack rates in unvaccinated residents (75.0%) were 3 times as high as those in vaccinated residents (25.4%; RR = 3.0; 95% confidence interval [CI] = 1.7–5.2) and in unvaccinated HCP (29.6%) were 4.1 times as high as those in vaccinated HCP (7.1%; RR = 4.1; 95% CI = 1.5–11.6). The estimated VE against SARS-CoV-2 infection among residents was 66.2% (95% CI = 40.5%–80.8%) and among HCP was 75.9% (95% CI = 32.5%–91.4%).

VE against symptomatic COVID-19 was 86.5% (95% CI = 65.6%–94.7%) among residents and 87.1% (95% CI = 46.4%–96.9%) among HCP. VE against hospitalization was 94.4% (95% CI = 73.9%–98.8%) among residents; no HCP were hospitalized. Three residents died, two of whom were unvaccinated (VE = 94.4%; 95% CI = 44.6%–99.4%).

Four possible reinfections were identified (one resident and three HCP); of these, one HCP was vaccinated. All four persons experienced symptomatic illness. One resident was infected 300 days earlier and had nine consecutive negative RT-PCR tests before reinfection, including two within 30 days of the outbreak. This resident was hospitalized and died.

Laboratory and Bioinformatics Findings

WGS was performed for 28 specimens (27 persons, including one who was reinfected); all had >97% genome coverage at a depth of >30x, therefore passing required quality control matrices.[§§] Examination of phylogeny revealed 28 clustered sequences sharing 14 amino acid mutations not present in the reference Wuhan-1 genome: ORF1a:A2584T, ORF1b:P314L, ORF1b:G1362R, ORF1b:P1936H, S:E484K, S:D614G, S:G769V, S:W152L, M:F28L, N:M1X, N:S187L, N:R203K, N:G204R, and N:Q418H. This cluster aligns with the R.1 lineage, which had not previously been identified in Kentucky. Whereas the 28 sequences share spike protein mutations E484K, D614G, G769V, and W152L with the R.1 root, the mutation ORF1a:A2584T places the cluster in a separate group on the phylogenetic tree.

Public Health Response

The local health department, along with the KDPH regional epidemiologist and regional infection preventionist, provided guidance on implementation of infection prevention strategies. These included the use of transmission-based precautions and hand hygiene, ongoing testing to identify new cases, exclusion of symptomatic HCP from work, isolation and quarantine of HCP, and provision of dedicated and separate spaces for care of infected and exposed residents, regardless of vaccination status.[¶¶]

Discussion

In a SNF with 90.4% of residents vaccinated, an outbreak of COVID-19 occurred after introduction from an unvaccinated, symptomatic HCP. WGS identified an R.1 lineage variant, characterized by E484K and other mutations within the spike protein. Attack rates were three to four times as high among unvaccinated residents and HCP as among those who were vaccinated; vaccinated persons were significantly less likely to experience symptoms or require hospitalization.

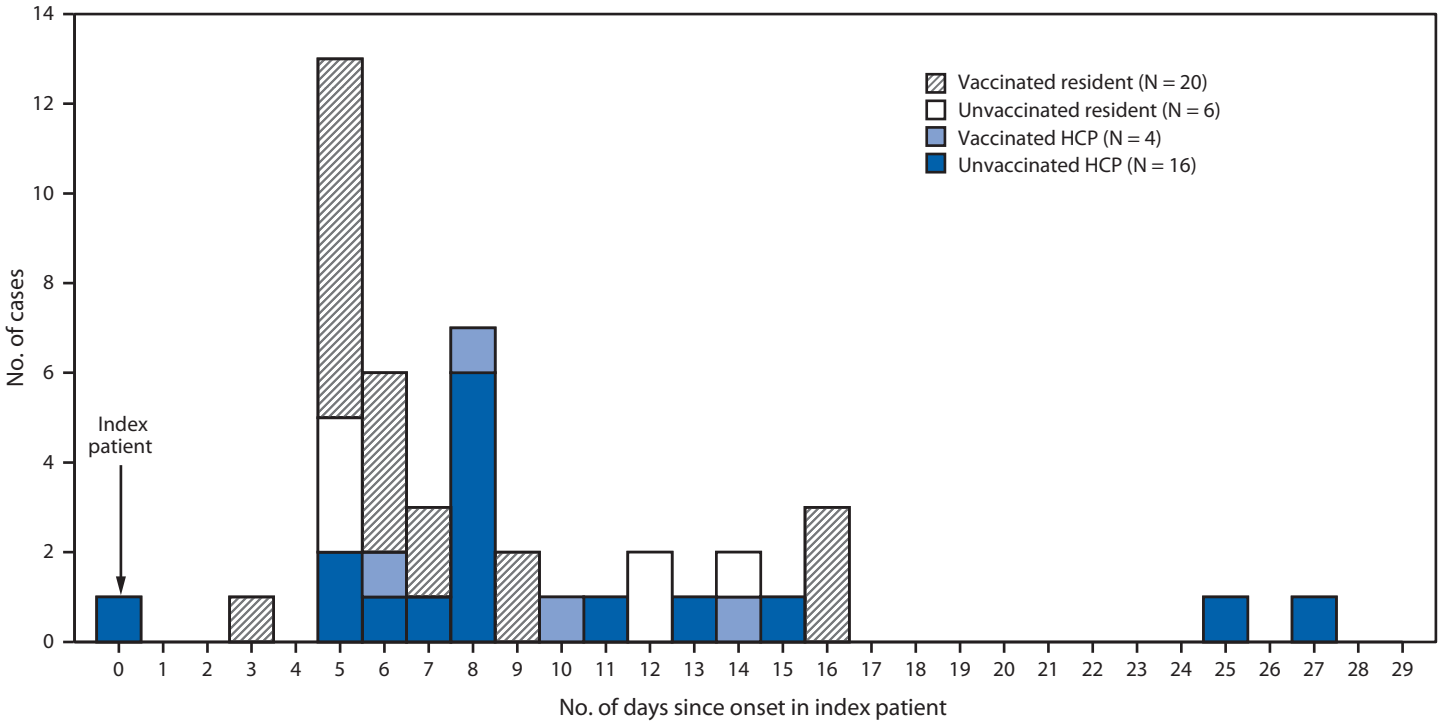
Although the R.1 variant is not currently identified as a CDC variant of concern or interest,[***] it does have several mutations of importance. The D614G mutation demonstrates evidence of increasing virus transmissibility (*4*). The E484K mutation, found within the receptor-binding domain of the spike protein, is also seen in the variants of concern B.1.351 and P.1, which show evidence of reduced neutralization by convalescent and postvaccination sera (*5*,*6*). Mutation W152L might reduce the effectiveness of neutralizing antibodies (*7*). Although vaccination was associated with decreased likelihood of infection and symptomatic illness, 25.4% of vaccinated residents and 7.1% of vaccinated HCP were infected, supporting concerns about potential reduced protective immunity to R.1. In addition, four possible reinfections were identified, providing some evidence of limited or waning natural immunity to this variant.

Point estimates for VE against SARS-CoV-2 infections were lower than were those reported from Israel's national vaccination program (*8*). Whereas this could reflect reduced

¶ https://staph-b.github.io/staphb_toolkit/workflow_docs/monroe/
** https://clades.nextstrain.org/
†† https://github.com/cov-lineages/pangolin
§§ Percentage of coverage and depth of coverage are metrics computed during genome assembly that correspond with data quality. The data quality threshold used by the Association of Public Health Laboratories is ≥90% and 10X depth for Illumina sequencing technology. https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARS-CoV-2-Sequencing.pdf

¶¶ https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
*** https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

FIGURE. SARS-CoV-2 illness onset* among residents and health care personnel (HCP) in a skilled nursing facility, relative to onset in the index patient, by vaccination status† — Kentucky, March 2021



* Symptom onset date or specimen collection date, if asymptomatic.
† Persons who received 2 doses of Pfizer-BioNTech vaccine are indicated as vaccinated; unvaccinated persons received no vaccine doses. Persons who received a second dose of vaccine <14 days before outbreak onset (four residents and five HCP) and those who received only a single dose of vaccine (one HCP) were excluded from the primary analysis; this resulted in exclusion of two cases that occurred in residents.

protection against R.1, other factors to consider include the smaller sample size in this study and the higher exposure risk associated with an outbreak in a congregate setting. In addition, testing, regardless of symptoms, was performed with high frequency for both residents and HCP, which contrasts with VE studies that use a primary reliance on individual test-seeking behavior. Such differences could influence VE estimates for infection; therefore, caution is urged when comparing these studies. Regardless of VE differences in SARS-CoV-2 infection, the estimated VE for COVID-19 symptom prevention (86.5% for residents; 87.1% for HCP) demonstrates a strong protective effect of vaccination.

The risk for poor outcomes among unvaccinated SNF residents is highlighted by the hospitalization of four of the six unvaccinated, infected residents, and two subsequent deaths, including in one previously infected resident. This underscores the importance of the Advisory Committee on Immunization Practices' recommendation that all persons, including those who have recovered from COVID-19, be vaccinated.†††

Low acceptance of vaccination among SNF HCP might increase the likelihood of SARS-CoV-2 introduction and transmission within a facility. Nationally, a median of 37.5% of HCP working in long-term care facilities had received at least 1 dose of vaccine by mid-January 2021 (*9*). Although the vaccination rate in this SNF surpassed this early national rate, approximately one half of HCP were vaccinated. To protect SNF residents, it is imperative that HCP, as well as SNF residents, be vaccinated. A continued emphasis on strategies for prevention of disease transmission, even among vaccinated populations, is also critical. Timely implementation of infection control strategies after outbreak identification likely contributed to the rapid decline in new cases during the second week of the outbreak.

The findings in this report are subject to at least three limitations. First, the health status of residents who declined vaccination might have differed from those who consented to vaccination. Thus, hospitalization and death outcomes might be biased when comparing the groups without controlling for underlying health conditions. Second, underlying health status and advance directives might affect decisions for resident hospitalization; therefore, association of vaccination with

††† https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

TABLE. Relative risk and estimated vaccine effectiveness for prevention of SARS-CoV-2 infection, symptomatic COVID-19, hospitalization, and death for fully vaccinated persons compared with unvaccinated persons during a COVID-19 outbreak in a skilled nursing facility (SNF) — Kentucky, 2021

Population and outcome	No. (% attack rate)		Unvaccinated versus vaccinated RR (95% CI)	Vaccine effectiveness[§] (95% CI)
	Vaccinated*	Unvaccinated[†]		
Total SNF population[¶]	**(n = 127)**	**(n = 62)**	—	—
SARS-CoV-2 infection	22 (17.3)	22 (35.5)	—	—
Symptomatic	8 (6.3)	20 (32.3)	—	—
Hospitalization	2 (1.6)	4 (6.5)	—	—
Death	1 (0.8)	2 (3.2)	—	—
Residents	**(n = 71)**	**(n = 8)**	—	—
SARS-CoV-2 infection	18 (25.4)	6 (75.0)	3.0 (1.7–5.2)	66.2 (40.5–80.8)
Symptomatic	6 (8.5)	5 (62.5)	7.4 (2.9–18.8)	86.5 (65.6–94.7)
Hospitalization	2 (2.8)	4 (50.0)	17.8 (3.8–82.1)	94.4 (73.9–98.8)
Death	1 (1.4)	2 (25.0)	17.8 (1.8–174.7)	94.4 (44.6–99.4)
Health care personnel	**(n = 56)**	**(n = 54)**	—	—
SARS-CoV-2 infection	4 (7.1)	16 (29.6)	4.1 (1.5–11.6)	75.9 (32.5–91.4)
Symptomatic	2 (3.6)	15 (27.8)	7.8 (1.9–32.4)	87.1 (46.4–96.9)
Hospitalization	0 (—)	0 (—)	—	—
Death	0 (—)	0 (—)	—	—

Abbreviations: CI = confidence interval; RR = relative risk.

* Receipt of 2 doses of Pfizer-BioNTech vaccine ≥14 days before identification of the SNF outbreak; persons who received a second dose of vaccine <14 days before the outbreak (four residents and five health care personnel) and those who received a single dose of vaccine (one health care worker) were excluded, which resulted in exclusion of two resident cases.

† Receipt of zero doses of COVID-19 vaccine.

§ Calculated as (1−RR of vaccinated versus unvaccinated) x100.

¶ Includes residents and health care personnel.

hospitalization in this SNF population might have limited generalizability. Finally, because of the reduced sensitivity of antigen testing in asymptomatic populations,[§§§] it is possible that some asymptomatic cases were not identified. If this introduced differential bias for identification of cases in either the vaccinated or unvaccinated groups, actual VE for the prevention of SARS-CoV-2 infections could differ from measured effectiveness.

An R.1 lineage variant, not previously detected in Kentucky, was identified in a SNF outbreak where 46 residents and HCP were infected. Compared with unvaccinated persons, vaccinated persons had reduced risk for SARS-CoV-2 infection and symptomatic COVID-19. A continued emphasis on vaccination of SNF populations, including HCP, is essential to reduce the risk for SARS-CoV-2 introduction, transmission, and severe outcomes in SNFs. An ongoing focus on infection prevention and control practices is also critical.

Summary

What is already known about this topic?

COVID-19 vaccines have demonstrated high efficacy in clinical trials. Limited data are available on effectiveness in skilled nursing facilities (SNFs) and against emerging variants.

What is added by this report?

In a COVID-19 outbreak at a Kentucky SNF involving a newly introduced variant to the region, unvaccinated residents and health care personnel (HCP) had 3.0 and 4.1 times the risk of infection as did vaccinated residents and HCP. Vaccine was 86.5% protective against symptomatic illness among residents and 87.1% protective among HCP.

What are the implications for public health practice?

Vaccination of SNF residents and HCP is essential to reduce the risk for symptomatic COVID-19, as is continued focus on infection prevention and control practices.

[§§§] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

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Health Care Utilization and Clinical Characteristics of Nonhospitalized Adults in an Integrated Health Care System 28–180 Days After COVID-19 Diagnosis — Georgia, May 2020–March 2021

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As of April 19, 2021, 21.6 million COVID-19 cases had been reported among U.S. adults, most of whom had mild or moderate disease that did not require hospitalization (*1*). Health care needs in the months after COVID-19 diagnosis among nonhospitalized adults have not been well studied. To better understand longer-term health care utilization and clinical characteristics of nonhospitalized adults after COVID-19 diagnosis, CDC and Kaiser Permanente Georgia (KPGA) analyzed electronic health record (EHR) data from health care visits in the 28–180 days after a diagnosis of COVID-19 at an integrated health care system. Among 3,171 nonhospitalized adults who had COVID-19, 69% had one or more outpatient visits during the follow-up period of 28–180-days. Compared with patients without an outpatient visit, a higher percentage of those who did have an outpatient visit were aged ≥50 years, were women, were non-Hispanic Black, and had underlying health conditions. Among adults with outpatient visits, 68% had a visit for a new primary diagnosis, and 38% had a new specialist visit. Active COVID-19 diagnoses* (10%) and symptoms potentially related to COVID-19 (3%–7%) were among the top 20 new visit diagnoses; rates of visits for these diagnoses declined from 2–24 visits per 10,000 person-days 28–59 days after COVID-19 diagnosis to 1–4 visits per 10,000 person-days 120–180 days after diagnosis. The presence of diagnoses of COVID-19 and related symptoms in the 28–180 days following acute illness suggests that some nonhospitalized adults, including those with asymptomatic or mild acute illness, likely have continued health care needs months after diagnosis. Clinicians and health systems should be aware of post-COVID conditions among patients who are not initially hospitalized for acute COVID-19 disease.

Patients aged ≥18 years who received positive results for SARS-CoV-2 (the virus that causes COVID-19) by polymerase chain reaction testing performed during April 4–September 17, 2020, and for whom ≥180 days had elapsed since their testing date were identified in KPGA EHR data. Patients were not included in the analysis if they were hospitalized in the 28 days† after COVID-19 diagnosis, were pregnant during the 12 months before or at the time of COVID-19 diagnosis, or were not continuously enrolled in KPGA during the year preceding COVID-19 diagnosis.§ Among 3,171 patients included in the analysis, health care utilization and *International Classification of Diseases, Tenth Revision* (ICD-10) diagnostic codes were obtained for outpatient (i.e., clinic or urgent care) and emergency department visits, and hospitalizations occurring 28–180 days after COVID-19 diagnosis.¶

Health care utilization was determined based on the number, type (i.e., video, telephone, and in-person), setting (i.e., clinic, urgent care, emergency department, and hospital), and clinical specialty of visits. New specialty visits were defined as specialists that a patient had not consulted in the 12 months preceding COVID-19 diagnosis. New specialty visits were classified as potentially related to COVID-19 based on previously described multiorgan effects in post-COVID conditions (*2*). Clinical characteristics were ascertained through active primary and secondary** ICD-10 codes for outpatient visits. ICD-10 codes were classified as new diagnoses if they had not been documented in the 12 months preceding COVID-19 diagnosis; otherwise, they were classified as preexisting conditions.†† Administrative ICD-10 codes§§ were

* A diagnosis was considered active if providers billed for it during a visit under the assumption it coexisted at the time of the visit and required or affected patient care, treatment, or management. "History of" diagnostic codes were not included in descriptions. For example, patients with a history of COVID-19 diagnosis that was not considered active were not included.

† Restriction of the analytic sample to patients not hospitalized within 28 days of COVID-19 diagnosis and seeking care ≥28 days after diagnosis was used to exclude adults with severe COVID-19 and adults with mild or moderate disease still in the acute phase of infection.

§ A total of 4,646 laboratory-confirmed COVID-19 cases occurred during April 4–September 17, 2020. The final analytic sample was 3,171 patients after exclusion of patients hospitalized in the first 28 days after SARS-CoV-2 diagnosis (281), patients aged <18 years (337), patients without 12 months of continuous enrollment in KPGA before their COVID-19 diagnosis (783), patients with Medicaid (one), and patients pregnant in the 12 months before or at the time of COVID-19 diagnosis (73).

¶ The follow-up period for the total cohort of patients was May 19, 2020–March 16, 2021.

** Primary visit diagnosis refers to the first-listed diagnosis after an outpatient visit that indicates the diagnosis chiefly responsible for a patient's visit. Secondary diagnoses include all other diagnoses listed at a visit after the primary diagnosis.

†† A 12-month retrospective EHR review was performed to determine whether ICD-10 codes were preexisting or new. Retrospective review of ICD-10 codes was performed at the three-letter level (e.g., I10, F22, and R00).

§§ Administrative ICD-10 codes include codes Z00–Z99 and R70–R99.

classified as "other." Primary diagnoses were used to classify visit type as being for a new or preexisting condition or other. Primary and secondary diagnoses were used to describe common visits diagnoses and were classified as COVID-19–related, potentially COVID-19–related, new, or preexisting.[¶] All health care utilization and clinical characteristics were described at 28–59, 60–119, and 120–180 days after COVID-19 diagnosis. Diagnoses were described as diagnosis-specific visit rates[***] (visits per 10,000 person-days). Continuous variables were compared using t-tests or Wilcoxon signed-rank tests, and proportions were compared using chi-square or Fisher's exact tests, as required. SAS (version 9.4; SAS Institute) was used to perform statistical analyses. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[†††]

Among 3,171 identified adults with COVID-19, a total of 2,177 (69%) had one or more outpatient visits 28–180 days after COVID-19 diagnosis (Table 1). The proportion of adults with one or more visits was significantly higher among adults aged ≥65 years (88%) than among those aged 18–49 years (66%), among women (76%) than among men (59%), among non-Hispanic Black adults (71%) than among all others (68%) (p = 0.04), and among adults with three or more underlying health conditions (83%) than among those with no (60%) or one or two (69%) underlying conditions.

Among adults with one or more outpatient visits, 7,991 visits occurred 28–180 days after COVID-19 diagnosis, with a median of two (interquartile range = 1–4) visits per patient (Table 2). Fewer than 2% (32) of patients were hospitalized 28–180 days after COVID-19 diagnosis. More than two thirds of patients (1,617; 68%) had visits for a new primary diagnosis. Among specialists visited, 1,627 (75%) patients visited a family, geriatric, or internal medicine provider, and 823 (38%) visited with a new specialist. Common new specialty visits potentially related to COVID-19 included dermatology (16%), behavioral/mental health (11%), gastroenterology (11%), and cardiology (10%). Overall, 58 (3%) patients saw a pulmonologist; 41 (71%) of these patients had not been evaluated by this specialty in the 12 months preceding their COVID-19 diagnosis.

COVID-19 was recorded as an active diagnosis for 210 (10%) of 2,177 patients who had one or more outpatient visit within 180 days of COVID-19 diagnosis (Table 3). COVID-19–related visits declined from 24 per 10,000 person-days during the 28–59-day interval to fewer than two per 10,000 person-days during the 120–180-day interval. Visits per 10,000 person-days for symptoms potentially related to COVID-19 declined during these same intervals, including those for throat or chest pain (from seven per 10,000 person-days to four), shortness of breath (from eight to three), cough (from four to two), and malaise and fatigue (from four to two). In contrast, rates of visits with chronic disease diagnoses (e.g., hypertension and diabetes) and urinary tract infections changed little over time.

Discussion

Among adult patients with COVID-19 and enrolled in an integrated health system in Georgia, who were not hospitalized for their acute illness, approximately two thirds had at least one outpatient medical encounter 28–180 days after diagnosis, and approximately two thirds of these persons received a new primary diagnosis at one or more visits. New diagnoses included cough, shortness of breath, chest or throat pain, and fatigue, which likely represent ongoing COVID-19 symptoms and are consistent with other reports of patient-reported symptoms months after SARS-CoV-2 infection (*3*–*7*). Although the frequency of visits for these symptom diagnoses decreased after 60 days, they persisted beyond 120 days among some patients. Clinicians and health care systems should be aware of the possibility of medical encounters related to a previous diagnosis of COVID-19 beyond the acute illness.

Whether the number of visits among nonhospitalized adults 28–180 days after COVID-19 diagnosis is higher compared with adults without COVID-19 remains unclear. However, compared with health care utilization among nonhospitalized adults with influenza in Spain during the 2009 H1N1 pandemic, the mean number of outpatient visits in the 120 days after diagnosis was higher in adults with COVID-19 (mean = 2.2, standard deviation = 1.7 among adults with positive test results for SARS-CoV-2; mean = 1.7, standard deviation = 1.3 among adults with positive test results for H1N1) (*8*).

More than one in three (38%) patients underwent a new specialist evaluation. Some of the common new specialist visits (e.g., gynecology, orthopedic and general surgery, and urology) are likely unrelated to COVID-19 and might have occurred because of specialty visits missed or avoided during stay-at-home orders or local increases in COVID-19 cases. Specialties related to multiorgan effects of post-COVID conditions (*2*), such as pulmonology, neurology, cardiology, and behavioral/mental health, were common in this patient population,

[¶] Descriptions of common diagnoses excluded administrative ICD-10 codes. Diagnoses potentially related to COVID-19 included symptom diagnoses such as cough, shortness of breath, and fatigue. Diagnoses potentially related to COVID-19 were only counted if they had not been documented in a patient's EHR in the 12 months preceding COVID-19 diagnosis.

[***] Person-time used to calculate rates of visits for a given diagnosis were calculated by determining the time from first SARS-CoV-2 positive test collection date to March 16, 2021. Once the total follow-up time was determined per patient, each patients' contribution to intervals of 28–59, 60–119, and 120–180-days was determined. Data for patients with >180 days of follow-up was truncated so that all outpatient visits occurring after 180 days were excluded from analysis.

[†††] 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.

TABLE 1. Demographic and clinical characteristics of nonhospitalized COVID-19 patients with and without visits 28–180 days after initial diagnosis — Kaiser Permanente Georgia, May 19, 2020–March 16, 2021

Characteristic	Total	Outpatient visit 28–180 days after COVID-19 diagnosis			
		No. (%) of patients without visits	No. (%) of patients with ≥1 visit	Median no. of visits (IQR)*	p-value†
All patients	**3,171**	**994 (31.3)**	**2,177 (68.7)**	**2 (1–5)**	—
Age group, yrs					
18–49	**2,003**	685 (34.2)	1,318 (65.8)	2 (1–4)	<0.001
50–64	**936**	280 (29.9)	656 (70.1)	3 (1–5)	
≥65	**232**	29 (12.5)	203 (87.5)	4 (2–7)	
Sex					
Female	**1,796**	428 (23.8)	1,368 (76.2)	3 (1–5)	<0.001
Male	**1,375**	566 (41.2)	809 (58.8)	2 (1–4)	
Race/Ethnicity					
Black, non-Hispanic	**1,663**	479 (28.8)	1,184 (71.2)	3 (1–5)	<0.001
White, non-Hispanic	**870**	261 (30.0)	609 (70.0)	2 (1–5)	
Hispanic	**251**	95 (37.9)	156 (62.1)	2 (1–4)	
Asian, non-Hispanic	**126**	42 (33.3)	84 (66.7)	2 (1–4)	
Insurance					
Commercial	**2,724**	910 (33.4)	1,814 (66.6)	—	<0.001
Medicare	**210**	20 (9.5)	190 (90.5)	—	
Influenza vaccination rate (%)§	**1,290**	314 (24.3)	976 (75.7)	—	<0.001
Smoker (%)¶	**290**	65 (22.4)	225 (77.6)	—	0.02
Physically inactive (%)**	**906**	234 (25.8)	672 (74.2)	—	<0.001
Underlying health conditions					
Obesity (BMI >30)	**1,452**	391 (12.3)	1,061 (73.1)	—	<0.001
Severe obesity (BMI >40)††	**322**	75 (23.3)	247 (76.7)	—	0.001
Hypertension	**894**	199 (22.3)	695 (77.7)	—	<0.001
Controlled hypertension (BP <140/90 mmHg)††, §§	**620**	128 (20.7)	492 (79.3)	—	0.6
Diabetes	**413**	97 (23.5)	316 (76.5)	—	<0.001
Poorly controlled diabetes (HbA1c >8.0%)††,§§	**106**	15 (14.2)	91 (85.8)	—	0.009
Asthma	**315**	68 (21.6)	247 (78.4)	—	<0.001
Coronary artery disease	**123**	26 (21.1)	97 (78.9)	—	0.01
Congestive heart failure	**107**	19 (17.8)	88 (82.2)	—	0.002
Arrythmia	**58**	5 (8.6)	53 (91.4)	—	<0.001
Chronic obstructive pulmonary disease	**44**	5 (11.4)	39 (88.6)	—	0.004
Cancer¶¶	**40**	4 (10.0)	36 (90.0)	—	0.03
Chronic kidney disease***	**33**	4 (12.1)	29 (87.9)	—	0.02
End-stage renal disease***	**1**	0 (0)	1 (100)	—	0.7
HIV infection	**30**	3 (10.0)	27 (90.0)	—	0.01
No. of underlying health conditions†††					
None	**1,101**	445 (40.4)	656 (59.6)	2 (1–4)	<0.001
1 or 2	**1,405**	433 (30.8)	972 (69.2)	2 (1–4)	
3 or more	**665**	116 (17.4)	549 (82.6)	4 (2–7)	
Charlson comorbidity index,§§§ mean (SD)	**1.6 (1.3)**	1.5 (1.1)	1.7 (1.4)	—	0.02

Abbreviations: BMI = body mass index; HbA1c = glycated hemoglobin A1c; IQR = interquartile range; SD = standard deviation.

* Median number of visits was not calculated for some categories because of small numbers.

† P-value for t-test for comparisons of means and chi-square or Fisher's exact test for categorical variables as applicable. P-value for comparisons of column percentages of patient with and without ≥1 outpatient visits.

§ Influenza vaccination rate during 2019–2020.

¶ Defined as currently smoking at the most recent clinical encounter within the last 12 months.

** Physical activity was based on patient reported weekly exercise minutes. Physical inactivity was defined as <10 minutes/week.

†† Represent subsets of categories in the row directly above them. Obesity, hypertension, and diabetes categories include severe obesity, controlled hypertension, and uncontrolled diabetes, respectively.

§§ Determined at the most recent clinical encounter within the last 12 months.

¶¶ Includes patients with a history of or active cancer.

*** Chronic kidney disease and end-stage renal disease are classified based on diagnosis reported by the *International Classification of Diseases, Tenth Revision* code in the patient's medical history.

††† Previous medical conditions included in this category include hypertension, diabetes, obesity, coronary artery disease, congestive heart failure, arrhythmia, asthma, chronic obstructive lung disease, chronic kidney disease, end-stage renal disease, HIV infection, or active or history of cancer.

§§§ Charlson comorbidity index predicts the 10-year mortality of a patient based on age and comorbidities. Scores are summed to provide a total predictive score. The lowest score of 0 corresponds to a 98% estimated 10-year survival rate. https://doi.org/10.1016/0021-9681(87)90171-8

TABLE 2. Health care visit frequency and characteristics of nonhospitalized COVID-19 patients with one or more outpatient visits 28–180 days after initial diagnosis — Kaiser Permanente Georgia, May 19, 2020–March 16, 2021

Characteristic	Total*	No. of days since COVID-19 diagnosis		
		28–59	60–119	120–180
All patients	**2,177**	**1,036**	**1,402**	**1,370**
No. of person-days follow-up†	**570,780**	98,301	187,089	190,260
Age, yrs, median (IQR)	**45 (32–55)**	46 (33–56)	45 (33–55)	46 (33–56)
Visit characteristics				
Total no. of visits	**7,991**	1,960	3,044	2,987
No. of clinic visits per patient, median (IQR)	**2 (1–4)**	1 (1–2)	2 (1–3)	2 (1–3)
Primary visit diagnosis,§ no. of patients (%)				
Preexisting diagnosis	**873 (36.7)**	341 (32.9)	494 (35.2)	432 (31.5)
New diagnosis	**1,617 (68.0)**	642 (62.0)	928 (66.2)	904 (66.0)
Other	**881 (37.0)**	267 (25.8)	402 (28.7)	397 (29.0)
Type of visit				
Video	**984 (45.2)**	570 (55.0)	728 (51.9)	700 (51.1)
Telephone	**1,121 (51.5)**	663 (64.0)	836 (59.6)	780 (56.9)
In-person	**1,693 (77.8)**	831 (80.2)	1,169 (83.4)	1,176 (85.8)
Visit setting				
Clinic¶	**2,177 (100.0)**	1,036 (100.0)	1,402 (100.0)	1,370 (100.0)
Urgent care	**484 (22.2)**	288 (27.8)	366 (26.1)	361 (26.4)
Emergency department	**62 (2.8)**	39 (3.8)	43 (3.1)	46 (3.4)
Hospitalization**	**32 (1.5)**	25 (2.4)	28 (2.0)	27 (2.0)
Visit specialty				
Primary care/Geriatrics	**1,627 (74.7)**	819 (79.1)	1,102 (78.6)	1,073 (78.3)
Behavioral health/Psychiatry	**262 (12.0)**	171 (16.5)	220 (15.7)	209 (15.3)
Dermatology	**236 (10.8)**	145 (14.0)	176 (12.6)	181 (13.2)
Cardiology	**146 (6.7)**	108 (10.4)	123 (8.8)	116 (8.5)
Gastroenterology	**134 (6.2)**	92 (8.9)	117 (8.3)	108 (7.9)
Neurology	**69 (3.2)**	52 (5.0)	60 (4.3)	57 (4.2)
Pulmonology	**58 (2.7)**	46 (4.4)	52 (3.7)	48 (3.5)
Other specialty	**1,309 (60.1)**	712 (68.7)	955 (68.1)	942 (68.8)
New specialty visits††,§§,¶¶				
Any specialist***	**823 (37.8)**	249 (24.0)	427 (30.5)	467 (34.1)
Potentially COVID-19–related†††				
Dermatology	**129 (15.7)**	31 (12.4)	52 (12.2)	59 (12.6)
Behavioral/Mental health	**92 (11.2)**	25 (10.0)	44 (10.3)	49 (10.5)
Gastroenterology	**88 (10.7)**	17 (6.8)	48 (11.2)	38 (8.1)
Cardiology	**79 (9.6)**	34 (13.7)	35 (8.2)	33 (7.1)
Otolaryngology	**63 (7.7)**	14 (5.6)	34 (8.0)	33 (7.1)
Pulmonology	**41 (5.0)**	13 (5.2)	19 (4.4)	16 (3.4)
Neurology	**32 (3.9)**	8 (3.2)	13 (3.0)	18 (3.9)
Other				
Gynecology	**167 (20.0)**	43 (17.3)	87 (20.4)	76 (16.3)
Orthopedic surgery	**101 (12.3)**	22 (8.8)	41 (9.6)	58 (12.4)
Ophthalmology	**56 (6.8)**	16 (6.4)	14 (3.3)	30 (6.4)
General surgery	**51 (6.2)**	11 (4.4)	27 (6.3)	29 (6.2)
Urology	**36 (4.4)**	9 (3.6)	18 (4.3)	18 (3.9)

Abbreviations: EHR = electronic health record; ICD-10 = *International Classification of Diseases, Tenth Revision;* IQR = interquartile range.

* Frequencies in this column do not represent the sum of time-interval specific frequencies because some patients might have had more than one visit within or across periods.

† Person-time was calculated for all patients with possible follow-up 28–180 days after COVID-19 diagnosis (n = 3,171).

§ Primary visit diagnosis was classified as preexisting diagnosis if the primary diagnosis for a visit had been recorded in a patient's EHR in the 12 months before COVID-19 diagnosis, new diagnosis if the primary diagnosis was not recorded in a patient's EHR in the 12 months before COVID-19 diagnosis, and other if the primary diagnosis was a screening or administrative code (i.e., ICD-10 codes Z00–Z99). ICD-10 codes Z00–Z99 are factors influencing health status and contact with health services and include encounters for general adult medical examination, encounters for administrative examination (e.g., preemployment and insurance purposes), and encounters for screening for disease (e.g., infectious and parasitic diseases and malignant neoplasms), among others.

¶ Clinic visits include in-person, video, and telephone visits.

** Hospitalizations for any diagnosis that occurred 28–180 days after initial COVID-19 diagnosis.

†† New specialist visits were defined as any visit that occurred after SARS-CoV-2 infection diagnosis in a specialty in which a patient had not been seen in the 12 months before their COVID-19 diagnosis. New specialty visit numbers are a subset of the total outpatient visit specialty category. For example, 41 (71%) of 58 patients who had a pulmonology visit were new patients in this specialty.

§§ Proportions of new specialist visits use the total of patients with a new specialist visit (n = 823) as the denominator rather than all adults with outpatient visits (n = 2,177).

¶¶ The order of the 12 most common new specialist visits were as follows: 1) gynecology, 2) dermatology, 3) orthopedic surgery, 4) behavioral/mental health, 5) gastroenterology, 6) cardiology, 7) otolaryngology, 8) ophthalmology, 9) general surgery, 10) pulmonology, 11) urology, and 12) neurology.

*** Excludes primary care/geriatrics, adult urgent care, podiatry, and optometry.

††† Specialties potentially related to COVID-19 were based on descriptions of symptoms and multiorgan effects in post-COVID conditions. https://doi.org/10.1038/s41591-021-01283-z

TABLE 3. Twenty most common new and preexisting outpatient diagnoses among nonhospitalized COVID-19 patients with one or more outpatient visits 28–180 days after initial diagnosis — Kaiser Permanente Georgia, May 19, 2020–March 16, 2021

Characteristic	Total	No. of days since COVID-19 diagnosis		
		28–59	60–119	120–180
All patients	**2,177**	**1,036**	**1,402**	**1,370**
No. of person-days follow-up*	**570,780**	98,301	187,089	190,260
Diagnoses†,§,¶ (ICD-10 code)	**No. (%) of patients**	**No. of visits (visits per 10,000 person-days)**		
COVID-19 (U07, J12, J20, B94)**	**210 (9.6)**	235 (23.9)	62 (3.3)	29 (1.5)
Symptoms potentially related to COVID-19††				
Pain in throat and chest (R07)	**145 (6.7)**	69 (7.0)	79 (4.2)	68 (3.6)
Shortness of breath/dyspnea (R06)	**128 (5.9)**	78 (7.9)	59 (3.2)	54 (2.8)
Headache (R51)	**101 (4.6)**	37 (3.8)	53 (2.8)	48 (2.5)
Malaise and fatigue (R53)	**96 (4.4)**	35 (3.6)	43 (2.3)	40 (2.1)
Cough (R05)	**86 (4.0)**	41 (4.2)	33 (1.8)	30 (1.6)
Sleep disorders (G47)	**80 (3.7)**	24 (2.4)	41 (2.2)	44 (2.3)
Abnormalities of heartbeat§§ (R00)	**68 (3.1)**	42 (4.3)	37 (2.0)	25 (1.3)
New diagnoses				
Back pain (M54)	**219 (10.1)**	80 (8.1)	94 (5.0)	135 (7.1)
Joint disorder (M25)	**211 (9.7)**	50 (5.1)	113 (6.0)	133 (7.0)
Muscle or soft tissue disorder (M79)	**172 (7.9)**	53 (5.4)	92 (4.9)	100 (5.3)
Abdominal and pelvic pain (R10)	**167 (7.7)**	52 (5.3)	100 (5.3)	84 (4.4)
Anxiety (F41)	**96 (4.4)**	33 (3.4)	51 (2.7)	68 (3.6)
Hyperlipidemia (E78)	**96 (4.4)**	25 (2.5)	42 (2.2)	43 (2.3)
Overweight/Obesity (E66)	**96 (4.4)**	23 (2.3)	43 (2.3)	42 (2.2)
Urinary tract infection and urinary incontinence (N39)	**76 (3.5)**	14 (1.4)	34 (1.8)	38 (2.0)
Hypertension (I10)	**73 (3.4)**	27 (2.7)	48 (2.6)	33 (1.7)
Diabetes mellitus (E11)	**72 (3.3)**	24 (2.4)	39 (2.1)	49 (2.6)
Disorders of refraction and accommodation (H52)	**67 (3.1)**	12 (1.2)	29 (1.6)	31 (1.6)
Gastresophageal reflux (K21)	**67 (3.1)**	19 (1.9)	29 (1.6)	38 (2.0)
Preexisting diagnoses				
Hypertension (I10)	**343 (15.8)**	127 (12.9)	216 (11.5)	201 (10.6)
Diabetes (E11)	**211 (9.7)**	96 (9.8)	168 (9.0)	143 (7.5)
Overweight/Obesity (E66)	**123 (5.6)**	28 (2.8)	61 (3.3)	57 (3.0)
Hyperlipidemia (E78)	**120 (5.5)**	34 (3.5)	60 (3.2)	54 (2.8)
Anxiety (F41)	**89 (4.1)**	48 (4.9)	86 (4.6)	63 (3.3)
Back pain (M54)	**63 (2.9)**	21 (2.1)	43 (2.3)	40 (2.1)
Cough (R05)	**63 (2.9)**	39 (4.0)	33 (1.8)	29 (1.5)
Major depressive disorder (F33)	**50 (2.3)**	34 (3.5)	58 (3.1)	38 (2.0)
Asthma (J45)	**49 (2.3)**	22 (2.2)	21 (1.1)	31 (1.6)
Attention-deficit hyperactivity disorders (F90)	**43 (2.0)**	16 (1.6)	38 (2.0)	29 (1.5)
Sleep disorders (G47)	**41 (1.9)**	14 (1.4)	25 (1.3)	22 (1.2)
Pain in throat and chest (R07)	**38 (1.7)**	21 (2.1)	17 (0.9)	18 (0.9)
Joint disorder (M25)	**37 (1.7)**	7 (0.7)	18 (1.0)	18 (0.9)
Gastroesophageal reflux (K21)	**35 (1.6)**	11 (1.1)	19 (1.0)	17 (0.9)
Shortness of breath/dyspnea (R06)	**35 (1.6)**	30 (3.1)	9 (0.5)	13 (0.7)
Abdominal and pelvic pain (R10)	**34 (1.6)**	7 (0.7)	27 (1.4)	12 (0.6)
Chronic ischemic heart disease (I25)	**34 (1.6)**	12 (1.2)	26 (1.4)	20 (1.1)
Glaucoma (H40)	**33 (1.5)**	12 (1.2)	22 (1.2)	21 (1.1)
Hypothyroidism (E03)	**33 (1.5)**	4 (0.4)	17 (0.9)	20 (1.1)
Chronic kidney disease (N18)	**29 (1.3)**	15 (1.5)	14 (0.7)	11 (0.6)

Abbreviation: ICD-10 = *International Classification of Diseases, Tenth Revision*.

* Person-time was calculated for all patients with possible follow-up 28–180 days after COVID-19 diagnosis (n = 3,171).

† A diagnosis was considered active if providers billed for it during a visit under the assumption it coexisted at the time of the visit and required or affected patient care, treatment, or management. "History of" diagnostic codes were not included in descriptions. For example, patients with a history of COVID-19 diagnosis that was not considered active were not included.

§ New diagnoses were defined as three-letter ICD-10 diagnosis codes that were not recorded in a patient's electronic health record in the 12 months before SARS-CoV-2 infection diagnosis.

¶ Preexisting diagnoses were defined as three-letter ICD-10 diagnosis codes that were recorded in a patient's electronic health record in the 12 months before SARS-CoV-2 infection diagnosis.

** U07 includes only U07.1; J12 and J20 were included if the associated written diagnosis included COVID-19, SARS-CoV-2, or coronavirus. Approximately 95% of diagnoses in this category were U07.1.

†† This list is not exhaustive and is based on ongoing or new symptoms ≥4 weeks after COVID-19 diagnosis commonly reported in the scientific literature.

§§ Includes palpitations, tachycardia, and bradycardia.

indicating that nonhospitalized adults might be referred for additional evaluation for COVID-19–related symptoms and conditions after the acute illness.

The prevalence of underlying health conditions was higher among patients with outpatient visits ≥28 days after the initial COVID-19 diagnosis than among those without such visits; this finding might be explained by increased engagement in care among patients with chronic medical problems. Some underlying health conditions in the study population, such as obesity and diabetes, are associated with increased risk for hospitalization and death from COVID-19 (*9*); however, whether underlying health conditions increase the risk for post–COVID-19 conditions remains unclear.

A higher proportion of women and non-Hispanic Black adults had one or more outpatient visits than did men and adults of other racial or ethnic groups. This could be a result of certain groups being disproportionately affected by COVID-19 (*9*), differences in care seeking and in the prevalence of underlying health conditions, or a higher risk for post–COVID-19 conditions among these populations. Women might be at higher risk for persistent pulmonary dysfunction and symptoms after SARS-CoV-2 infection (*10*); however, studies of post–COVID-19 conditions have not reported race/ethnicity (*3*–*5*) or have had low representation by certain racial or ethnic groups (*7*). Future evaluations of post–COVID-19 conditions should include diverse racial/ethnic groups and examine differences by sex and race/ethnicity to guide health care planning and estimates of health care utilization.

The findings in this report are subject to at least six limitations. First, approximately three quarters of adults included in this study were commercially insured patients in a single integrated health system whose health care utilization might differ from that of other U.S. populations, including uninsured or publicly insured adults. Examining records in other health systems is needed to confirm these findings. Second, use of diagnostic symptom codes by providers might not record all symptoms. Third, without a non–COVID-19 control group, it was not possible to evaluate associations between COVID-19 and diagnostic codes and health care utilization. Fourth, 12-month retrospective reviews of diagnostic codes and specialty visits might have missed previous diagnoses and care. Fifth, it is unclear whether the use of a COVID-19 diagnosis visit code was used by providers for patients with prolonged symptoms or clinical findings from the initial SARS-CoV-2 infection. Finally, it was not possible to determine whether patients might have been experiencing symptoms of reinfection with SARS-CoV-2, rather than ongoing COVID-19 symptoms.

Summary

What is already known about this topic?

Health care needs in the months after a COVID-19 diagnosis among nonhospitalized adults have not been well studied.

What is added by this report?

Among 3,171 nonhospitalized adult COVID-19 patients, 69% had one or more outpatient visits 28–180 days after the diagnosis. Two thirds had a visit for a new primary diagnosis, and approximately one third had a new specialist visit. Symptoms potentially related to COVID-19 were common new visit diagnoses. Visits for these symptoms decreased after 60 days but for some patients continued through 120–180 days.

What are the implications for public health practice?

Clinicians and health care systems should be aware of the potential for post-COVID conditions.

Approximately two thirds of nonhospitalized patients sought medical care 28–180 days after their COVID-19 diagnosis. The presence of active COVID-19, symptoms of COVID-19 diagnoses, and specialty referrals suggest that some nonhospitalized adults, including those with asymptomatic or mild acute illness, likely have continued health care needs months after diagnosis. Raising awareness among patients, clinicians, and health systems about common new diagnoses and health needs, including specialist evaluation, after acute SARS-CoV-2 infection is important to understand the long-term effects of the illness.

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Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021

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On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Janssen COVID-19 (Ad.26.COV2.S) vaccine (Janssen Biotech, Inc., a Janssen Pharmaceutical company, Johnson & Johnson; New Brunswick, New Jersey), and on February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for its use in persons aged ≥18 years (*1*,*2*). On April 13, 2021, CDC and FDA recommended a pause in the use of the Janssen COVID-19 vaccine after reports of six U.S. cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia, a rare thromboembolic syndrome, among Janssen COVID-19 vaccine recipients (*3*). Two emergency ACIP meetings were rapidly convened to review reported cases of thrombosis with thrombocytopenia syndrome (TTS) and to consider updated recommendations for use of the Janssen COVID-19 vaccine in the United States. On April 23, 2021, after a discussion of the benefits and risks of resuming vaccination, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under the FDA's EUA, which now includes a warning that rare clotting events might occur after vaccination, primarily among women aged 18–49 years. Patient and provider education about the risk for TTS with the Janssen COVID-19 vaccine, especially among women aged <50 years, as well as the availability of alternative COVID-19 vaccines, is required to guide vaccine decision-making and ensure early recognition and clinical management of TTS.

Since June 2020, ACIP has convened 13 public meetings to review data on COVID-19 epidemiology and the potential use of COVID-19 vaccines, including the Janssen COVID-19 vaccine. The COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics, has held weekly meetings since April 2020 to review COVID-19 surveillance data, evidence for vaccine efficacy and safety, and implementation considerations for COVID-19 vaccines. The work group met three times during the Janssen COVID-19 vaccine pause to review clinical trial and postauthorization safety data for TTS after receipt of this vaccine. The work group also reviewed a risk-benefit assessment of TTS events after receipt of the Janssen COVID-19 vaccine that used an adapted Evidence to Recommendations framework* to guide the assessment. In addition, the COVID-19 Vaccines Safety Technical Work Group, comprising independent vaccine safety expert consultants, held two meetings during the vaccine pause and conducted an independent review of safety data for thromboembolic events that occurred after receipt of the Janssen COVID-19 vaccine. A summary of the data reviewed and work group discussions was presented to ACIP during its emergency meetings on April 14 and April 23, 2021. On April 23, 2021, ACIP voted 10–4 in favor of reaffirming its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under the FDA's EUA. One ACIP member recused herself from voting because of participation in clinical trials or other studies involving companies producing COVID-19 vaccines. After the vote, ACIP members who voted "no" indicated that they would have preferred stronger language regarding the risk for TTS among women aged 18–49 years. All ACIP members agreed that provider and patient education regarding the risk for TTS after vaccination among women aged 18–49 years and awareness of other COVID-19 vaccine options are critical as Janssen COVID-19 vaccination resumes.

TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin.† Although the mechanism that causes TTS is not fully understood, TTS appears to be similar to heparin-induced thrombocytopenia (*4*), a rare reaction to heparin treatment. In the United States, 12 of 15 persons with TTS that occurred after Janssen COVID-19 vaccination had CVST with thrombocytopenia. The clinical presentation of the reported cases among recipients of the Janssen COVID-19 vaccine (which is based on a human adenoviral

* https://www.cdc.gov/vaccines/acip/recs/grade/downloads/ACIP-evidence-rec-frame-508.pdf

† https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-interim-case-definition

vector) is similar to that of recently reported cases from Europe after receipt of the AstraZeneca COVID-19 vaccine (which is based on a chimpanzee adenoviral vector), a vaccine that is not authorized for use in the United States (*5*,*6*). All postauthorization U.S. cases occurred among women; one case of CVST with thrombocytopenia occurred in a man, in the 18–49 years age group, during the Janssen Phase III clinical trial. No cases of CVST with thrombocytopenia have been reported after receipt of either of the two mRNA COVID-19 vaccines authorized for use in the United States (CDC, unpublished data, 2021).

As of April 21, 2021, approximately 7.98 million doses of the Janssen COVID-19 vaccine had been administered in the United States. During March 2–April 21, 2021, the Vaccine Adverse Event Reporting System (VAERS) (*7*), the national vaccine safety monitoring system, had received 15 reports of TTS after Janssen COVID-19 vaccination, with clots located in the cerebral venous sinuses and other unusual locations, including in the portal vein and splenic vein, and a combination of venous and arterial thromboses. These 15 reports were confirmed by physician reviewers at CDC and FDA and reviewed with Clinical Immunization Safety Assessment Project investigators,[§] including hematologists. Thirteen TTS cases occurred among women aged 18–49 years, and two occurred among women aged ≥50 years; no cases postauthorization were reported among men.[¶] TTS reporting rates to VAERS were 7.0 cases per million Janssen COVID-19 vaccine doses administered to women aged 18–49 years and 0.9 per million to women aged ≥50 years. Among subgroups by age (18–29, 30–39, 40–49, 50–64, and ≥65 years), the reported rate was highest among women aged 30–39 years, with 11.8 TTS cases per 1 million Janssen COVID-19 doses administered. The median age was 37 years (range = 18–59 years), and the median interval from vaccination to symptom onset was 8 days (range = 6–15 days). Certain patients had underlying medical conditions or risk factors for hypercoagulability (e.g., obesity [seven patients], combined oral contraceptive use [two patients], hypothyroidism [two patients], and hypertension [two patients]); no cases occurred among women who were pregnant or had given birth in the previous 12 weeks, and none had a documented history of previous thrombotic events, a known diagnosis of an underlying clotting disorder, or a family or personal history of clotting disorders. None of the patients had any known previous exposure to heparin. All 15 patients were hospitalized, and 12 were admitted to an intensive care unit (ICU). As of the most recent follow-up,[**] three patients had died, four remained in an ICU, three remained hospitalized (not in an ICU), and five had been discharged home.

While evaluating the evidence to support updated interim recommendations for the use of the Janssen COVID-19 vaccine in the United States, ACIP reviewed a risk-benefit assessment of TTS events after vaccination. This assessment took into account 1) the rate and characteristics of TTS cases; 2) recent COVID-19 epidemiology; 3) modeling and risk-benefit analysis results to quantify COVID-19 hospitalizations, ICU admissions, and deaths prevented with resumption of use of the Janssen COVID-19 vaccine in the United States; and 4) data from jurisdictional COVID-19 vaccination programs regarding whether changes to ACIP recommendations would disproportionately affect certain populations.

The risk-benefit analysis included an assessment of both population- and individual-level risks and benefits. Full details of the analysis methods and results are available (https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/risk-benefit-analysis.html). The population-level risk-benefit analysis assumed continued use of the mRNA vaccines and estimated the number of COVID-19–related hospitalizations, ICU admissions, and deaths that could be prevented by use of the vaccines; benefits from vaccination were applied to the entire population, both directly to vaccinated persons and indirectly because of herd immunity. The modeling data showed that in 6 months, resuming use of the Janssen COVID-19 vaccine among persons aged ≥18 years at 50% of the prepause administration rate could prevent 3,926–9,395 COVID-19–related hospital admissions, 928–2,236 ICU admissions, and 586–1,435 deaths (depending on assumed future COVID-19 transmission levels), compared with 26 expected cases of TTS (Table 1). Resuming vaccination only among persons aged ≥50 years could prevent 1,361–3,532 COVID-19–related hospitalizations, 295–799 ICU admissions, and 54–257 deaths, compared with two expected TTS cases. The individual-level risk-benefit analysis assessed the risks and benefits of receiving versus not receiving a Janssen COVID-19 vaccine during the 1-month period after the Janssen COVID-19 vaccine pause. For every 1 million doses of the Janssen COVID-19 vaccine administered to women aged 18–49 years, 297 hospitalizations, 56 ICU admissions, and six deaths related to COVID-19 could be prevented, compared with seven expected TTS cases. Among women aged ≥50 years, 2,454 hospitalizations, 661 ICU admissions, and 394 deaths could be prevented, compared with one expected TTS case (Table 2). The benefits (prevention of COVID-19–related hospitalizations and ICU admissions) outweighed the risks (expected TTS cases after vaccination) in all populations. However, the balance of risks and benefits varied by age and sex because cases of TTS were primarily identified among women aged 18–49 years.

[§] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
[¶] One case of CVST with thrombocytopenia occurred in a man in the 18–49 years age group during the Janssen Phase III clinical trial.
[**] As of April 21, 2021.

TABLE 1. Population-level estimated number of and percent decrease in COVID-19–related hospitalizations, intensive care unit admissions, and deaths after resuming use of Janssen COVID-19 vaccine for 6 months* and number of expected cases of thrombosis with thrombocytopenia syndrome, by age group and SARS-CoV-2 transmission level† — United States, 2021

Benefits and harms from resuming vaccination	Resumption strategy			
	Recommended for adults aged ≥18 yrs		Recommended for adults aged ≥50 yrs	
	Low SARS-CoV-2 transmission	Moderate SARS-CoV-2 transmission	Low SARS-CoV-2 transmission	Moderate SARS-CoV-2 transmission
No. of persons expected to receive the Janssen COVID-19 vaccine	9.8 million		3.6 million	
Benefits, no. (% decrease§)				
Hospitalizations prevented	3,926 (1.4)	9,395 (1.6)	1,361 (0.5)	3,532 (0.6)
ICU admissions prevented	928 (1.4)	2,236 (1.5)	295 (0.4)	799 (0.5)
Deaths prevented	586 (1.6)	1,435 (1.8)	54 (0.1)	257 (0.3)
Harms				
No. of TTS cases expected	26	26	2	2

Abbreviations: ICU = intensive care unit; TTS = thrombosis with thrombocytopenia syndrome.
* Resumption of vaccination after a 10-day pause that commenced on April 13, 2021. https://emergency.cdc.gov/han/2021/han00442.asp
† This model evaluated the direct and indirect effects of resuming 50% of Janssen COVID-19 administration rates (compared with rate before use was paused) among all adults aged ≥18 years or only among adults ≥50 years compared with not resuming vaccination. The model was also calibrated to both low and moderate COVID-19 transmission levels based on varying assumptions about nonpharmaceutical interventions during the modeled time period.
§ Compared with no resumption of Janssen vaccination.

TABLE 2. Individual-level estimated number of COVID-19–related hospitalizations, intensive care unit admissions, and deaths prevented after resuming use of Janssen COVID-19 vaccine for 1 month* and number of expected cases of thrombosis with thrombocytopenia syndrome per 1 million vaccine doses, by sex and age group† — United States, 2021

Benefits and harms from resuming vaccination	No. per million vaccine doses administered§			
	Females		Males	
	18–49 yrs	≥50 yrs	18–49 yrs¶	≥50 yrs
Benefits				
Hospitalizations prevented	297	2,454	272	2,821
ICU admissions prevented	56	661	51	760
Deaths prevented	6	394	6	471
Harms				
TTS cases expected	7	1	1	0

Abbreviations: ICU = intensive care unit; TTS = thrombosis with thrombocytopenia syndrome.
* Resumption of vaccination after a 10-day pause that began on April 13, 2021. https://emergency.cdc.gov/han/2021/han00442.asp
† This analysis evaluated direct benefits and harms, per 1 million Janssen COVID-19 vaccine doses, over 30 days.
§ Compared with no resumption of Janssen vaccination.
¶ Analyses incorporated one TTS case that occurred in the Phase III trial in a man in the 18–49 years age group.

The summary of evidence showed that the single-dose Janssen COVID-19 vaccine is a highly effective and flexible (e.g., stored at refrigerator temperatures) prevention tool that can be useful in communities with increasing COVID-19 incidence and emerging variants of SARS-CoV-2, the virus that causes COVID-19 (Table 3). Limiting vaccine use to specific populations (i.e., by age or sex) could reduce numbers of TTS cases but could also challenge public health implementation, limit personal choice, and disproportionately affect populations with barriers to vaccine access or who have difficulty returning for a second dose. If the Janssen COVID-19 vaccine were no longer available, excess COVID-19 cases and deaths could occur. Based on this risk-benefit assessment, on April 23, 2021, ACIP reaffirmed its interim recommendation for the use of the Janssen COVID-19 vaccine in all persons aged ≥18 years. This recommendation allows for flexibility, choice, and improved access to authorized vaccine products. ACIP emphasized the importance of providing education for vaccination providers and the public about the risk for TTS and availability of other COVID-19 vaccine options, particularly for women aged 18-49 years.

FDA has added a warning to the Janssen COVID-19 vaccine EUA and fact sheets regarding rare clotting events that have been reported among vaccine recipients (*1*). Updated patient education and communication materials reflecting this warning are critical to ensure that women aged <50 years are aware of the increased risk for TTS and that other COVID-19 vaccines are available (i.e., mRNA vaccines) (*8*,*9*). The EUA fact sheet should be provided to all vaccine recipients and their caregivers (as relevant) for careful review before vaccination with any authorized COVID-19 vaccine.

Treatment for TTS that occurs after receipt of the Janssen COVID-19 vaccine is different from the treatment typically administered for blood clots††; notably, heparin should not be administered, and consultation with hematology specialists is strongly recommended. A Health Alert Network notification published on April 13, 2021 (*3*) provided additional information and recommendations concerning the identification and treatment of suspected cases of TTS after Janssen COVID-19 vaccination for clinicians, public health officials, and the public. Additional clinical considerations for use of COVID-19 vaccines are available (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html).

CDC and FDA will continue to closely monitor reports of TTS after receipt of the Janssen COVID-19 vaccine and will bring any additional data needed to guide benefits and risks to ACIP for consideration. The risk-benefit analysis can be updated as needed to reflect changes in the COVID-19 pandemic and additional information on the risk for TTS after COVID-19 vaccination. The ACIP recommendation for use of the Janssen COVID-19 vaccine under an EUA is interim and will be updated as additional information becomes available.

†† https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

TABLE 3. Summary of risk-benefit assessment for the Janssen COVID-19 vaccine — United States, 2021

Domain	Summary of evidence
Public health problem	• COVID-19 cases continue to occur widely throughout the United States; the 7-day average of daily new cases (69,577) is increasing.* • During March 1–April 17, 2021, the cumulative COVID-19 incidence among adults was 710.9 cases per 100,000 persons, and the cumulative COVID-19 hospitalization rate for adults was 20.6 per 100,000 persons. • Most hospitalizations and deaths continue to occur among adults aged ≥65 years; however, the proportions of hospitalizations and deaths among adults aged ≥65 years are decreasing with increasing vaccination rates in this age group. • COVID-19 cases and hospitalizations are increasing in some areas of the country and among younger persons who have not yet been vaccinated. The reasons for these increases might be related to emerging SARS-CoV-2 variants† that are becoming predominant in some communities, as well as reduced use of nonpharmaceutical interventions. • Ongoing expansion of COVID-19 vaccination programs is needed to reduce disease incidence among persons who are eligible for vaccination.
Benefits and harms	• Benefits and harms were estimated based on CDC models that estimate COVID-19 hospitalizations, ICU admissions, and deaths that could be prevented by continued use of the Janssen COVID-19 vaccine, as well as expected cases of TTS. • These models showed that in the upcoming 6 months, resuming use of the Janssen COVID-19 vaccine among adults aged ≥18 years at 50% of prepause administration rates could prevent 928–2,236 ICU admissions and 586–1,435 deaths, compared with an estimated 26 expected cases of TTS. • Resuming use of the Janssen COVID-19 vaccine only among adults aged ≥50 years could result in prevention of 295–799 ICU admissions and 54–257 deaths, compared with two expected TTS cases.
Values and acceptability	• Values and acceptability were assessed among U.S. adults to understand intent to receive a 1-dose COVID-19 vaccine, change in intent to receive the Janssen COVID-19 vaccine over time, and change in overall vaccine confidence after the Janssen COVID-19 vaccine pause. • After the pause was announced, only 37% of respondents considered the Janssen COVID-19 vaccine to be safe, a decrease of 15% compared with the previous 2–3 days.§ • Willingness to receive the Janssen COVID-19 vaccine decreased from 49% before the pause to 19% as of April 19, 2021, compared with 56%–68% for mRNA vaccines.¶ • A recent poll suggested that overall intent to be vaccinated has increased, with 40% of respondents reporting they are more likely to receive COVID-19 vaccine now than they were 1 month ago and 36% reporting no change in their intent to be vaccinated.** • In contrast, another survey found that since the pause in the Janssen COVID-19 vaccine has occurred, approximately half of respondents who are unvaccinated reported they were less likely to receive a COVID-19 vaccine, regardless of brand (CVS Health, personal communication, April 20, 2021).
Feasibility and equity	• Feasibility and equity were assessed based on direct responses to a CDC telephone survey of jurisdictional COVID-19 vaccination programs; the survey included questions on the impact of the pause in Janssen COVID-19 vaccination and implications of possible changes to the Janssen COVID-19 vaccine recommendation. • Before the pause, most jurisdictions reported focusing Janssen COVID-19 vaccination efforts on mobile populations or those hard to reach with a second dose, especially persons experiencing homelessness (68%), homebound persons (64%), and those who are involved in the justice system (57%). • Jurisdictions reported extensive use of Janssen COVID-19 vaccine in mobile units, hospitals, emergency departments, urgent care settings, and school-based clinics. • When asked about populations that would be disproportionately affected by a change in the Janssen COVID-19 recommendation, jurisdictions reported that persons who are experiencing homelessness, homebound persons, those involved in the justice system, and persons working in migrant or seasonal jobs would be the groups most likely to be negatively affected.

Abbreviations: ICU = intensive care unit; TTS = thrombosis with thrombocytopenia syndrome.

* CDC. COVID data tracker weekly review. Atlanta, GA: US Department of Health and Human Services, CDC; 2021. Accessed April 22, 2021. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

† CDC. SARS-CoV-2 variant classifications and definitions. Atlanta, GA: US Department of Health and Human Services, CDC; 2021. Accessed April 22, 2021. https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html

§ Frankovic K. Economist/YouGov survey: decision to pause Johnson & Johnson vaccine causes public confidence in vaccine to sink. YouGov. April 15, 2021. https://today.yougov.com/topics/politics/articles-reports/2021/04/15/johnson-johnson-vaccine-confidence

¶ SurveyMonkey Research. Poll: demand for J&J vaccine plummets, but vaccine confidence holds mostly steady; data from SurveyMonkey and Outbreaks Near Me. Survey Monkey's Weekly Research Newsletter. April 20, 2021. https://surveymonkey.substack.com/p/jj-pause

** de Beaumont Foundation. Poll: vaccine confidence grows despite J&J pause. de Beaumont Foundation. https://debeaumont.org/news/2021/poll-vaccine-confidence-grows-despite-jj-pause/

Reporting of Vaccine Adverse Events

FDA requires that vaccine providers report vaccination administration errors, serious adverse events,[§§] cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of a COVID-19 vaccine under an EUA (*10*). Adverse events that occur after receipt of any COVID-19 vaccine should be reported to VAERS. 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, whether or not it is clear that a vaccine caused the adverse event. In addition, CDC has developed a new, voluntary smartphone-based online tool (referred to as v-safe) that uses text messaging and online surveys to provide near real-time health check-ins after receipt of a COVID-19 vaccine. In cases of v-safe reports

[§§] https://vaers.hhs.gov/faq.html

Summary

What is already known about this topic?

On April 13, 2021, CDC and the Food and Drug Administration (FDA) recommended pausing use of the Janssen COVID-19 vaccine after reports of thrombosis with thrombocytopenia syndrome (TTS) among vaccine recipients.

What is added by this report?

On April 23, the Advisory Committee on Immunization Practices concluded that the benefits of resuming Janssen COVID-19 vaccination among persons aged ≥18 years outweighed the risks and reaffirmed its interim recommendation under FDA's Emergency Use Authorization, which includes a new warning for rare clotting events among women aged 18–49 years.

What are the implications for public health practice?

Resuming use of the Janssen COVID-19 vaccine will ensure flexibility, choice, and improved access. Education about TTS risk with Janssen COVID-19 vaccine is critical.

that include possible medically attended significant health events, CDC's v-safe call center follows up with the vaccine recipient to collect additional information for completion of a VAERS report. Information on v-safe is available at https://www.cdc.gov/vsafe.

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Erratum

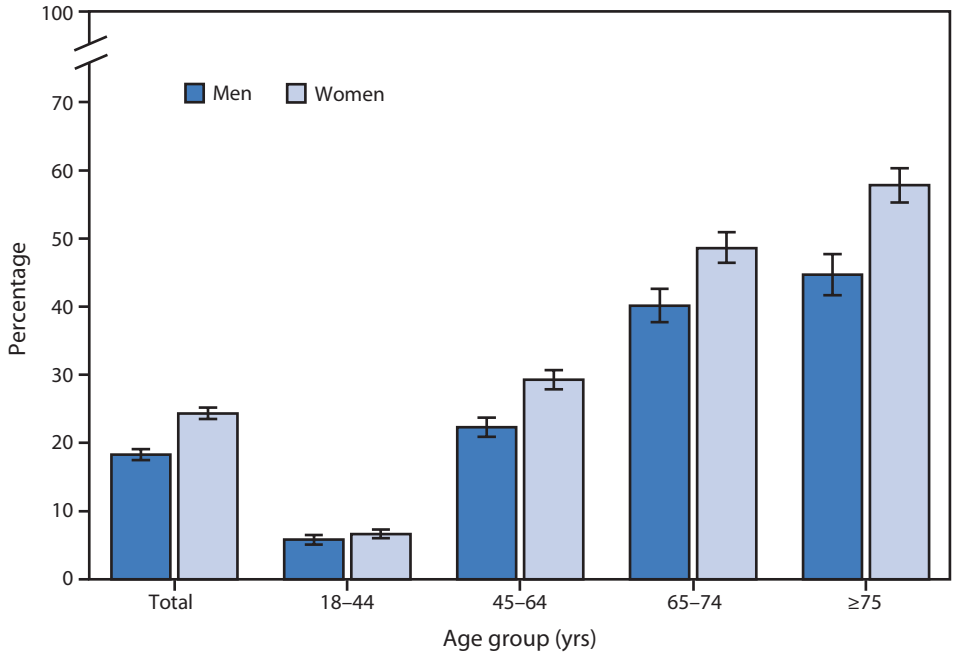
Vol. 70, No. 12

In the report "Low SARS-CoV-2 Transmission in Elementary Schools — Salt Lake County, Utah, December 3, 2020–January 31, 2021," on page 445, the fourth footnote of Table 2 should have read, "¶ Restricted to students (n = 908). **The five students in grade 7 or higher were contacts of two index patients at the same school: three were exposed to an elementary school student on the school bus and two to a school staff member in a nonclassroom space at the school.** Bus contacts were not routinely included on the list of school contacts for all 51 index patients."

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Adults Aged ≥18 Years with Arthritis,† by Sex and Age Group — National Health Interview Survey,§ United States, 2019



* With 95% confidence intervals indicated with error bars.
† Arthritis is based on a "yes" response to a survey question that asked, "Have you ever been told by a doctor or other health professional that you had some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?"
§ Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population.

In 2019, among adults aged ≥18 years, prevalence of arthritis (including rheumatoid arthritis, gout, lupus, and fibromyalgia) increased with age among both men and women. For men, prevalence increased from 5.8% among those aged 18–44 years to 22.3% among those aged 45–64 years, 40.1% among those aged 65–74 years, and 44.7% among those aged ≥75 years. For women, prevalence increased from 6.6% among those aged 18–44 years to 29.3% among those aged 45–64 years, 48.6% among those aged 65–74 years, and 57.8% among those aged ≥75 years. Women were more likely to have arthritis than were men overall (24.3% versus 18.3%) and in all age groups except 18–44 years, where the difference did not reach statistical significance.

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

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