Weekly / Vol. 69 / No. 51-52

Morbidity and Mortality Weekly Report

January 1, 2021

Implications of Shortened Quarantine Among Household Contacts of Index Patients with Confirmed SARS-CoV-2 Infection — Tennessee and Wisconsin, April–September 2020

Melissa A. Rolfes, PhD¹; Carlos G. Grijalva, MD²; Yuwei Zhu, MD²; Huong Q. McLean, PhD³; Kayla E. Hanson, MPH³; Edward A. Belongia, MD³; Natasha B. Halasa, MD²; Ahra Kim, MPH²; Jennifer Meece, PhD³; Carrie Reed, DSc²; H. Keipp Talbot, MD²; Alicia M. Fry, MD¹

To prevent further transmission of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), CDC currently recommends that persons who have been in close contact with someone with SARS-CoV-2 infection should quarantine (stay away from other persons) for 14 days after the last known contact.* However, quarantine might be difficult to maintain for a prolonged period. A shorter quarantine might improve compliance, and CDC recommends two options to reduce the duration of quarantine for close contacts without symptoms, based on local circumstances and availability of testing: 1) quarantine can end on day 10 without a test or 2) quarantine can end on day 7 after receiving a negative test result.† However, shorter quarantine might permit ongoing disease transmission from persons who develop symptoms or become infectious near the end of the recommended 14-day period. Interim data from an ongoing study of household transmission of SARS-CoV-2 were analyzed to understand the proportion of household contacts that had detectable virus after a shortened quarantine period. Persons who were household contacts of index patients completed a daily symptom diary and self-collected respiratory specimens for 14 days. Specimens were tested for SARS-CoV-2 using reverse transcriptionpolymerase chain reaction (RT-PCR). Among 185 household contacts enrolled, 109 (59%) had detectable SARS-CoV-2 at any time; 76% (83/109) of test results were positive within 7 days, and 86% (94 of 109) were positive within 10 days after the index patient's illness onset date. Among household contacts who received negative SARS-CoV-2 test results and

were asymptomatic through day 7, there was an 81% chance (95% confidence interval [CI] = 67%–90%) of remaining asymptomatic and receiving negative RT-PCR test results through day 14; this increased to 93% (95% CI = 78%–98%) for household members who were asymptomatic with negative RT-PCR test results through day 10. Although SARS-CoV-2 quarantine periods shorter than 14 days might be easier to

INSIDE

- 1638 Opportunities to Address Men's Health During the Perinatal Period Puerto Rico, 2017
- 1642 Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses — Wisconsin, September–October 2020
- 1648 Impact of COVID-19 Pandemic on Global Poliovirus Surveillance
- 1653 The Advisory Committee on Immunization
 Practices' Interim Recommendation for Use of
 Moderna COVID-19 Vaccine United States,
 December 2020
- 1657 The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020
- 1664 COVID-19 Stats
- 1665 QuickStats

Continuing Education examination available at https://www.cdc.gov/mmwr/mmwr_continuingEducation.html

[†] https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html.



^{*}https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.

adhere to, there is a potential for onward transmission from household contacts released before day 14.

A CDC-supported study of household transmission of SARS-CoV-2 is currently ongoing in Nashville, Tennessee, and Marshfield, Wisconsin (1). Household contacts of an index patient who had symptoms compatible with COVID-19 for <7 days and laboratory-confirmed SARS-CoV-2 infection were eligible for the study if they had not had symptoms of an acute respiratory illness up to the date of the index patient's illness onset. Enrolled household contacts were instructed to self-collect respiratory specimens (nasal swab only or nasal swab and saliva) and complete a daily symptom diary for 14 days. The study protocol was reviewed and approved by the Vanderbilt University Medical Center's and Marshfield Clinic Research Institute's Institutional Review Boards and was conducted consistent with applicable federal law and CDC policy.**

For each household contact, the number of days from the index patient's illness onset to 1) the day of first positive test result, 2) the day of first symptoms, or 3) the end of the follow-up period, whichever occurred first, was calculated. Survival analysis, accounting for left-censoring, †† was used to estimate the conditional probability that a household contact who was asymptomatic and whose specimens tested negative for SARS-CoV-2 by RT-PCR through day 5, 7, or 10 would remain asymptomatic and negative through day 14. Sensitivity analyses were conducted, excluding households with possible co-primary patients (households with household contacts who had illness onset or positive test <2 days after the index patient's illness onset) and household contacts with possible tertiary transmission (household contacts who had a positive test >2 days after another nonindex household contact had a positive test result).

During April–September 2020, among 105 index patients, 185 household contacts were enrolled (median of one household contact per index patient, interquartile range [IQR] = 1–2; 45% of household contacts were male; median age of household contacts = 27 years, IQR = 15–45 years). Enrollment occurred a median of 4 days (IQR = 2–4 days) after the index patient's illness onset and study follow-up concluded a median of 16 days (IQR = 15–17 days) after the index

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

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2020;69:[inclusive page numbers].

Centers for Disease Control and Prevention

Robert R. Redfield, MD, Director
Anne Schuchat, MD, Principal Deputy Director
Ileana Arias, PhD, Acting Deputy Director for Public Health Science and Surveillance
Rebecca Bunnell, PhD, MEd, Director, Office of Science
Jennifer Layden, MD, PhD, Deputy Director, Office of Science
Michael F. Iademarco, MD, MPH, Director, Center for Surveillance, Epidemiology, and Laboratory Services

MMWR Editorial and Production Staff (Weekly)

Charlotte K. Kent, PhD, MPH, Editor in Chief
Jacqueline Gindler, MD, Editor
Paul Z. Siegel, MD, MPH, Guest Associate Editor
Mary Dott, MD, MPH, Online Editor
Terisa F. Rutledge, Managing Editor
Teresa M. Hood, MS, Acting Lead Technical Writer-Editor
Glenn Damon, Soumya Dunworth, PhD,
Stacy Simon, MA, Jeffrey D. Sokolow, MA
Technical Writer-Editors

Matthew L. Boulton, MD, MPH Carolyn Brooks, ScD, MA Jay C. Butler, MD Virginia A. Caine, MD Jonathan E. Fielding, MD, MPH, MBA David W. Fleming, MD Martha F. Boyd, Lead Visual Information Specialist
Alexander J. Gottardy, Maureen A. Leahy,
Julia C. Martinroe, Stephen R. Spriggs, Tong Yang,
Visual Information Specialists
Quang M. Doan, MBA, Phyllis H. King,
Terraye M. Starr, Moua Yang,
Information Technology Specialists

MMWR Editorial Board

Timothy F. Jones, MD, *Chairman*Kate Galatas, MPH
William E. Halperin, MD, DrPH, MPH
Jewel Mullen, MD, MPH, MPA
Jeff Niederdeppe, PhD
Celeste Philip, MD, MPH
Patricia Quinlisk, MD, MPH

Ian Branam, MA, Acting Lead Health Communication Specialist Shelton Bartley, MPH, Lowery Johnson, Amanda Ray, Jacqueline N. Sanchez, MS, Health Communication Specialists Will Yang, MA, Visual Information Specialist

Patrick L. Remington, MD, MPH Carlos Roig, MS, MA William Schaffner, MD Nathaniel Smith, MD, MPH Morgan Bobb Swanson, BS

[§] Index patients (or their parent/guardian) were asked "Have all other members of their household had fever, cough, cold, or other respiratory symptoms?" [Marshfield, Wisconsin site] or "Has anyone in your home, besides you, been sick with a fever, cough, cold, or flu-like symptoms in the 7 days before your illness began?" [Nashville, Tennessee site]. If the response was yes, the household was ineligible to participate.

The following signs and symptoms were solicited from participants on the daily diary: fever/feverishness, cough, sore throat, runny nose, trouble breathing or shortness of breath, nasal congestion, chills, fatigue or feeling run down, wheezing, chest tightness or chest pain, abdominal pain, diarrhea, vomiting, headache, muscle or body aches, and loss of taste or smell.

^{** 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.

^{††} Household contacts who had positive SARS-CoV-2 RT-PCR test results on the date of enrollment were considered left-censored because the date of initial infection was not observed during the study period.

patient's illness onset. Overall, 109 (59%) household contacts had SARS-CoV-2 detected in respiratory specimens during the follow-up period, with the first positive specimen collected a median of 5 days (IQR = 3–7 days) after the index patient's illness onset. Among all infected household contacts, 76% (83 of 109) had infection detected within 7 days after the index patient's illness onset and 86% (94 of 109) within 10 days.

The probability that a household contact who was asymptomatic and had negative RT-PCR test results through day 7 would remain asymptomatic with negative RT-PCR test results through 14 days after the index patient's illness onset was 81% (95% CI = 67%–90%); the probability increased to 93% (95% CI = 78%–98%) if the household contact remained asymptomatic with negative test results through day 10 (Table). After excluding 22 households (including 45 household contacts) with possible co-primary index patients and 10 infected household contacts with possible tertiary transmission, the conditional probability that the contact would remain asymptomatic with negative RT-PCR test results through day 14 was 95% (95% CI = 81%–99%) if the person was asymptomatic and negative through day 10.

Discussion

Quarantine can stop onward transmission of SARS-CoV-2; however, adherence to a 14-day quarantine can be challenging. Analysis of data from an ongoing study of SARS-CoV-2 detection after exposure to an infected household member found an 81% chance that a household contact who had negative SARS-CoV-2 RT-PCR test results and was asymptomatic for 7 days after the index patient's illness onset date would remain asymptomatic and continue to receive negative RT-PCR test results through 14 days. Conversely, one in five household contacts would become symptomatic or receive positive SARS-CoV-2 RT-PCR test results between day 7 and 14, suggesting that, compared with no quarantine, reducing quarantine to <14 days might decrease but not eliminate the risk for spreading SARS-CoV-2.

With consistent adherence, quarantine prevents transmission from persons who were exposed to the virus and who might become infectious, but who do not have symptoms or signs of infection (i.e., who are presymptomatic or who will remain asymptomatic). The length of quarantine is typically based on the known incubation period, or the interval between exposure to an infectious pathogen and the development of symptoms or signs of infection, which for SARS-CoV-2 ranges from 2 to 14 days. §§ However, quarantine efforts will not effectively reduce transmission if adherence is low. Evidence

suggests that adherence to recommended quarantine during the COVID-19 pandemic varies and might be low in some settings (2,3). France, Belgium, and now some jurisdictions in the United States have shortened the quarantine period for persons exposed to someone with COVID-19 from 14 days to 10 or 7 days, but there is ongoing concern that shortening quarantine for all exposed persons could increase community transmission (4). Modeling studies suggest that combining a shorter quarantine with a timely diagnostic test at the end, to detect asymptomatic or presymptomatic infections, might carry some residual risk for transmission but could be an alternative to a 14-day quarantine period if the shorter quarantine length enhances compliance. \$\mathbf{9},****

In this analysis of SARS-CoV-2 detection following household exposure, the more time that had passed since the index patient's illness onset, the higher the likelihood that an asymptomatic household contact with negative SARS-CoV-2 test results would remain asymptomatic and RT-PCR negative. If the household contact remained asymptomatic with negative SARS-CoV-2 RT-PCR test results through day 7, the probability of their becoming symptomatic or having a positive RT-PCR test result the following week was 19%. However, this probability declined to 7% if the contact remained asymptomatic with negative RT-PCR test results through day 10. To minimize the potential risk for further spread, persons who have been released from a shortened quarantine should continue to monitor their health for symptoms of COVID-19, avoid close contact with others (including persons in their household), and cover their nose and mouth with a mask when around others for the remainder of the 14 days. †††

The findings in this report are subject to at least five limitations. First, the index patient's illness onset date was used as a proxy for last exposure. This might not have been the actual date of last exposure, affecting calculations on timing of positive specimens and symptom onset. Second, chains of transmission are challenging to recreate with observational studies; however, the main findings were robust in several sensitivity analyses designed to account for possible misclassification of secondary infections. Third, household contacts were assumed to have acquired infection from the index patient; however, the possibility that some infections might have been introduced from the community cannot be excluded. Fourth, a highly sensitive assay was used to detect SARS-CoV-2 nucleic acids; in some settings, however, this type of testing might not be available or yield timely results. Finally, these findings might

^{\$\$} https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.

⁵⁵ https://www.medrxiv.org/content/10.1101/2020.10.27.20211631v1.full.pdf.
*** https://www.medrxiv.org/content/10.1101/2020.08.21.20177808v3.full.pdf.

^{†††} https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

TABLE. Cumulative frequency and conditional probability of SARS-CoV-2 detection or symptoms over time among household contacts who received positive SARS-CoV-2 test results or developed symptoms — Tennessee and Wisconsin, April–September 2020

		No. of	household contact		
	No. of days from index patient's	SARS-CoV-2 detected	Symptomatic	Symptomatic or SARS-CoV-2 detected	Conditional probability of remaining asymptomatic with negative test results until day 14
Main analysis	illness onset	n = 109	n = 122	n = 145	% (95% CI)*
All households and all household	5	68 (62)	101 (83)	119 (82)	71 (57–81)
contacts included [†]	7	83 (76)	110 (90)	130 (90)	81 (67–90)
	10	94 (86)	116 (95)	138 (95)	93 (78–98)
	14	104 (95)	121 (99)	141 (97)	<u> </u>
Sensitivity analyses					
Excluding households with possible	_	n = 75	n = 84	n = 103	_
co-primary patients§	5	41 (55)	68 (81)	80 (78)	74 (59–84)
	7	52 (69)	74 (88)	88 (85)	80 (66–89)
	10	62 (83)	79 (94)	96 (93)	93 (77–98)
	14	70 (93)	83 (99)	99 (96)	· <u> </u>
Excluding household contacts that	_	n = 99	n = 118	n = 135	_
are possibly tertiary transmissions¶	5	68 (69)	99 (84)	117 (87)	76 (61–86)
	7	80 (81)	108 (92)	127 (94)	87 (72–94)
	10	88 (89)	113 (96)	127 (94)	95 (82–99)
	14	97 (98)	118 (100)	134 (99)	<u> </u>
Excluding households with possible	_	n = 66	n = 81	n = 94	_
co-primary patients and	5	41 (62)	67 (83)	79 (84)	80 (64–89)
household contacts that are	7	50 (76)	73 (90)	86 (91)	86 (71–94)
possibly tertiary transmissions**	10	57 (86)	77 (95)	86 (91)	95 (81–99)
	14	64 (97)	81 (100)	93 (99)	

^{*} The conditional probability is the probability of remaining negative by reverse transcription—polymerase chain reaction and asymptomatic to day 14 after the index patient's illness onset, given that the household contact has been negative and asymptomatic through day 5, 7, or 10. 95% Cls were estimated using Greenwood's exponential Cls (Major Greenwood, Jr. [1926]. The Natural Duration of Cancer. Reports of Public Health and Related Subjects, Vol. 33, HMSO, London).

not be directly translatable to use of point-of-care assays, which yield more rapid results but with lower sensitivity.

A 14-day quarantine of all close contacts who are exposed to a person with COVID-19, such as in the household, is the most effective strategy to reduce the spread of COVID-19. Although persons might be more adherent to a shorter quarantine period, such a policy is not without risk for further spread. Timely access to a sufficiently sensitive test at the end of a shorter quarantine period will help identify household contacts with SARS-CoV-2 infection and might enable an effective shorter quarantine period for household contacts who remain asymptomatic and have negative test results, who pose lower risk for further spread of COVID-19.

Summary

What is already known about this topic?

After exposure to COVID-19, a 14-day quarantine period can prevent further spread but might be challenging to maintain.

What is added by this report?

Among persons exposed to COVID-19 in the household who were asymptomatic and had negative laboratory test results through 7 days after symptom onset in the index patient, 19% experienced symptoms or received positive test results in the following week.

What are the implications for public health practice?

A shorter quarantine after household exposure to COVID-19 might be easier to adhere to but poses some risk for onward transmission. Persons released from quarantine before 14 days should continue to avoid close contact and wear masks when around others until 14 days after their last exposure.

[†] Analysis included 104 households and 185 household contacts.

§ Analysis included 82 households and 141 household contacts. Households were excluded if any household contact had illness onset or positive test <2 days after the index patient's illness onset.

Analysis included 104 households and 175 household contacts. Household contacts were excluded if they had a positive test >2 days after another nonindex household contact became positive.

^{**} Analysis included 82 households and 132 household contacts.

Acknowledgments

Judy King, Dayna Wyatt, Robert Lyons, Carleigh Frazier, Emily Jookar, Karen Malone, Olivia Doak, Sarah Davis, Jorge Celedonio, Rendie McHenry, Claudia Guevara, Vanderbilt University Medical Center; Lynn Ivacic, Hannah Berger, Vicki Moon, Jennifer Anderson, Elizabeth Armagost, Keegan Brighton, Gina Burbey, Kari Christophersen, Deanna Cole, Eric DeJarlais, Joe Finamore, Wayne Frome, Erica Joy Graves, Sherri Guzinski, Linda Heeren, Jacob Johnston, Chris Kadolph, Julie Karl, Sarah Kohn, Tamara Kronenwetter Koepel, Diane Kohnhorst, Erik Kronholm, Eric LaRose, Jim Linneman, Karen McGreevey, Sudha Medabalimi, Nidhi Mehta, Elizabeth Osterbauer, Nan Pan, Rebecca Pilsner, DeeAnn Polacek, Martha Presson, Carla Rottscheit, Jacklyn Salzwedel, Kristin Seyfert, Ram Shrestha, Sandy Strey, Gail Weinand, Melissa Wendt, Marshfield Clinic Research Institute; Constance Ogokeh, CDC COVID-19 Response.

Corresponding author: Melissa Rolfes, ydi8@cdc.gov.

¹CDC COVID-19 Response Team; ²Vanderbilt University Medical Center, Nashville, Tennessee; ³Marshfield Clinic Research Institute, Marshfield, Wisconsin.

All authors have completed and submitted the International Committee of Medical Journal potential conflicts of interest were disclosed. Carlos G. Grijalva reports personal consulting fees from Sanofi, Merck, and Pfizer; grants from Sanofi, Campbell Alliance, the National Institutes of Health, and the Agency for HealthCare Research and Quality; and a contract from the Food and Drug Administration, outside the submitted work. Natasha B. Halasa reports grants from Sanofi and Quidel, and personal fees from Genetech, outside the submitted work. No other potential conflicts of interest were disclosed.

References

- 1. Grijalva CG, Rolfes MA, Zhu Y, et al. Transmission of SARS-COV-2 infections in households—Tennessee and Wisconsin, April–September 2020. MMWR Morb Mortal Wkly Rep 2020;69:1631–4. PMID:33151916 https://doi.org/10.15585/mmwr.mm6944e1
- Ryu S, Hwang Y, Yoon H, Chun BC. Self-quarantine non-compliance during the COVID-19 pandemic in South Korea. Disaster Med Public Health Prep 2020;12:1–4. PMID:33040761 https://doi.org/10.1017/ dmp.2020.374
- Steens A, Freiesleben de Blasio B, Veneti L, et al. Poor self-reported adherence to COVID-19-related quarantine/isolation requests, Norway, April to July 2020. Euro Surveill 2020;25:2001607. PMID:32945254 https://doi.org/10.2807/1560-7917.ES.2020.25.37.2001607
- Atlani-Duault L, Lina B, Malvy D, Yazdanpanah Y, Chauvin F, Delfraissy JF. COVID-19: France grapples with the pragmatics of isolation. Lancet Public Health 2020;5:e573

 –4. PMID:33045184 https://doi.org/10.1016/ S2468-2667(20)30235-8

Opportunities to Address Men's Health During the Perinatal Period — Puerto Rico, 2017

Beatriz Salvesen von Essen, MPH^{1,2,3}; Katherine Kortsmit, PhD^{1,4}; Denise V. D'Angelo, MPH¹; Lee Warner, PhD¹; Ruben A. Smith, PhD¹; Clarissa Simon, PhD⁵; Craig F. Garfield, MD⁵; Wanda Hernández Virella, MPH²; Manuel I. Vargas Bernal, MD²

Decreased use of health care services (1), increased exposure to occupational hazards, and higher rates of substance use (2) might contribute to men's poorer health outcomes when compared with such outcomes for women (3). During the transition to fatherhood, paternal health and involvement during pregnancy might have an impact on maternal and infant outcomes (4–6). To assess men's health-related behaviors and participation in fatherhood-related activities surrounding pregnancy, the Puerto Rico Department of Health and CDC analyzed data from the paternal survey of the Pregnancy Risk Assessment Monitoring System–Zika Postpartum Emergency Response (PRAMS-ZPER)* study. Fewer than one half (48.3%) of men attended a health care visit for themselves in the 12 months before their newborn's birth. However, most fathers attended one or more prenatal care visits (87.2%), were present at the birth (83.1%), and helped prepare for the newborn's arrival (e.g., by preparing the home [92.4%] or purchasing supplies [93.9%]). These findings suggest that opportunities are available for public health messaging directed toward fathers during the perinatal period to increase attention to their own health and health behaviors, and to emphasize the role they can play in supporting their families' overall health and well-being.

Men are less likely than are women to see or talk to a doctor or other health care professional about their own health (1), limiting opportunities for providers to engage with men regarding any health concerns, conditions, or risk behaviors. Men's higher exposure to occupational hazards (e.g., chemical and physical exposures) and higher prevalence of substance use (e.g., alcohol and illicit drugs) (2), compared with women, might contribute to men's poorer health status (3). Men also have a lower life expectancy and higher prevalence of cardiovascular disease and suicide (2).

Addressing men's health needs is especially important during the transition into fatherhood. Associations between the transition into fatherhood and increases in poor physical (7) and mental health (8) have been observed, both of which might negatively affect men's involvement in family life (9). Paternal involvement during pregnancy has been associated with maternal adoption of healthy prenatal (e.g., early prenatal

care and smoking cessation) (4) and postpartum behaviors (e.g., breastfeeding) (5). Fathers' engagement with their children has also been associated with improved child outcomes (e.g., cognition, language, social, and emotional development) (6).

The PRAMS-ZPER study, a multiphase, collaborative project between the Puerto Rico Department of Health and CDC, was implemented from August 2016 to April 2018 to gather information about experiences related to the prevention and detection of Zika virus infection during pregnancy among women with a recent live birth. To gather information from newborns' fathers† about their own experiences before and during pregnancy, a survey was implemented during November–December 2017 in hospitals with ≥100 births during 2016. Data from the 30 participating hospitals represented 94% of births in Puerto Rico during the study period. The study sample was identified by randomly selecting newborn delivery dates (clusters) for each hospital. Fathers were initially approached in the hospital shortly after their newborn's birth. They were eligible to participate if their newborn's mother had a live birth and was a resident of Puerto Rico. Fathers who consented to participate completed a self-administered survey using paper or electronic forms before the newborn and mother were discharged from the hospital.

PRAMS-ZPER study data were weighted to account for the complex sampling design. Weighted prevalence estimates and 95% confidence intervals (CIs) were calculated for sociode-mographic characteristics of participants, their attendance at health care visits during the 12 months before their newborn's birth, and involvement in selected pregnancy-related activities. Chi-squared tests and 95% CIs were used to assess differences in attendance at health care visits by paternal age, education, employment, and insurance coverage. All analyses were conducted using SAS-callable SUDAAN (version 11.0; RTI International). This study was reviewed and approved by CDC and the University of Puerto Rico Institutional Review Boards.§

^{*}https://www.cdc.gov/prams/special-projects/zika/index.htm.

[†] Men were eligible to participate if they were identified by the newborn's mother as the father or if they were the mother's current partner. No additional verifications were completed to determine whether the respondent completing the survey was the biological father, the person acknowledging paternity on the birth certificate, or someone else.

^{§ 45} C.F.R. part 46; 21 C.F.R. part 56.

Among 1,535 eligible men, 1,178 (76.7%) elected to participate. Most were Hispanic (97.8%), aged \geq 25 years (74.2%), had some college education or higher (63.8%), were employed (85.1%), and had health insurance (85.9%) (Table 1).

Approximately one half of participants (48.3%) reported attending a health care visit for themselves in the 12 months before the newborn's birth (Table 1). Attendance at health care visits was higher among men who completed college, compared with men with a high school education or less, and among men who were insured compared with those who were uninsured. Among men attending a health care visit, a regular checkup (60.9%) was the most commonly reported type of visit, followed by dental cleaning (23.4%), and visits for an illness (13.6%) (Figure).

Approximately 45.5% of the men were first-time fathers, and 53.1% reported the pregnancy was intended. Most reported living with the newborn's mother during the entire pregnancy (83.6%); talking with the newborn's mother about pregnancy, birth, and infant care (91.1%); purchasing supplies such as a crib and stroller (93.9%); preparing the home by setting up a space for the newborn (92.4%); and being satisfied with their level of involvement in the pregnancy (93.3%). Nearly three quarters (71.0%) reported seeking information about pregnancy and birth on the Internet or from other sources (Table 2).

Overall, 87.2% of men attended prenatal care visits, with 50.3% reporting attending all visits (Table 2). The most common reasons for not attending visits included inability to take time off from work or school (80.6%) and inconvenient appointment times (15.1%) (unpublished data, CDC, 2017). Most men (83.1%) also reported attending their newborn's birth (Table 2). The most common reasons for nonattendance were that the birth occurred unexpectedly (30.9%) or they were not allowed to attend by medical staff members (26.4%) (unpublished data, CDC, 2017).

Discussion

Among men in Puerto Rico whose partner had a recent live birth, fewer than one half reported having a health care visit during the 12 months before the newborn's birth. Despite having limited interaction with the health care system for themselves, approximately 80% of recent fathers in Puerto Rico reported being present during prenatal care visits and at the time of their newborn's delivery. Approximately 90% of recent fathers reported purchasing supplies for the newborn, and approximately 70% reported seeking information on pregnancy and birth from the Internet or other sources. These findings highlight opportunities for public health messaging directed toward fathers during health care visits throughout

TABLE 1. Characteristics of recent fathers and prevalence of reported health care visits during the 12 months before the newborn's birth, overall and by selected paternal characteristics — Pregnancy Risk Assessment Monitoring System–Zika Postpartum Emergency Response Study, Puerto Rico, 2017

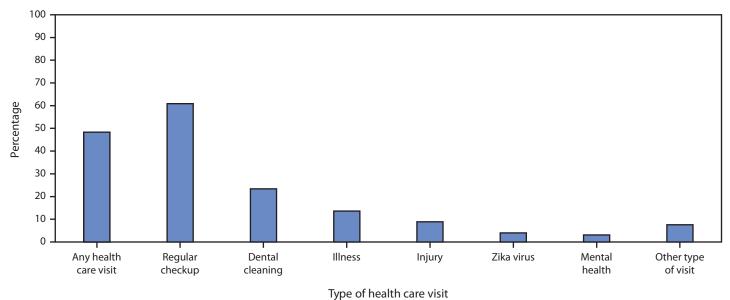
		Total	Attendance at any health care visit in the past 12 months		
Paternal characteristic	Unweighted no.*	Weighted % (95% CI)	Unweighted no.	Weighted % (95% CI)	Chi-squared p-value
Overall	1,178	_	1,151	48.3 (45.8–50.7)	_
Ethnicity					
Hispanic	1,132	97.8 (96.9-98.4)	1,106	47.4 (44.9-49.9)	†
Non-Hispanic	25	2.2 (1.6-3.1)	25	†	
Age group, yrs					
≤24	288	25.8 (23.7-28.0)	282	43.9 (38.9-49.0)	0.05
25–34	566	50.1 (47.7-52.5)	558	48.1 (44.7-51.5)	
≥35	271	24.1 (22.0-26.2)	265	52.1 (47.6-56.6)	
Education					
High school or less	414	36.2 (33.9-38.5)	404	45.5 (41.4-49.6)	< 0.01
Completed some college or technical school	389	33.5 (31.4-35.7)	385	46.4 (42.3-50.5)	
Completed college or higher	352	30.3 (28.2-32.5)	345	53.9 (49.8-58.0)	
Employment status					
Employed	965	85.1 (83.3-86.7)	948	47.9 (45.2-50.5)	0.59
Unemployed	169	14.9 (13.3-16.7)	167	49.7 (43.3-56.2)	
Insurance					
Private	469	40.3 (38.1-42.6)	463	52.9 (49.1-56.7)	< 0.001
Government insurance/Medicaid	527	45.1 (42.8-47.4)	517	49.3 (45.8-52.8)	
Uninsured	162	14.1 (12.5–16.0)	158	32.7 (26.7–39.3)	
Other	6	0.5 (0.3-0.9)	6	t	

Abbreviation: CI = confidence interval.

^{*} Sample size varies because of missing responses in survey.

[†] <30 respondents, estimate unreliable.

FIGURE. Percentage of health care visits* attended in the 12 months before the newborn's birth among recent fathers reporting any health care visit, by type of visit† — Pregnancy Risk Assessment Monitoring System–Zika Postpartum Emergency Response Study, Puerto Rico, 2017



^{*} Among all respondents.

the perinatal period. Messaging might also reach new and expectant fathers through other sources or locations they visit frequently around the time of pregnancy, such as pregnancy and infant-related websites and businesses. Public health messaging could focus on increasing men's attention to their own health and opportunities to help positively influence their family's overall well-being.

This analysis was strengthened by the large, representative sample of fathers in Puerto Rico reporting on their experiences and behaviors around the time of their partner's pregnancy and newborn's birth. The high response rate was comparable to that of the Fragile Families study, a representative father-specific, hospital-based survey in the United States (10), and illustrates that fathers are receptive to being approached for such surveys shortly after newborn delivery. This study provides evidence of men's willingness to participate in pregnancy-related research activities in hospital settings.

The findings in this report are subject to at least four limitations. First, data were collected from men who were present in the hospital with their partner who had a live birth and was a resident of Puerto Rico and might not be representative of other men. Second, survey data were self-reported and thus subject to recall and social desirability bias. Third, data were collected in 2017 shortly after Puerto Rico experienced a Zika virus outbreak and Hurricanes Irma and María when increased stressors might have influenced men's health care—seeking behaviors and pregnancy involvement. Finally,

Summary

What is already known about this topic?

Men are less likely than are women to seek health care services and are more likely to engage in higher risk health behaviors.

What is added by this report?

Fewer than one half (48%) of surveyed recent fathers in Puerto Rico had a health care visit for themselves in the 12 months before their newborn's birth; however, most attended prenatal care visits with their partner (87%), were present at the birth (83%), and purchased infant supplies (94%).

What are the implications for public health practice?

The perinatal period represents an opportunity for public health messaging that encourages men to increase attention to their own health and the role they can play in supporting their families' overall health and well-being.

this analysis did not address health care barriers among recent fathers. The higher proportion of college-educated and insured men who attended health care visits highlights the value of addressing barriers to health care access for less educated and uninsured persons.

The finding of moderate levels of men's attendance at health care visits for themselves in the 12 months before their newborn's birth, but high levels of attendance at both prenatal visits and newborn delivery, suggests opportunities for health care providers to engage with expectant and new

[†] Among respondents who reported having a health care visit.

TABLE 2. Prevalence of paternal characteristics and participation in selected pregnancy-related activities by recent fathers — Pregnancy Risk Assessment Monitoring System–Zika Postpartum Emergency Response Study, Puerto Rico, 2017

	Overall total			
Paternal characteristic	Unweighted no.*	Weighted % (95% CI)†		
Parity				
First child	515	45.5 (43.1-47.9)		
Second child	313	27.4 (25.5-29.4)		
Third or later child	308	27.1 (25.0–29.2)		
Pregnancy intention				
Unintended	418	37.5 (35.3-39.7)		
Intended	589	53.1 (51.0-55.3)		
Unsure	105	9.4 (8.0-10.9)		
Living with infant's mother of	J. J.	()		
Yes, all the time	966	83.6 (81.8–85.2)		
Yes, part of the time	109	9.6 (8.3–11.1)		
No	79	6.8 (5.7–8.2)		
Pregnancy-related activities				
Talked with the newborn's m caring for a new baby	other about pregnar	ncy, birth, and		
Yes	1,003	91.1 (89.7–92.3)		
No	97	8.9 (7.7–10.3)		
Prepared the home by settin	g up a space for the i	newborn		
Yes	1,013	92.4 (91.1–93.4)		
No	85	7.6 (6.6–8.9)		
Purchased supplies such as a bottles, or blankets	crib, stroller, clothin	g, diapers,		
Yes	1,030	93.9 (92.8-94.9)		
No	67	6.1 (5.1–7.2)		
Satisfied with pregnancy inv		o (o 7.2)		
Yes	1,029	93.3 (92.0-94.4)		
No, I wanted to be	1,029	93.3 (92.0-94.4)		
more involved	68	6.1 (5.0-7.3)		
No, I wanted to be		01. (310 713)		
less involved	6	0.6 (0.3-1.1)		
Sought information about p	regnancy and birth f	rom the		
Yes	767	71.0 (68.8–73.1)		
No	315	29.0 (26.9–31.2)		
		27.0 (20.7–31.2)		
Prenatal care visits attendan	ce			
Attendance at some prenatal care visits	419	36.9 (34.7–39.0)		
Attendance at all prenatal	419	30.9 (34.7-39.0)		
care visits	569	50.3 (48.0-52.5)		
No.	149	12.9 (11.5–14.5)		
Attendance at newborn's bir		12.5 (11.5 11.5)		
Yes	950	83.1 (81.2–84.8)		
No	187	16.9 (15.2–18.8)		
		10.5 (13.2-10.0)		
Abbreviation: CI = confidence	e interval.			

fathers during perinatal visits. Providers could talk to men about their health and discuss opportunities to positively influence their family's overall health. In addition, the inclusion of public health messaging targeted toward men through sources for obtaining pregnancy-related information or supplies might help reinforce men's attention to their health and involvement in pregnancy-related activities. Understanding optimal approaches for integrating health messages for men into activities and encounters during the perinatal period requires additional research.

Corresponding author: Beatriz Salvesen von Essen, omo2@cdc.gov, 404-718-3248.

¹Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC; ²Division of Maternal, Child and Adolescent Health, Puerto Rico Department of Health; ³CDC Foundation, Atlanta, Georgia; ⁴Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee; ⁵Department of Pediatrics, Northwestern Medical School, Chicago, Illinois.

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.

References

- CDC. QuickStats: percentage of adults aged ≥18 years who have seen
 or talked to a doctor or other health care professional about their own
 health in the past 12 months, by sex and age group—National Health
 Interview Survey, United States, 2015. MMWR Morb Mortal Wkly
 Rep 2017;66:65. PMID:28103213 https://doi.org/10.15585/mmwr.
 mm6602a12
- CDC. Health, United States, 2018–data finder. Atlanta, GA: US
 Department of Health and Human Services, CDC; 2018. https://www.cdc.gov/nchs/hus/contents2018.htm
- 3. Baker P, Dworkin SL, Tong S, Banks I, Shand T, Yamey G. The men's health gap: men must be included in the global health equity agenda. Bull World Health Organ 2014;92:618–20. PMID:25197149 https://doi.org/10.2471/BLT.13.132795
- Martin LT, McNamara MJ, Milot AS, Halle T, Hair EC. The effects of father involvement during pregnancy on receipt of prenatal care and maternal smoking. Matern Child Health J 2007;11:595–602. PMID:17557201 https://doi.org/10.1007/s10995-007-0209-0
- Abbass-Dick J, Stern SB, Nelson LE, Watson W, Dennis CL. Coparenting breastfeeding support and exclusive breastfeeding: a randomized controlled trial. Pediatrics 2015;135:102–10. PMID:25452653 https:// doi.org/10.1542/peds.2014-1416
- Cabrera NJ, Shannon JD, Tamis-LeMonda C. Fathers' influence on their children's cognitive and emotional development: from toddlers to pre-k. Appl Dev Sci 2007;11:208–13. https://doi.org/10.1080/10888690701762100
- 7. Garfield CF, Duncan G, Gutina A, et al. Longitudinal study of body mass index in young males and the transition to fatherhood. Am J Men Health 2016;10:NP158–67. PMID:26198724 https://doi.org/10.1177/1557988315596224
- 8. Garfield CF, Duncan G, Rutsohn J, et al. A longitudinal study of paternal mental health during transition to fatherhood as young adults. Pediatrics 2014;133:836–43. PMID:24733877 https://doi.org/10.1542/peds.2013-3262
- Kotelchuck M, Lu M. Father's role in preconception health. Matern Child Health J 2017;21:2025–39. PMID:28983715 https://doi. org/10.1007/s10995-017-2370-4
- 10. Reichman NE, Teitler JO, Garfinkel I, McLanahan SS. Fragile families: sample and design. Child Youth Serv Rev 2001;23:303–26. https://doi.org/10.1016/S0190-7409(01)00141-4

^{*} Sample size varies because of missing responses or skip patterns in survey.

[†] Percentages might not sum to 100% because of rounding.

Morbidity and Mortality Weekly Report

Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses — Wisconsin, September-October 2020

Ian W. Pray, PhD^{1,2,3,*}; Laura Ford, PhD^{1,2,*}; Devlin Cole, MD^{3,4}; Christine Lee, PhD^{1,5}, John Paul Bigouette, PhD^{1,2}; Glen R. Abedi, MPH¹; Dena Bushman, MSN, MPH^{1,2}; Miranda J. Delahoy, PhD^{1,2}; Dustin Currie, PhD^{1,2}; Blake Cherney, MS¹; Marie Kirby, PhD¹; Geroncio Fajardo, MD¹; Motria Caudill, PhD^{1,6}; Kimberly Langolf, MS⁷; Juliana Kahrs, MS⁷; Patrick Kelly, MD^{4,8}; Collin Pitts, MD^{4,8}; Ailam Lim, PhD⁹; Nicole Aulik, PhD⁹; Azaibi Tamin, PhD¹; Jennifer L. Harcourt, PhD¹; Krista Queen, PhD¹; Jing Zhang, PhD¹; Brett Whitaker, PhD¹; Hannah Browne¹; Magdalena Medrzycki, PhD¹; Patricia Shewmaker, PhD¹; Jennifer Folster, PhD¹; Bettina Bankamp, PhD¹; Michael D. Bowen, PhD¹; Natalie J. Thornburg, PhD¹; Kimberly Goffard, MBA¹⁰; Brandi Limbago, PhD¹; Allen Bateman, PhD^{7,11}; Jacqueline E. Tate, PhD¹; Douglas Gieryn¹⁰; Hannah L. Kirking, MD¹; Ryan Westergaard, MD, PhD^{3,4}; Marie Killerby, VetMB¹; CDC COVID-19 Surge Laboratory Group

Antigen-based tests for SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), are inexpensive and can return results within 15 minutes (1). Antigen tests have received Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for use in asymptomatic and symptomatic persons within the first 5-12 days after symptom onset (2). These tests have been used at U.S. colleges and universities and other congregate settings (e.g., nursing homes and correctional and detention facilities), where serial testing of asymptomatic persons might facilitate early case identification (3–5). However, test performance data from symptomatic and asymptomatic persons are limited. This investigation evaluated performance of the Sofia SARS Antigen Fluorescent Immunoassay (FIA) (Quidel Corporation) compared with real-time reverse transcription-polymerase chain reaction (RT-PCR) for SARS-CoV-2 detection among asymptomatic and symptomatic persons at two universities in Wisconsin. During September 28-October 9, a total of 1,098 paired nasal swabs were tested using the Sofia SARS Antigen FIA and real-time RT-PCR. Virus culture was attempted on all antigenpositive or real-time RT-PCR-positive specimens. Among 871 (79%) paired swabs from asymptomatic participants, the antigen test sensitivity was 41.2%, specificity was 98.4%, and in this population the estimated positive predictive value (PPV) was 33.3%, and negative predictive value (NPV) was 98.8%. Antigen test performance was improved among 227 (21%) paired swabs from participants who reported one or more symptoms at specimen collection (sensitivity = 80.0%; specificity = 98.9%; PPV = 94.1%; NPV = 95.9%). Virus was isolated from 34 (46.6%) of 73 antigen-positive or real-time RT-PCR-positive nasal swab specimens, including two of 18 that were antigen-negative and real-time RT-PCR-positive (false-negatives). The advantages of antigen tests such as low cost and rapid turnaround might allow for rapid identification of infectious persons. However, these advantages need to be

balanced against lower sensitivity and lower PPV, especially among asymptomatic persons. Confirmatory testing with an FDA-authorized nucleic acid amplification test (NAAT), such as RT-PCR, should be considered after negative antigen test results in symptomatic persons, and after positive antigen test results in asymptomatic persons (1).

Paired nasal swabs were collected from students, faculty, staff members, and other affiliates[†] at two Wisconsin university campuses during university-based testing programs. At university A, all persons tested (screening or diagnostic) at the university testing center during October 1–9 were eligible to participate. At university B, only students who were quarantined during September 28–October 6 after exposure to persons with COVID-19 could participate.

All participants completed a questionnaire and provided information on demographic characteristics, current and past (14 days) symptoms, and recent exposure to persons with COVID-19. For each participant, two mid-turbinate nasal swabs were collected by health care personnel at university A and were self-collected under supervision at university B. Both nostrils were sampled with each of the two swabs. Swabs for antigen testing were analyzed according to the manufacturer's instructions.** Swabs for real-time RT-PCR were stored in viral transport media at 39°F (4°C) and analyzed within 24–72 hours of collection. At university A, real-time RT-PCR was performed using the CDC 2019-nCoV real-time RT-PCR

^{*} These authors contributed equally to this report.

[†] Other affiliates were participants who did not mark "student" or "staff" on the questionnaire (they selected "other" or did not respond); the majority of these persons were family members of staff members.

Symptom list was based on the interim position statement for COVID-19 case definitions from the Council of State and Territorial Epidemiologists, updated August 7, 2020. Clinical criteria for COVID-19 included fever, cough, shortness of breath, fatigue, sore throat, headache, muscle aches, chills, nasal congestion, difficulty breathing, diarrhea, nausea, vomiting, abdominal pain, rigors, loss of taste, and loss of smell. https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/positionstatement2020/Interim-20-ID-02_COVID-19.pdf.

[¶] Recent exposure was defined as being within 6 feet of a person with a COVID-19 diagnosis for ≥15 minutes in the past 14 days.

^{**} https://www.fda.gov/media/137885/download.

diagnostic panel (6), with cycle threshold (Ct) values reported for the N1 and N2 viral nucleocapsid protein gene regions. At university B, real-time RT-PCR was performed using the TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific). Viral culture^{††} (7) was attempted on residual RT-PCR specimens if the RT-PCR or antigen test result was positive.

Statistical analyses were performed using Stata (version 16.1; StataCorp). Sensitivity, specificity, PPV, and NPV were calculated for antigen testing compared with real-time RT-PCR results. Ninety-five percent confidence intervals (CIs) were calculated using the exact binomial method; t-tests were used for Ct value comparisons p-values <0.05 were considered statistically significant. This investigation was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy. Ethical review boards at both universities determined the activity to be nonresearch public health surveillance (2).

Among a total of 1,105 total nasal swab pairs submitted, seven (0.06%) were excluded for having inconclusive antigen or real-time RT-PCR results. Test comparisons were performed on 1,098 paired nasal swabs (2,196 total swabs), including 1,051 pairs (95.7%) from university A and 47 pairs (4.3%) from university B (Table 1). Among the 1,098 pairs evaluated, 994 (90.5%) were provided by students aged 17-53 years (median = 19 years), 82 (7.5%) by university faculty or staff members aged 22-63 years (median = 38 years), and 22 (2.0%) by other university affiliates aged 15-64 years (median = 29 years). Fifty-seven persons participated more than once on different testing days. Overall, 453 (41.3%) participants were male, and 917 (83.5%) were non-Hispanic White. At specimen collection, 227 (20.7%) participants reported experiencing one or more COVID-19 symptoms, and 871 (79.3%) reported no symptoms.

Among 227 paired specimens from symptomatic participants, 34 (15.0%) were antigen-positive, and 40 (17.6%) were real-time RT-PCR-positive. The median interval from symptom onset to specimen collection was 3 days (interquartile range = 1–6 days; 7.5% missing). Among symptomatic participants, antigen testing sensitivity was 80.0% (32 of 40), specificity was 98.9% (185 of 187), PPV was 94.1% (32 of 34),

and NPV was 95.9% (185 of 193) (Table 2). For specimens collected within 5 days of reported symptom onset (72.4%; 152 of 210), sensitivity was 74.2% (23 of 31), and specificity was 99.2% (120 of 121).

Among 871 paired specimens from asymptomatic participants, 21 (2.4%) were antigen-positive and 17 (2.0%) were real-time RT-PCR-positive. Antigen testing sensitivity was 41.2% (seven of 17), specificity was 98.4% (840 of 854), PPV was 33.3% (seven of 21), and NPV was 98.8% (840 of 850). Test performance was not significantly (p>0.05) different when excluding 53 (6.1%) of 871 participants who were asymptomatic at the time of testing but had reported one or more symptoms in the preceding 14 days.

Sixteen paired swabs were antigen-positive and real-time RT-PCR-negative (i.e., false-positive), including 14 (66.7%) of 21 positive antigen results from asymptomatic participants and two (5.9%) of 34 from symptomatic participants. Eight of the 16 false-positive results were recorded during a 1-hour period at university A. In this instance, a series of consecutive positive results in asymptomatic persons was noted, and investigators offered repeat antigen testing to the affected participants. Six of eight participants were reswabbed within 1 hour, and all six received negative test results on a second antigen test. All eight initial paired swabs from these participants were negative on real-time RT-PCR. Because no user errors could be identified, the false-positive results were included in analysis. Eighteen false-negative antigen test results were obtained, including 10 (58.8%) of 17 real-time RT-PCR-positive tests from asymptomatic participants, and eight (20.0%) of 40 from symptomatic participants. All false-negative results from symptomatic participants were from specimens collected <5 days after onset of symptoms (median = 2 days). Ct values for specimens with false-negative antigen results were significantly higher compared with antigen- and real-time RT-PCR-positive specimens (mean N1 Ct = 32.3 versus 23.7; p<0.01) (Figure).

Virus was recovered from 34 (46.6%) of 73 positive specimens, including 32 (82.1%) of 39 specimens with concordant positive results and two (11.1%) of 18 with false-negative antigen results; no virus was recovered from 16 specimens with false-positive antigen test results. The two specimens with false-negative antigen results that were culture-positive were from two symptomatic participants who had specimens collected at day 2 and day 4 after symptom onset.***

^{††} Specimens were used to perform a limiting-dilution inoculation of Vero CCL-81 cells, and cultures showing evidence of cytopathic effect (CPE) were tested by real-time RT-PCR for the presence of SARS-CoV-2 RNA. Viral recovery was defined as any culture in which the first passage had an N1 Ct at least twofold lower than the corresponding clinical specimen.

^{§§} Ct values from real-time RT-PCR were only compared for specimens collected at university A that were analyzed with the CDC 2019-nCoV real-time RT-PCR diagnostic panel for detection of SARS-CoV-2.

^{55 45} C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

^{***} The participant with a false-negative result 2 days after symptom onset had a repeat specimen 2 days later; the results of testing were positive by antigen test and by real-time RT-PCR.

TABLE 1. Characteristics and symptoms of persons providing paired nasal swabs (N = 1,098),* by results for SARS-CoV-2 real-time reverse transcription–polymerase chain reaction (RT-PCR) and Sofia SARS Antigen Fluorescent Immunoassay testing† — two universities, Wisconsin, September–October 2020

			No (%)		
	True positives (N = 39)	False negatives (N = 18)	False positives (N = 16)	True negatives (N = 1,025)	Total (N = 1,098)
Testing site					
University A [§]	37 (94.9)	17 (94.4)	15 (93.8)	982 (95.8)	1,051 (95.7)
University B [¶]	2 (5.1)	1 (5.6)	1 (6.3)	43 (4.2)	47 (4.3)
Sex					
Male	16 (41.0)	9 (50.0)	12 (75.0)	416 (40.6)	453 (41.3)
- emale	23 (59.0)	9 (50.0)	4 (25.0)	609 (59.4)	645 (58.7)
Age group (yrs)					
15–24**	35 (89.7)	16 (88.9)	11 (68.8)	909 (88.7)	971 (88.4)
≥25	4 (10.3)	2 (11.1)	5 (31.3)	116 (11.3)	127 (11.6)
Race/Ethnicity ^{††}					
White	31 (79.5)	17 (94.4)	12 (75.0)	857 (83.6)	917 (83.5)
Hispanic/Latino	6 (15.4)	0 (0)	1 (6.3)	54 (5.3)	61 (5.6)
Black/African-American	0 (0)	1 (5.6)	2 (12.5)	26 (2.5)	29 (2.6)
Asian/Pacific Islander	0 (0)	0 (0)	0 (0)	49 (4.8)	49 (4.5)
American Indian/Alaska Native	0 (0)	0 (0)	0 (0)	3 (0.3)	3 (0.3)
Other/Unknown/Multiple races	2 (5.1)	0 (0)	1 (6.3)	36 (3.5)	39 (3.6)
Jniversity status					
Student	35 (89.7)	17 (94.4)	13 (81.3)	929 (90.6)	994 (90.5)
Faculty or staff member	4 (10.3)	1 (5.6)	3 (18.8)	74 (7.2)	82 (7.5)
Other affiliate or unknown ^{§§}	0 (0)	0 (0)	0 (0)	22 (2.2)	22 (2.0)
Exposure ^{¶¶} to a COVID-19 case					
Been in close contact in the past 14 days	13 (33.3)	9 (50.0)	4 (25.0)	128 (12.5)	154 (14.0)
Ouarantine status					
Quarantined at time of specimen collection	17 (43.6)	6 (33.3)	3 (18.8)	109 (10.6)	135 (12.3)
Time between quarantine initiation to specimen collection, median days (range)	1 (0–8)	3.5 (0–6)	1 (0–4)	4 (0–28)	4 (0–28)
Reported symptoms	7 (17.9)	10 (55.6)	14 (07 5)	940 (92.0)	071 (70.3)
No current symptoms	7 (17.9) 2 (28.6)	10 (55.6)	14 (87.5)	840 (82.0)	871 (79.3)
One or more symptoms in the past 14 days No symptoms in the past 14 days	2 (28.6) 5 (71.4)	1 (10.0) 9 (90.0)	0 (0) 14 (100.0)	50 (6.0) 790 (94.0)	53 (6.1) 818 (93.9)
Contable fortunation and the great great	J (/ 1.4)	9 (90.0)	14 (100.0)	790 (94.0)	010(93.9)

See table footnotes on the next page.

Discussion

The Sofia SARS Antigen FIA received FDA EUA on May 8, 2020, for use in symptomatic persons within 5 days of symptom onset (2). In this investigation, among persons reporting COVID-19–compatible symptoms at specimen collection, the test was less accurate (sensitivity = 80.0%; specificity = 98.9%) than reported in the FDA EUA (sensitivity = 96.7%; specificity = 100%) (2). Two of eight specimens from symptomatic persons that had false-negative antigen test results were positive by viral culture, indicating that potentially infectious persons might not be detected by antigen testing. To reduce the impact of false-negative antigen test results, confirmatory testing with an FDA-authorized NAAT, such as RT-PCR, should be considered following negative antigen test results in symptomatic persons (1).

Among asymptomatic participants, antigen test sensitivity was 41.2%, specificity was 98.4%, and PPV in this population was 33.3%. This low PPV was observed despite a relatively high

prevalence of SARS-CoV-2 in this population (5.2% prevalence overall; 2.0% among asymptomatic persons), suggesting that PPV could be even lower when using this antigen test among populations with lower expected SARS-CoV-2 prevalence. To account for false-positive results when using antigen tests for asymptomatic screening, confirmatory NAAT testing should be considered following positive antigen test results in asymptomatic persons, particularly when pretest probability of SARS-CoV-2 infection is low (1). The NPV of antigen testing among asymptomatic participants was 98.8%, and virus was not cultured from asymptomatic participants with antigen-negative results, indicating that asymptomatic persons with negative antigen results are unlikely to be infected with SARS-CoV-2 and would not require confirmatory NAAT (1).

The findings in this report are subject to at least four limitations. First, participants were predominantly young adults in university settings where ongoing serial testing was being conducted. Antigen test performance might differ in other

TABLE 1. (Continued) Characteristics and symptoms of persons providing paired nasal swabs (N = 1,098),* by results for SARS-CoV-2 real-time reverse transcription-polymerase chain reaction (RT-PCR) and Sofia SARS Antigen Fluorescent Immunoassay testing† — two universities, Wisconsin, September-October 2020

			No (%)		
Characteristic	True positives (N = 39)	False negatives (N = 18)	False positives (N = 16)	True negatives (N = 1,025)	Total (N = 1,098)
One or more current symptoms	32 (82.1)	8 (44.4)	2 (12.5)	185 (18.0)	227 (20.7)
Nasal congestion	24 (75.0)	2 (25.0)	1 (50.0)	87 (47.0)	114 (50.2)
Sore throat	12 (37.5)	5 (62.5)	1 (50.0)	79 (42.7)	97 (42.7)
Headache	17 (53.1)	3 (37.5)	1 (50.0)	66 (35.7)	87 (38.3)
Cough	18 (56.3)	6 (75.0)	1 (50.0)	45 (24.3)	70 (30.8)
Fatigue	14 (43.8)	3 (37.5)	1 (50.0)	42 (22.7)	60 (26.4)
Muscle aches	11 (34.4)	2 (25.0)	0 (0)	30 (16.2)	43 (18.9)
Shortness of breath	7 (21.9)	1 (12.5)	0 (0)	16 (8.6)	24 (10.6)
Chills	4 (12.5)	0 (0)	0 (0)	14 (7.6)	18 (7.9)
Diarrhea	3 (9.4)	0 (0)	0 (0)	15 (8.1)	18 (7.9)
Nausea or vomiting	3 (9.4)	0 (0)	0 (0)	14 (7.6)	17 (7.5)
Loss of taste	8 (25.0)	2 (25.0)	1 (50.0)	3 (1.6)	14 (6.2)
Loss of smell	8 (25.0)	2 (25.0)	1 (50.0)	2 (1.1)	13 (5.7)
Fever	6 (18.8)	0 (0)	0 (0)	5 (2.7)	11 (4.8)
Difficulty breathing	3 (9.4)	0 (0)	0 (0)	8 (4.3)	11 (4.8)
Abdominal pain	1 (3.1)	0 (0)	0 (0)	6 (3.2)	7 (3.1)
Rigors	0 (0)	0 (0)	0 (0)	0 (0)	0 (0.0)
Other reported symptoms***	1 (3.1)	0 (0)	0 (0)	4 (2.2)	5 (2.2)
Symptom onset date reported	31 (96.9)	8 (100)	2 (100)	169 (91.4)	210 (92.5)
≤5 days between reported symptom onset and specimen collection	23 (74.2)	8 (100)	1 (50.0)	120 (71.0)	152 (72.4)

^{*} Includes 57 participants who received multiple tests and were included more than once in the analysis.

populations with different characteristics and testing schedules. Second, given the limitations of RT-PCR, some false-positive antigen test results might represent true infections not identified by RT-PCR. Third, the ability to recover infectious virus in culture is limited and decreases for specimens with higher Ct values (8); a lack of virus recovery by culture does not indicate that a person is not infectious. Finally, this investigation evaluated the Sofia SARS Antigen FIA, and cannot be generalized to other FDA-authorized SARS-CoV-2 antigen tests.

Serial testing of asymptomatic and symptomatic persons has been proposed for prevention and control of SARS-CoV-2 transmission (9,10) and is currently being implemented at U.S. colleges and universities and in other congregate settings (3–5). Despite reduced sensitivity compared with real-time RT-PCR, the use of antigen tests for serial testing in these settings, particularly when RT-PCR tests are not available or have a prolonged turnaround time, might still allow rapid identification of infectious persons and control of outbreaks

Summary

What is already known about this topic?

Antigen tests for SARS-CoV-2 are inexpensive and can return results within 15 minutes, but test performance data in asymptomatic and symptomatic persons are limited.

What is added by this report?

Compared with real-time reverse transcription—polymerase chain reaction (RT-PCR) testing, the Sofia antigen test had a sensitivity of 80.0% and specificity of 98.9% among symptomatic persons; accuracy was lower (sensitivity 41.2% and specificity 98.4%) when used for screening of asymptomatic persons.

What are the implications for public health practice?

To account for reduced antigen test accuracy, confirmatory testing with a nucleic acid amplification test (e.g., RT-PCR) should be considered after negative antigen test results in symptomatic persons and positive antigen test results in asymptomatic persons.

[†] True positive = antigen-positive and RT-PCR-positive; false negative = antigen-negative and RT-PCR-positive; false positive = antigen-positive and RT-PCR-negative; true negative = antigen-negative and RT-PCR-negative; these definitions do not reflect results from viral culture.

[§] At university A, real-time RT-PCR was performed using the CDC 2019-nCoV real-time RT-PCR diagnostic panel for detection of SARS-CoV-2.

At university B, real-time RT-PCR was performed using Thermo Fisher Scientific's TaqPath COVID-19 Combo Kit for detection of SARS-CoV-2.

^{**} One university staff member's child aged 15 years. All other participants were aged ≥17 years.

^{††} Non-Hispanic ethnicity represented for all White, Black/African-American, Asian/Pacific Islander, American Indian/Alaska Native, Other/Unknown/Multiple races.

^{§§} Other affiliates were participants who did not mark "student" or "staff" on the questionnaire (they selected "other" or did not respond); the majority of these persons were family members of staff members.

[¶] Ever in close contact was defined as within 6 feet for ≥15 minutes of a person with a diagnosis of COVID-19.

^{***} Other reported symptoms included allergies, cough that is not dry, and difficulty breathing from anxiety.

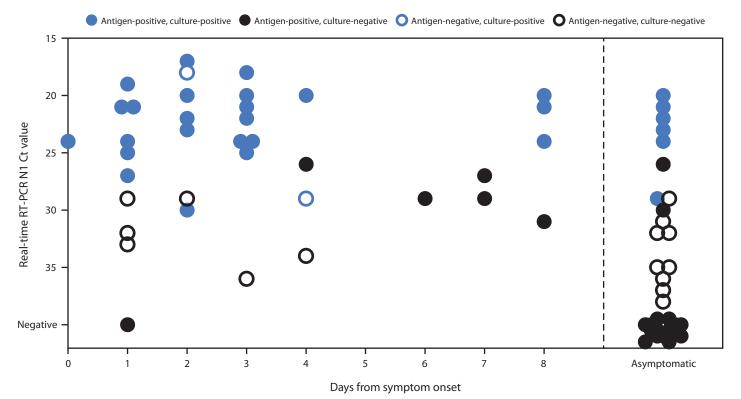
TABLE 2. Sensitivity, specificity, positive predictive value, and negative predictive value of Sofia SARS Antigen Fluorescent Immunoassay compared with real-time reverse transcription-polymerase chain reaction (RT-PCR) among asymptomatic and symptomatic persons — two universities, Wisconsin, September-October 2020

		RT-PCR result, no.				
Antigen test	Asymp	tomatic (N =	= 871)	Sympto	omatic* (N =	= 227)
result	Positive	Negative	Total	Positive	Negative	Total
Positive	7	14	21	32	2	34
Negative	10	840	850	8	185	193
Total	17	854	871	40	187	227
Test evaluation,	% (95% CI))				
Sensitivity	41.	2 (18.4–67.1	1)	80.	.0 (64.4–90.9	9)
Specificity	98.	4 (97.3–99.1	1)	98.	.9 (96.2–99.9	9)
Positive predictive value	33.3 (14.6–57.0) 94.1 (80.3–99.3)			3)		
Negative predictive value		.8 (97.8–99.4	1)	95.	.9 (92.0–98.2	2)

Abbreviation: CI = confidence interval.

(1). However, antigen-based testing strategies should account for the lower sensitivity and lower PPV when used for asymptomatic screening by considering confirmatory testing with an FDA-authorized NAAT, such as RT-PCR, after a positive antigen test result in an asymptomatic person. Confirmatory testing should also be considered following a negative antigen test result in a person experiencing COVID-19-compatible symptoms. All persons with negative antigen test results should continue to take measures to prevent SARS-CoV-2 transmission, including wearing a mask, reducing contact with nonhousehold members, and getting tested if they experience symptoms or have close contact with someone who has COVID-19.††† Symptomatic persons with negative antigen test results should continue to follow CDC guidance for persons who might have COVID-19, including staying home except to get medical care and protecting household members by staying in a separate room, wearing a mask indoors, washing hands often, and frequently disinfecting surfaces.

FIGURE. Viral culture results among participants with positive Sofia SARS Antigen Fluorescent Immunoassay or positive SARS-CoV-2 real-time reverse transcription–polymerase chain reaction (RT-PCR) results (n = 69),* by cycle threshold (Ct) value[†] and the interval between specimen collection and reported symptom onset or asymptomatic status — university A, Wisconsin, September–October 2020



^{*} n = 30 antigen- and culture-positive; n = 22 antigen-positive and culture-negative; n = 15 antigen- and culture-negative; n = two antigen-negative and culture-positive.

^{*} One or more symptoms reported.

^{††††} https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html.

[†] Ct values represent cycle thresholds for the N1 target probe during SARS-CoV-2 real-time RT-PCR; Ct values are represented on the y-axis in descending order to indicate that lower Ct values represent higher levels of RNA in the specimen.

Acknowledgments

Edward Samuel Rivera, Daniel J. O'Donnell, University of Wisconsin-Oshkosh; Margaret Okomo-Adhiambo, Umesh Parashar, Paul Rota, Lauren Franco, Gerardo Garcia-Lerma, CDC; Neeti Dahal, Wisconsin Veterinary Diagnostic Laboratory-Wisconsin State Laboratory of Hygiene COVID Laboratory, University of Wisconsin-Madison.

CDC COVID-19 Surge Laboratory Group

Baoming Jiang, CDC; Jan Vinjé, CDC; Amy L. Hopkins, CDC; Eric Katz, CDC; Leslie Barclay, CDC; Mathew Esona, CDC; Rashi Gautam, CDC; Slavica Mijatovic-Rustempasic, CDC; Sung-Sil Moon, CDC; Theresa Bessey, CDC; Preeti Chhabra, CDC; Sarah L. Smart, CDC; Raydel Anderson, CDC; Kay W. Radford, CDC; Gimin Kim, CDC; Dexter Thompson, CDC; Congrong Miao, CDC; Min-hsin Chen, CDC; Lalitha Gade, CDC; Renee Galloway, CDC; Kashif Sahibzada, CDC; Nhien M. Tran, CDC; Srinivasan Velusamy, CDC; HaoQiang Zheng, CDC; Kenny Nguyen, Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee; Claire Hartloge, Oak Ridge Institute for Science and Education, Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee; Phili Wong, Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee.

Corresponding author: Ian Pray, ian.pray@dhs.wisconsin.gov.

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.

References

- 1. CDC. Coronavirus disease 2019 (COVID-19): interim guidance for antigen testing for SARS-CoV-2. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- Food and Drug Administration. In vitro diagnostics EUAs. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/medical-devices/ coronavirus-disease-2019-covid-19-emergency-use-authorizationsmedical-devices/vitro-diagnostics-euas
- 3. CDC. Coronavirus disease 2019 (COVID-19): guidance for testing, screening, and outbreak response for institutions of higher education (IHEs). Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html
- 4. CDC. Coronavirus disease 2019 (COVID-19): testing guidelines for nursing homes. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
- CDC. Coronavirus disease 2019 (COVID-19): interim considerations for SARS-CoV-2 testing in correctional and detention facilities. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/coronavirus/2019-ncov/community/correctiondetention/testing.html
- 6. Lu X, Wang L, Sakthivel SK, et al. US CDC real-time reverse transcription PCR panel for detection of severe acute respiratory syndrome coronavirus 2. Emerg Infect Dis 2020;26:1654–65. PMID:32396505 https://doi.org/10.3201/eid2608.201246
- 7. Harcourt J, Tamin A, Lu X, et al. Severe acute respiratory syndrome coronavirus 2 from patient with coronavirus disease, United States. Emerg Infect Dis 2020;26:1266–73. PMID:32160149 https://doi.org/10.3201/eid2606.200516
- 8. Gniazdowski V, Morris CP, Wohl S, et al. Repeat COVID-19 molecular testing: correlation of SARS-CoV-2 culture with molecular assays and cycle thresholds. Clin Infect Dis 2020;ciaa1616. PMID:33104776 https://doi.org/10.1093/cid/ciaa1616
- 9. Walke HT, Honein MA, Redfield RR. Preventing and responding to COVID-19 on college campuses. JAMA 2020;324:1727–8. PMID:32991681 https://doi.org/10.1001/jama.2020.20027
- Paltiel AD, Zheng A, Walensky RP. Assessment of SARS-CoV-2 screening strategies to permit the safe reopening of college campuses in the United States. JAMA Netw Open 2020;3:e2016818. PMID:32735339 https:// doi.org/10.1001/jamanetworkopen.2020.16818

¹CDC COVID-19 Response Team; ²Epidemic Intelligence Service, CDC; ³Wisconsin Department of Health Services; ⁴School of Medicine and Public Health, University of Wisconsin-Madison; ⁵Laboratory Leadership Service, CDC; ⁶Agency for Toxic Substances and Disease Registry, Atlanta, Georgia; ⁷University of Wisconsin-Oshkosh; ⁸University Health Services, University of Wisconsin-Madison; ⁹Wisconsin Veterinary Diagnostic Laboratory, University of Wisconsin-Madison; ¹⁰Winnebago County Health Department, Oshkosh, Wisconsin; ¹¹Wisconsin State Laboratory of Hygiene.

Impact of COVID-19 Pandemic on Global Poliovirus Surveillance

Delayo J. Zomahoun, MD¹; Ashley L. Burman, MPH¹; Cynthia J. Snider, PhD²; Claire Chauvin, MPH¹; Tracie Gardner, PhD¹; Jacquelyn S. Lickness, MPH²; Jamal A. Ahmed, MD¹; Ousmane Diop, PhD¹; Sue Gerber, PhD³; Abhijeet Anand, MBBS²

On January 30, 2020, the World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19) a Public Health Emergency of International Concern (1). On March 24, 2020, the Global Polio Eradication Initiative (GPEI) suspended all polio supplementary immunization activities and recommended the continuation of polio surveillance (2). In April 2020, GPEI shared revised polio surveillance guidelines in the context of the COVID-19 pandemic, which focused on reducing the risk for transmission of SARS-CoV-2, the virus that causes COVID-19, to health care workers and communities by modifying activities that required personto-person contact, improving hand hygiene and personal protective equipment use practices, and overcoming challenges related to movement restrictions, while continuing essential polio surveillance functions (3). GPEI assessed the impact of the COVID-19 pandemic on polio surveillance by comparing data from January to September 2019 to the same period in 2020. Globally, the number of acute flaccid paralysis (AFP) cases reported declined 33% and the mean number of days between the second stool collected and receipt by the laboratory increased by 70%. Continued analysis of AFP case reporting and stool collection is critical to ensure timely detection and response to interruptions of polio surveillance.

The primary means of detecting poliovirus circulation is through syndromic surveillance* for AFP among children aged <15 years by testing stool specimens for laboratory confirmation of poliovirus.[†] In many locations, environmental surveillance supplements AFP surveillance through the regular collection and testing of sewage to assess the geographic distribution and duration of poliovirus circulation. AFP stool

specimens and sewage samples are tested in WHO-accredited laboratories within the Global Polio Laboratory Network (GPLN). This report describes the impact of the COVID-19 pandemic on polio surveillance by comparing polio surveillance data (i.e., the numbers of AFP cases reported, AFP cases with two stool specimens collected, active environmental sites collecting specimens, specimen transportation time to laboratories, and specimens tested) during the first 9 months of 2019 with those during the same period in 2020, using data reported to GPEI's Polio Information System (POLIS). Following the declaration of the COVID-19 pandemic a Public Health Emergency of International Concern, GPEI created a dashboard using POLIS data to flag country-level changes in the WHO Africa Region (AFR), the Region of the Americas (AMR), Eastern Mediterranean Region (EMR), European Region (EUR), South-East Asia Region (SEAR), and the Western Pacific Region (WPR). The dashboard was used to compare the number of reported AFP cases in 2019 with the number reported during 2020, as well as the collection and testing of laboratory specimens from AFP cases and environmental sites, to identify changes in surveillance before and during the pandemic (3). In addition, data from a separate reporting mechanism that GPEI developed to track delays in specimen transport and testing in WHO-accredited laboratories within the GPLN were reviewed for changes to routine laboratory activities and availability of resources.

Acute Flaccid Paralysis Surveillance

Worldwide, the number of AFP cases reported during January–September declined 33%, from 81,439 in 2019 to 54,631 in 2020. The decline in reported AFP cases from 2019 to 2020 varied by region, with the largest decline in SEAR (53%), followed by AMR (45%), EUR (43%), WPR (20%), EMR (19%), and AFR (13%) (Table). The difference in monthly reported AFP cases in 2020 compared with those in 2019 varied widely across all regions (Figure 1). Among 159 countries for which data were available, AFP case reporting increased from 2019 to 2020 in 29 countries, most notably

^{*} Syndromic surveillance for polio identifies and tests acute flaccid paralysis that includes both polio and nonpolio.

[†]Two important indicators, the nonpolio AFP (NPAFP) rate and the percentage of stool specimens collected from AFP patients that are received in the lab in good condition, measure the sensitivity and quality of polio surveillance. rate is defined as the number of NPAFP cases per 100,000 children aged <15 years per year; an NPAFP rate ≥2 is considered sufficiently sensitive to detect circulating poliovirus. Stool adequacy is defined as the collection of adequate stool specimens from AFP patients (i.e., two stool specimens collected ≥24 hours apart and within 14 days of paralysis onset) and arrival of these specimens at a WHO-accredited laboratory by reverse cold chain (storing and transporting samples at recommended temperatures from the point of collection to the laboratory) and in good condition (i.e., without leakage or desiccation) from ≥80% of persons with AFP.

[§] https://polioeradication.org/polio-today/polio-now/surveillance-indicators/the-global-polio-laboratory-network-gpln/.

[¶]https://extranet.who.int/polis.

TABLE. Polio surveillance system data reported during COVID-19 pandemic — worldwide and by region, January-September 2019 and 2020

				Region			
Characteristic	AFR	AMR	EMR	EUR	SEAR	WPR	Global
AFP surveillance							
No. of AFP cases reported							
2019	19,227	1,766	18,860	1,279	35,176	5,130	81,438
2020	16,778	967	15,359	728	16,526	4,273	54,631
% Change 2019–2020	-13	-45	-19	-43	-53	-20	-33
% of AFP cases with two stool specim	ens collected						
2019	99.2	*	97.1	93.9	97.4	94.2	95.4
2020	99.2	_	97.2	94.1	94.8	94.4	95.1
% Change 2019–2020	none	_	0.1	0.2	-3	0.2	-0.3
No. of days from paralysis onset to 2r	nd stool collection	ı (mean) [†]					
2019	10	_	8.1	7.2	8.7	10.3	9
2020	9.9	_	8.3	7.9	9.8	9.7	9.4
% Change 2019–2020	-1	_	2	10	13	-6	4
No. of days from second stool collecti	ion to receipt in la	ab					
Mean							
2019	7.9	_	4.6	_	3.8	_	5.4
2020	11.6	_	6.2	_	11.3	_	9.2
% Change 2019–2020	47	_	13	_	197	_	70
Median							
2019	4	_	3	_	3	_	3
2020	7	_	4	_	4	_	4
% Change 2019–2020	75	_	33	_	33	_	33
Environmental surveillance§							
No. of samples per environmental sur	rveillance site pei	month (mean)					
2019	1.6	_	1.1	_	2.1	_	1.6
2020	1	_	1	_	1.6	_	1.1
% Change 2019–2020	-38	_	-9	_	-24	_	-31
Laboratory surveillance							
No. of human specimens tested							
2019	44,366	1,513	42,816	7,568	69,288	1,505	167,056
2020	37,625	848	34,597	3,038	29,699	2,892	108,699
% Change 2019–2020	-15	-44	-19	-60	-57	92	-35
No. of environmental samples tested							
2019	4,724	_	1,741	2,762	1,599	408	11,234
2020	2,968	_	1,630	1,713	1,103	439	7,853
% Change 2019–2020	-37	_	-6	-38	-31	8	-30

Abbreviations: AFP = acute flaccid paralysis; AFR = Africa Region; AMR = Region of the Americas; COVID-19 = coronavirus disease 2019; EMR = Eastern Mediterranean Region; EUR = European Region; SEAR = South-East Asia Region; WPR = Western Pacific Region.

* Data not available.

in Burkina Faso (292 to 864; 196%), Côte D'Ivoire (324 to 523; 61%), Zambia (157 to 228; 45%), Guinea (182 to 264; 45%), and the Philippines (552 to 726; 32%). Declines in reported AFP cases were observed in 122 countries and were largest in Indonesia (1,416 to 316; 78%), Papua New Guinea (194 to 55, 72%), Congo (161 to 72, 55%), India (31,539 to 14,842, 53%), Niger (721 to 414; 43%), and Pakistan (11,070 to 8,863; 20%). Pakistan is one of two countries with ongoing wild poliovirus circulation. No change in AFP case reporting was noted in eight countries.

Overall, the percentage of AFP cases with two stool specimens collected declined 0.3% (from 95.4% in 2019 to 95.1% in 2020). A monthly comparison across the regions

for January–September 2020 found that the collection of two stools ranged from a low of 85.5% in SEAR in April to a high of 100% in EUR in May (Figure 2). The percentage of AFP cases with two stool specimens fluctuated monthly during 2020, with an observed 1.3% difference from the lowest to the highest reported in AFR, a 3% difference in EMR, 9% in EUR and WPR, and 12% in SEAR. The largest decline in completeness of stool collection occurred in India, from 98% of AFP cases in January 2020 to 84% in April. The median number of days between the collection of the second stool specimen and receipt by the laboratory increased by 75% in AFR (from 4 to 7 days) and 33% SEAR and EMR (from 3 to 4 days) from 2019 to 2020. The mean number of days from

 $^{^{\}dagger}$ 2019 = 2,718, 2020 = 1,950 cases with no second stool specimen collected and not included in flag calculation. § Environmental site details for EUR and WPR are incomplete.

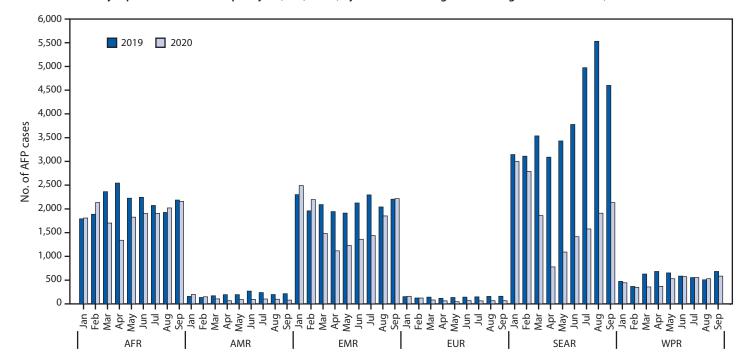


FIGURE 1. Monthly reported acute flaccid paralysis (AFP) cases, by World Health Organization region — worldwide, 2019 and 2020

Abbreviations: AFR = African Region; AMR = Region of the Americas; EMR = Eastern Mediterranean Region; EUR = European Region; SEAR = South-East Asia Region; WPR = Western Pacific Region.

the collection of the second stool to receipt by the laboratory increased by 70% from 2019 to 2020, from 5.4 to 9.2 days. The mean number of days between collection of the second stool specimen and receipt by the laboratory increased by 35% in EMR, from 4.6 in 2019 to 6.2 days in 2020, 47% in AFR, from 7.9 to 11.6 days, and 197% in SEAR, from 3.8 to 11.3 days, highlighting more occurrences of longer delays. The 197% increase in mean number of days between collection of second stool specimen and receipt by the laboratory in SEAR is primarily attributable to significant increases in India.

Environmental Surveillance

During 2020, the mean number of monthly samples collected per active site declined from 1.2 in January to 0.8 in July, August, and September (33%) in AFR, from 2.3 in January to 0.8 in April and May (65%) in SEAR, and from 1.1 in January to 0.9 in March (18%) in EMR. Among 45 countries, 620 active environmental surveillance sites** reported to POLIS in 2020, an increase of 15% from the 537 sites that reported in 2019. Field staff members collected a mean of 1.6 samples per active site each month in 2019 compared with 1.1 per active site each month in 2020 (Table).

Global Polio Laboratory Network

Countries reported movement and transportation restrictions that posed challenges with domestic or international transport of human and environmental specimens. At the height of these restrictions in June 2020, the inability to ship specimens to WHO-accredited laboratories led to the storage of over 850 human specimens (from AFP patients, AFP contacts, and healthy children) and approximately 50 environmental surveillance samples globally. With fewer AFP cases reported overall, GPLN tested 108,699 human specimens from January to September in 2020 compared with 167,056 human specimens during the same period in 2019, a 35% decline. Among regions for which data are available, environmental surveillance samples^{††} tested declined 30%, from 11,234 samples in 2019 compared with 7,853 in 2020 (Table).

Discussion

Polio surveillance data indicate a 33% decline in AFP case reporting during the first 9 months of 2020 compared with the same period in 2019. Precautions taken to mitigate the spread of COVID-19 might have affected the ability of surveillance officers to conduct routine surveillance activities, which would have had an impact on the number of AFP cases reported.

^{**} Active environmental sites: sites where at least one sample was collected and reported from November 1, 2019 to January 31, 2020.

^{††} Environmental surveillance data for AFR, SEAR, and EMR regions.

2019 2020 100 90 80 70 60 Percentage 40 30 20 10 Jun Jan Feb Mar Apr May Jun Jul Aug Sep Jan Feb Mar Mar Apr May \exists Мау Jun AFR **EMR EUR** WPR **SFAR**

FIGURE 2. Percentage of acute flaccid paralysis cases with two stool specimens collected, by World Health Organization (WHO) region — five WHO regions,* 2019 and 2020

Abbreviations: AFR = African Region; EMR = Eastern Mediterranean Region; EUR = European Region; SEAR = South-East Asia Region; WPR = Western Pacific Region. * Data for the number of cases with two stools are not available for the Region of the Americas.

Despite a decline in case reporting, surveillance officers in most regions were able to collect two stool specimens from reported AFP patients with only a slight decrease in 2020, suggesting that the quality of case investigations did not decline. Assessment of completeness of collection of two stool specimens from patients with AFP by month found that the largest overall decline within the 9-month period occurred in India, from a high of 98% of AFP cases in January 2020 to 84% in April. The mean interval from the second stool collection to receipt by the laboratory increased 70%, from 5.4 to 9.2 days worldwide, indicating delays in stool transport. Although environmental surveillance has expanded in 2020, the mean number of samples collected per site declined, and transport of samples to the laboratory in AFR and SEAR was delayed. Several laboratories reported using polio staff members to support COVID-19 testing, which might have created a heavier workload for some staff members. Regional and country-specific variations in polio surveillance from 2019 to 2020 might have resulted from changes in COVID-19 epidemiology in some areas and associated restrictions on movement of polio staff members, diversion of resources from polio to the COVID-19 response, or the emergence and spread of type 2 circulating vaccine derived-poliovirus outbreaks (4).

Whereas the decline in polio surveillance coincided with the initial high spread of COVID-19, country-specific operational

assessments would be required before attributing the declines to the pandemic. For instance, data from Pakistan suggest that the decrease in the number of reported AFP cases from 1,010 in March 2020 to only 585 in April corresponded with the increases in COVID-19 cases (16,117 COVID-19 cases by April 30) (5). In addition, in several countries, polio surveillance officers have played an important role in supporting the COVID-19 response, which affected the time they spent on polio surveillance activities (6). However, several instances of decreases in AFP reporting and environmental surveillance sample collection were not attributable to COVID-19. For example, a worker strike by polio field staff members in the Central African Republic in March 2020 resulted in a decline in AFP reporting; however, the number of reported AFP cases subsequently increased. In addition, a decrease observed in environmental surveillance collection in Angola in March and April 2020 was the result of challenges in transport that were unrelated to the pandemic and was not attributable to a decrease in sample collection (personal communication, Ticha Johnson Muluh, MD, World Health Organization, April 2020).

The findings in this report are subject to at least two limitations. First, although polio surveillance is often affected by many factors, including changes in resources and prioritized activities in outbreak-affected countries and neighboring

Summary

What is already known about this topic?

Surveillance for acute flaccid paralysis (AFP) is critical to detecting poliovirus circulation. Environmental (sewage) surveillance supplements AFP surveillance in many locations.

What is added by this report?

Poliovirus surveillance activities were modified as a result of the COVID-19 pandemic. Reported AFP cases declined 33% from January to September of 2020 compared with the same period in 2019, and the number of environmental samples per site declined. The decline in polio surveillance coincided with the spread of COVID-19.

What are the implications for public health practice?

Interruptions to poliovirus surveillance might have negative consequences on detection of poliovirus circulation. Continued analysis of AFP reporting trends is necessary to better understand the long-term impact to the eradication initiative . The Global Polio Eradication Initiative remains committed to global polio eradication.

countries, the amount and availability of funding, and global GPEI support for surveillance enhancement, none of these factors were included in this assessment. Second, surveillance trends before 2019 were not analyzed, restricting this analysis to monthly comparisons between 2020 and 2019.

The decline in AFP case reporting and sewage specimen collection, delays in transport, and limited surveillance activities suggest that global polio surveillance was negatively affected in 2020 by the COVID-19 pandemic. This has, in turn, negatively affected the ability of GPEI to detect poliovirus circulation. Recently, the impact of this was observed in delayed detection of poliovirus in Sudan, South Sudan, and Guinea caused by delays in shipping specimens. To mitigate further impact of the COVID-19 pandemic on polio surveillance, GPEI has implemented a series of measures to continue surveillance operations, including negotiating with national authorities for special specimen shipment clearance across closed borders, providing personal protective equipment for field officers, and updating guidance on polio surveillance practices in the context of COVID-19 (3). Surge staffing in countries with declines in polio surveillance performance could offset the diversion of resources to COVID-19. Implementing these measures will result in higher financial costs to polio field and laboratory surveillance operations and could affect sustainability. Although COVID-19 has introduced changes to routine operations that require new thinking and innovations, GPEI has a history of adapting to and addressing unforeseen challenges and remains committed to global polio eradication.

Acknowledgments

Global Polio Eradication Initiative; Surveillance Task Team members; Muhammad Obaid-ul Islam Butt, Sudhir Joshi, Ticha Johnson Muluh, Tigran Avagyan, Jude Tuma, Global Polio Laboratory Network.

Corresponding author: Delayo J. Zomahoun, dzomahoun@who.int.

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.

References

- World Health Organization. WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV). Geneva, Switzerland: World Health Organization; 2020. https://www.who.int/ director-general/speeches/detail/who-director-general-s-statement-on-ihremergency-committee-on-novel-coronavirus-(2019-ncov)
- Global Polio Eradication Initiative. Polio oversight board meeting summary. Geneva, Switzerland: Global Polio Eradication Initiative; 2020. http://polioeradication.org/wp-content/uploads/2020/04/POB-meetingsummary-20200324.pdf
- Global Polio Eradication Initiative. Interim guidance for the poliomyelitis (polio) surveillance network in the context of coronavirus disease (COVID19). Geneva, Switzerland: Global Polio Eradication Initiative; 2020. http://polioeradication.org/wp-content/uploads/2020/06/Interim-Guidance-Polio-Surveillance-in-the-context-of-COVID19-20200514.pdf
- Chard AN, Datta SD, Tallis G, et al. Progress toward polio eradication—worldwide, January 18–March 2020. MMWR Morb Mortal Wkly Rep 2020;69:784–9. PMID:32584798
- World Health Organization. WHO coronavirus disease (COVID-19) dashboard. Geneva, Switzerland: World Health Organization; 2020. https://covid19.who.int/
- 6. World Health Organization. Contributions of the polio network to the COVID-19 response: turning the challenge into an opportunity for polio transition. Geneva, Switzerland: World Health Organization; 2020. https://apps.who.int/iris/handle/10665/336261

¹Polio Eradication Department, World Health Organization, Geneva, Switzerland; ²Global Immunization Division, Center for Global Health, CDC; ³Bill and Melinda Gates Foundation, Seattle, Washington.

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020

Sara E. Oliver, MD¹; Julia W. Gargano, PhD¹; Mona Marin, MD¹; Megan Wallace, DrPH^{1,2}; Kathryn G. Curran, PhD¹; Mary Chamberland, MD^{1,3}; Nancy McClung, PhD¹; Doug Campos-Outcalt, MD⁴; Rebecca L. Morgan, PhD⁵; Sarah Mbaeyi, MD¹; José R. Romero, MD⁶; H. Keipp Talbot, MD⁷; Grace M. Lee, MD⁸; Beth P. Bell, MD⁹; Kathleen Dooling, MD¹

On December 20, 2020, this report was posted as an MMWR Early Release on the MMWR website (https://www.cdc.gov/mmwr).

On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 (mRNA-1273) vaccine (ModernaTX, Inc; Cambridge, Massachusetts), a lipid nanoparticleencapsulated, nucleoside-modified mRNA vaccine encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19) (1). This vaccine is the second COVID-19 vaccine authorized under an EUA for the prevention of COVID-19 in the United States (2). Vaccination with the Moderna COVID-19 vaccine consists of 2 doses (100 µg, 0.5 mL each) administered intramuscularly, 1 month (4 weeks) apart. On December 19, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation* for use of the Moderna COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19. To guide its deliberations regarding the vaccine, ACIP employed the Evidence to Recommendation (EtR) Framework, tusing the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Use of all COVID-19 vaccines authorized under an EUA, including the Moderna COVID-19 vaccine, should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines (3). The ACIP recommendation for the use of the Moderna COVID-19 vaccine under EUA is interim and will be updated as additional information becomes available.

Since June 2020, ACIP has convened 10 public meetings to review data on the epidemiology of COVID-19 and the potential use of COVID-19 vaccines, including the Moderna COVID-19 vaccine (4). Within the EtR Framework, ACIP considered the importance of the public health problem of COVID-19, as well as resource use, benefits and harms, patients' values and preferences, acceptability, feasibility, and equity for the Moderna COVID-19 vaccine. To inform the EtR Framework, the COVID-19 Vaccines

Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics, held 28 meetings to review COVID-19 surveillance data, evidence for vaccine efficacy and safety, and implementation considerations for COVID-19 vaccines, including the Moderna COVID-19 vaccine. After a systematic review of available data, the Work Group used the GRADE approach to assess the certainty of evidence for outcomes related to the vaccine, rated on a scale of 1 (high certainty) to 4 (very low certainty) (5). Work Group conclusions regarding certainty of evidence for the Moderna COVID-19 vaccine were presented to ACIP at public meetings.

The body of evidence for the Moderna COVID-19 vaccine was primarily informed by one large, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants aged 18–95 years (median = 52 years) (6–9). Interim findings from this clinical trial, using data from participants with a median of 2 months of follow-up, indicate that the Moderna COVID-19 vaccine efficacy after 2 doses was 94.1% (95% confidence interval = 89.3%-96.8%) in preventing symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection, which was the primary study endpoint. High efficacy (≥86%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Ten hospitalizations due to COVID-19 were documented; nine in the placebo group and one in the vaccine group (9). Preliminary data suggest that the Moderna COVID-19 vaccine might also provide some protection against asymptomatic SARS-CoV-2 infection (7). Among vaccine recipients, reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination, were frequent but mostly mild to moderate. Systemic adverse reactions were more commonly reported after the second dose than after the first dose and were more frequent and severe in persons aged 18-64 years than in those aged ≥65 years. Most local and systemic adverse reactions occurred within the first 1-2 days after vaccine receipt and resolved in a median of 2-3 days. Severe local or systemic adverse reactions (grade ≥3 reactions 9) occurred more commonly

^{*}On December 19, 2020, ACIP voted 11–0 in favor of the interim recommendation for use of the Moderna COVID-19 vaccine. Three ACIP members recused themselves because of participation in clinical trials and/or other studies involving companies producing COVID-19 vaccines.

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

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

⁹ Grade 3 reactions are defined as use of a prescription pain reliever or those preventing daily activity, fever (temperature 102.1–104.0°F [39–40°C]); grade 4 reactions are defined as those that require emergency department visit or hospitalization, temperature >104°F (40°C).

in vaccine recipients than in placebo recipients (21.6% versus 4.4%). Among vaccine recipients, 9.1% reported a grade ≥3 local injection site reaction, and 16.5% reported a grade ≥3 systemic adverse reaction. The frequency of serious adverse events** observed was low in both the vaccine (1.0%) and placebo (1.0%) recipients and without meaningful imbalances for specific serious adverse events between the two groups (8). No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, underlying medical conditions, or previous SARS-CoV-2 infection. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html.

From the GRADE evidence assessment, the level of certainty for the benefits of the Moderna COVID-19 vaccine was type 1 (high certainty) for the prevention of symptomatic COVID-19. Evidence was type 2 (moderate certainty) for the estimate of prevention of COVID-19-associated hospitalization and type 4 (very low certainty) for the estimates of prevention of asymptomatic SARS-CoV-2 infection and all-cause death. Data on COVID-19-associated hospitalizations and deaths are limited at this time; however, a vaccine that effectively prevents symptomatic infection is expected to also prevent associated hospitalizations and deaths. Regarding certainty of evidence related to possible harms after vaccination, evidence was type 2 (moderate certainty) for the estimate of serious adverse events and type 1 (high certainty) for the estimate of reactogenicity. Data reviewed within the EtR Framework supported the use of the Moderna COVID-19 vaccine. ACIP determined that COVID-19 is a major public health problem and that use of the Moderna COVID-19 vaccine is a reasonable and efficient allocation of resources. Whereas there might be uncertainty about how all populations value the vaccine, it was determined that for most populations, the desirable effects outweigh the undesirable effects, making the vaccine acceptable to implementation stakeholders. In addition, implementation of administration of the Moderna COVID-19 vaccine is feasible. Although the vaccine requires a freezer (-20°C [-4°F]) for long-term storage, it is stable at refrigerator temperatures (2-8°C [35-46°F]) for up to 30 days after thawing. This characteristic will facilitate feasibility of administration of the Moderna COVID-19 vaccine in most community settings, once supply allows. Advancing health equity, however, will require efforts to identify and reduce access-related barriers to vaccination, as well as engagement with community organizations and leaders among groups who experience disproportionate COVID-19-related morbidity and mortality, and to

expand access to clear and accurate information on COVID-19 vaccines (10). The GRADE evidence profile and supporting evidence for the EtR Framework are available at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine.html and https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-etr.html.

Before vaccination, the EUA Fact Sheet (11) should be provided to recipients and caregivers. Providers should counsel Moderna COVID-19 vaccine recipients about expected local and systemic reactogenicity. The Moderna COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products; the safety and efficacy of a mixed-product series have not been evaluated. ACIP does not state a product preference; a person may receive any recommended COVID-19 vaccine series. However, persons should complete the series with the same COVID-19 product they received for the first dose. Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant, immunocompromised or who have a history of severe allergic reactions) are available at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. The interim recommendation and clinical considerations are based on use of the Moderna COVID-19 vaccine under an EUA and might change as more evidence becomes available. ACIP will continue to review additional data as they become available; updates to recommendations or clinical considerations will be posted on the ACIP website (3).

Reporting of Vaccine Adverse Events

Adverse events that occur in a recipient after receipt of COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS). FDA requires that vaccination 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 COVID-19 vaccine under EUA. Reporting by anyone who gives or receives a COVID-19 vaccine is encouraged for any clinically significant adverse event, whether or not it is clear that a vaccine caused the adverse event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or 1-800-822-7967. In addition, CDC has developed a new, voluntary smartphonebased tool, v-safe, that uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. The CDC/v-safe call center follows up on reports to v-safe that indicate a medically significant health impact to collect additional information for completion of a VAERS report. Information on v-safe is available at https:// www.cdc.gov/vsafe. Information on how to use both reporting systems is included in the EUA Fact Sheet (11).

^{**} Serious adverse events are defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent disability/incapacity.

Summary

What is already known about this topic?

On December 18, 2020, the Food and Drug Administration issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 vaccine.

What is added by this report?

On December 19, 2020, after a transparent, evidence-based review of available data, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19.

What are the implications for public health practice?

Use of all COVID-19 vaccines authorized under an EUA, including the Moderna COVID-19 vaccine, should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines.

Acknowledgments

Voting members of the Advisory Committee on Immunization Practices: Robert L. Atmar, Baylor College of Medicine; Kevin A. Ault, University of Kansas Medical Center; Lynn Bahta, Minnesota Department of Health; Henry Bernstein, Zucker School of Medicine at Hofstra/Northwell Cohen Children's Medical Center; Sharon E. Frey, Saint Louis University Medical School; Paul Hunter, City of Milwaukee Health Department; Veronica V. McNally, Franny Strong Foundation; Katherine A. Poehling, Wake Forest School of Medicine; Pablo J. Sánchez, The Research Institute at Nationwide Children's Hospital; Peter Szilagyi, University of California, Los Angeles. Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group: Edward Belongia, Center for Clinical Epidemiology & Population Health, Marshfield Clinic Research Institute; Dayna Bowen Matthew, George Washington University Law School; Oliver Brooks, National Medical Association; Matthew Daley, Institute for Health Research, Kaiser Permanente Colorado; Jillian Doss-Walker, Indian Health Service; Marci Drees, Society for Healthcare Epidemiology of America; Jeffrey Duchin, Infectious Diseases Society of America; Doran Fink, Food and Drug Administration; Sandra Fryhofer, American Medical Association; Jason M. Goldman, American College of Physicians; Michael Hogue, American Pharmacists Association; Denise Jamieson, American College of Obstetricians and Gynecologists; Jeffery Kelman, Centers for Medicare & Medicaid; David Kim, U.S. Department of Health and Human Services; Kathy Kinlaw, Center for Ethics, Emory University; Susan Lett, Council of State and Territorial Epidemiologists; Kendra McMillan, American Nurses Association; Kathleen Neuzil, Center for Vaccine Development and Global Health, University of Maryland School of Medicine; Sean O'Leary, American Academy of Pediatrics; Christine Oshansky, Biomedical Advanced Research and Development Authority; Stanley Perlman, Department of Microbiology and Immunology, University of Iowa; Marcus Plescia, Association of State and Territorial Health Officials; Chris Roberts, National Institutes of Health; William Schaffner,

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

Corresponding author: Sara E. Oliver, yxo4@cdc.gov.

¹CDC COVID-19 Response Team; ²Epidemic Intelligence Service, CDC; ³General Dynamics Information Technology, Falls Church, Virginia; ⁴University of Arizona, College of Medicine, Phoenix, Arizona; ⁵Department of Health Research Methods, Evidence, and Impact, Hamilton, Ontario, Canada; ⁶Arkansas Department of Health; ⁷Vanderbilt University School of Medicine, Nashville, Tennessee; ⁸Stanford University School of Medicine, Stanford, California; ⁹University of Washington, Seattle, Washington.

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.

References

- Food and Drug Administration. Moderna COVID-19 vaccine Emergency Use Authorization. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/Moderna-covid-19-vaccine
- Food and Drug Administration. Pfizer COVID-19 vaccine Emergency Use Authorization. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www. fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine
- Advisory Committee on Immunization Practices. COVID-19 ACIP Vaccine Recommendations. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
- Advisory Committee on Immunization Practices. ACIP meeting information. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/vaccines/acip/meetings/index.html
- Advisory Committee on Immunization Practices. Advisory Committee on Immunization Practices (ACIP): GRADE (grading of recommendations, assessment, development and evaluation). Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/ vaccines/acip/recs/grade
- 6. Vaccines and Related Biological Products Advisory Committee. Vaccines and Related Biological Products Advisory Committee December 17, 2020, meeting: sponsor briefing document. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144452/download
- Vaccines and Related Biological Products Advisory Committee. Vaccines and Related Biological Products Advisory Committee December 17, 2020, meeting: sponsor briefing document addendum. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144453/download
- 8. Vaccines and Related Biological Products Advisory Committee. Vaccines and Related Biological Products Advisory Committee December 17, 2020, meeting: FDA briefing document. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144434/download

Morbidity and Mortality Weekly Report

- Vaccines and Related Biological Products Advisory Committee December 17, 2020 meeting presentation: FDA review of efficacy and safety of Moderna COVID-19 vaccine EUA. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144585/download
- McClung N, Chamberland M, Kinlaw K, et al. The Advisory Committee on Immunization Practices' ethical principles for allocating initial supplies of COVID-19 vaccine—United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1782–6. PMID:33237895 https://doi. org/10.15585/mmwr.mm6947e3
- 11. Food and Drug Administration. Fact sheet for recipients and caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in individuals 18 years of age and older. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/media/144638/download

The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020

Kathleen Dooling, MD¹; Mona Marin, MD¹; Megan Wallace, DrPH^{1,2}; Nancy McClung, PhD¹; Mary Chamberland, MD^{1,3}; Grace M. Lee, MD⁴; H. Keipp Talbot, MD⁵; José R. Romero, MD⁶; Beth P. Bell, MD⁷; Sara E. Oliver, MD¹

On December 22, 2020, this report was posted as an MMWR Early Release on the MMWR website (https://www.cdc.gov/mmwr).

The first vaccines for prevention of coronavirus disease 2019 (COVID-19) in the United States were authorized for emergency use by the Food and Drug Administration (FDA) (1) and recommended by the Advisory Committee on Immunization Practices (ACIP) in December 2020.* However, demand for COVID-19 vaccines is expected to exceed supply during the first months of the national COVID-19 vaccination program. ACIP advises CDC on population groups and circumstances for vaccine use.† On December 1, ACIP recommended that 1) health care personnel[§] and 2) residents of long-term care facilities be offered COVID-19 vaccination first, in Phase 1a of the vaccination program (2). On December 20, 2020, ACIP recommended that in Phase 1b, vaccine should be offered to persons aged ≥75 years and frontline essential workers (non-health care workers), and that in Phase 1c, persons aged 65-74 years, persons aged 16-64 years with high-risk medical conditions, and essential workers not recommended for vaccination in Phase 1b should be offered vaccine.** These recommendations for phased allocation provide guidance for federal, state, and local jurisdictions while vaccine supply is limited. In its deliberations, ACIP considered scientific evidence regarding COVID-19 epidemiology, ethical principles, and vaccination program implementation considerations. ACIP's recommendations for COVID-19 vaccine allocation are interim and might be updated based on changes in conditions of FDA Emergency Use Authorization, FDA authorization for new COVID-19 vaccines, changes in vaccine supply, or changes in COVID-19 epidemiology.

Since June 2020, ACIP has convened 10 public meetings to review evidence-based information pertaining to COVID-19 vaccines, including initial allocation of COVID-19 vaccine supplies.†† To inform policy options for ACIP, the COVID-19 Vaccines Work Group, comprising experts in infectious

diseases, vaccinology, vaccine safety, public health, and ethics, held 28 meetings to review data regarding vaccine candidates, COVID-19 surveillance, modeling of allocation scenarios, and vaccination program implementation issues. The Work Group also considered the relevant scientific literature, including ethical principles related to vaccine allocation in the setting of limited supply. Following ACIP's interim recommendation for vaccine allocation in Phase 1a (2), the Work Group proposed vaccine allocation for Phases 1b and 1c. A description of the population groups in these phases, supporting scientific data, consideration of ethical principles, and considerations for vaccination program implementation are presented in this report, and supporting evidence is available at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html.

Phase 1b

Approximately 49 million persons, including frontline essential workers (non-health care workers) and persons aged ≥75 years are recommended to receive vaccine in Phase 1b of the COVID-19 vaccination program (Table). Essential workers perform duties across critical infrastructure sectors and maintain the services and functions that U.S. residents depend on daily. The Cybersecurity and Infrastructure Security Agency (CISA) of the U.S. Department of Homeland Security has developed a list intended to guide jurisdictions in identifying essential critical infrastructure workers, who may be exempted during stay-at-home-orders (3). ACIP used CISA guidance to define frontline essential workers as the subset of essential workers likely at highest risk for work-related exposure to SARS-CoV-2, the virus that causes COVID-19, because their work-related duties must be performed on-site and involve being in close proximity (<6 feet) to the public or to coworkers. ACIP has classified the following non-health care essential workers as frontline workers: first responders (e.g., firefighters and police officers), corrections officers, food and agricultural workers, U.S. Postal Service workers, manufacturing workers, grocery store workers, public transit workers, and those who work in the education sector (teachers and support staff members) as well as child care workers. §§ A tiered approach

^{*} https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html.

[†] https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf.

[§] https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html.

[¶] https://www.cdc.gov/longtermcare/index.html.

^{**} On December 20, 2020, ACIP voted 13 to 1 in favor of the Phase 1b and 1c allocation recommendations.

^{††} https://www.cdc.gov/vaccines/acip/meetings/index.html.

^{\$\$} https://www.cdc.gov/vaccines/covid-19/categories-essential-workers.html.

TABLE. Advisory Committee on Immunization Practices recommendations for allocation of COVID-19 vaccines to persons aged \geq 16 years — United States, December 2020

	_	No. (millions)				
Phase	Groups recommended to receive COVID-19 vaccine	Total persons in each group*	Unique persons in each group [†]	Unique persons in each phase		
1a	Health care personnel Long-term care facility residents	21 3	21 3	24		
1b	Frontline essential workers [§] Persons aged ≥75 years	30 21	30 19	49		
1c	Persons aged 65–74 years Persons aged 16–64 years [¶] with high-risk medical conditions	32 110	28 81	129		
	Essential workers [§] not recommended for vaccination in Phase 1b	57	20			
2	All persons aged ≥16 years¶ not previously recommended for vaccination	All remaining	All remaining	All remaining		

Abbreviation: COVID-19 = coronavirus disease 2019.

 ¶ As of December 18, only the Pfizer-BioNTech COVID-19 vaccine is authorized for use in persons aged 16–17 years.

for essential workers builds on the occupations identified by the National Academies of Science, Engineering and Medicine for early vaccination (4).

Although there is no national surveillance for COVID-19 among frontline or other essential workers, reports of high incidence and outbreaks within multiple critical infrastructure sectors illustrate the COVID-19 risk in these populations and the disproportionate impact of COVID-19 on workers who belong to racial and ethnic minority groups. During March-June, for example, the Utah Department of Heath reported 1,389 COVID-19 cases associated with workplace outbreaks in 15 industry sectors, accounting for 12% of all COVID-19 cases in Utah during the same period (5). In addition, despite representing 24% of Utah workers in all affected sectors, Hispanic and non-White workers accounted for 73% of COVID-19 cases in workplace-associated outbreaks (5). Among 23 states reporting COVID-19 outbreaks in meat and poultry processing facilities during April and May, 16,233 outbreak-associated cases were reported from 239 facilities, including 86 COVID-19-related deaths (6). The percentage of workers with COVID-19 ranged from 3% to 25% per facility, and among cases with information on race and ethnicity reported, 87% occurred among workers from racial or ethnic minority groups (6).

Persons aged ≥75 years are at high risk for COVID-19—associated morbidity and mortality. As of December 20, 2020, the cumulative incidence [¶] of COVID-19 among persons in this

age group was 3,839 per 100,000 persons, with a cumulative hospitalization rate of 1,211 per 100,000, and a mortality rate of 719 per 100,000 (*7*–*9*). The overall proportion of persons aged ≥75 years who live in a multigenerational household is 6%; the proportion among non-Hispanic White persons is 4%, and the proportion among racial or ethnic minority groups is higher (non-Hispanic Black persons, 10%; Hispanic or Latino persons, 18%; non-Hispanic persons of other races, 20%).***

Phase 1c

In Phase 1c, vaccine should be offered to persons aged 65–74 years, persons aged 16–64 years^{†††} with medical conditions that increase the risk for severe COVID-19, and essential workers not previously included in Phase 1a or 1b. Approximately 129 million persons are included in Phase 1c (Table), accounting for the overlap between groups in Phase 1c and earlier phases; for example, some adults aged 65–74 years reside in long-term care facilities, and many essential workers have high-risk medical conditions. Persons aged 65–74 years are at high risk for COVID-19–associated morbidity and mortality. As of December 20, 2020, the cumulative COVID-19 incidence in this age group was 3,109 per 100,000 persons,

^{*} Data sources for each group: health care personnel (American Community Survey, 2019; https://www.census.gov/programs-surveys/acs/data.html); long-term care facility residents (Minimum Data Set. Centers for Medicare & Medicaid Services; https://data.cms.gov/); frontline and other essential workers (American Community Survey, 2019; https://www.census.gov/programs-surveys/acs/data.html); age-specific groups (U.S. Census; https://data.census.gov/cedsci/); high-risk medical conditions (Behavioral Risk Factors Surveillance System, 2018; https://www.cdc.gov/brfss/annual_data/annual_data.htm).

[†] Excludes persons who were recommended to receive vaccine in an earlier phase (e.g., persons aged 65–74 years who are living in long-term care facilities or who are health care personnel, who would have been included in Phase 1a) and accounting for overlap between groups within the same phase (e.g., essential workers with high risk medical conditions).

[§] Estimates for frontline and other essential workers are approximate and derived from prepandemic survey data; relative proportions will vary by state.

⁵⁵ Incidences were calculated using age-specific population denominators from the U.S. Census. https://www.census.gov/data.html.

^{***} Data from the U.S. Census Bureau 2019 American Community Survey 1-Year Public Use Microdata Samples [CSV file]. https://www2.census.gov/programs-surveys/acs/data/pums/2019/1-Year/. Accessed December 16, 2020.

^{†††} As of December 18, 2020, two COVID-19 vaccines have been authorized for use under an Emergency Use Authorization (EUA), but only the Pfizer-BioNTech COVID-19 vaccine is authorized for use in persons aged 16–17 years.

with a cumulative hospitalization rate of 642 per 100,000, and a mortality rate of 188 per 100,000 (*7–9*).

Based on ongoing review of the literature, CDC has identified medical conditions or risk behaviors that are associated with increased risk for severe COVID-19. SSS The risk for COVID-19-associated hospitalization increases with the number of high-risk medical conditions, from 2.5 times the risk for hospitalization for persons with one condition to 5 times the risk for those with three or more conditions (10). According to a recent analysis of 2018 Behavioral Risk Factor Surveillance System data, ^{\$55} at least 56% of persons aged 18–64 years report at least one high-risk medical condition (CDC COVID-19 Response Team, Division of Population Health, personal communication, December 2020). Essential worker sectors recommended for vaccination in Phase 1c include those in transportation and logistics, water and wastewater, food service, shelter and housing (e.g., construction), finance (e.g., bank tellers), information technology and communications, energy, legal, media, public safety (e.g., engineers), and public health workers.****

ACIP's ethical principles for allocating initial supplies of COVID-19 vaccine, namely, to maximize benefits and minimize harms, promote justice, and mitigate health inequities (11), support the allocation scheme for Phases 1b and 1c. Allocation of COVID-19 vaccine to essential workers and persons at increased risk for severe COVID-19 disease balances the vaccination program priorities of minimizing societal disruption and preventing morbidity and mortality. Essential workers constitute a large and heterogenous group. Allocation of vaccine to frontline essential workers in Phase 1b acknowledges their increased risk for occupational exposure compared with other essential worker categories, as well as the

Summary

What is already known about this topic?

On December 1, the Advisory Committee on Immunization Practices (ACIP) recommended that health care personnel and long-term care facility residents be offered COVID-19 vaccination first (Phase 1a).

What is added by this report?

On December 20, ACIP updated interim vaccine allocation recommendations. In Phase 1b, COVID-19 vaccine should be offered to persons aged ≥75 years and non-health care frontline essential workers, and in Phase 1c, to persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b.

What are the implications for public health practice?

Federal, state, and local jurisdictions should use this guidance for COVID-19 vaccination program planning and implementation.

benefits to society of maintaining these essential functions. Allocation to persons aged ≥75 years is supported by their high risk for COVID-19—associated morbidity and mortality and is anticipated to also reduce hospitalizations in this group, easing the burden on strained health care systems. Populations included in Phase 1c are either at an increased risk for severe COVID-19 compared with the general population or support ongoing critical infrastructure operations. In addition, certain essential worker groups have high proportions of some racial and ethnic minority groups who have experienced disproportionate COVID-19 incidence, morbidity, and mortality (12).

Implementing vaccination programs to reach essential workers will pose challenges. Use of multiple strategies is recommended to reduce barriers to vaccination, †††† such as providing vaccination opportunities at or close to the workplace. State and local health authorities will need to take local COVID-19 epidemiology and demand for vaccine into account when deciding to proceed to the next phase or to subprioritize within an allocation phase if necessary. A flexible approach to allocation will facilitate efficient management and ensure that COVID-19 vaccine is administered equitably and without delay. Additional interim considerations for phased implementation of COVID-19 vaccines are available at https://www.cdc.gov/vaccines/covid-19/initial-populations.html and https://www.cdc.gov/vaccines/covid-19/phased-implementation.html.

Phase 2

Phase 2 includes all other persons aged ≥16 years not already recommended for vaccination in Phases 1a, 1b, or 1c. Currently, in accordance with recommended age and conditions of use (1),

SSS Adults of any age with the following conditions are at increased risk for severe COVID-19-associated illness: cancer; chronic kidney disease; chronic obstructive pulmonary disease (COPD); heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies; immunocompromised state (weakened immune system) from solid organ transplant; obesity (body mass index [BMI] ≥30 kg/m² but <40 kg/m²); severe obesity (BMI ≥40 kg/m²); sickle cell disease; smoking; type 2 diabetes mellitus; and pregnancy. No data are currently available on the safety of COVID-19 vaccines in pregnant persons. If pregnant persons are part of a group that is recommended to receive a COVID-19 vaccine (e.g., health care personnel or essential worker), they may choose to be vaccinated. A conversation between the patient and the patient's clinical team might assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19. Guidance for pregnant persons will be updated as new data becomes available at https://www.cdc.gov/vaccines/covid-19/ info-by-product/clinical-considerations.html. The list of high-risk medical conditions is updated routinely as new data becomes available at https:// www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-withmedical-conditions.html.

fff https://www.cdc.gov/brfss/annual_data/annual_data.htm.

^{****} Certain occupations in Phase 1b might be related to sectors listed in Phase 1c (public transit [transportation and logistics], grocery store workers [food services], and corrections workers [public safety]).

^{†††††} COVID-19 Vaccination Communication Toolkit. https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html.

any authorized COVID-19 vaccine may be used. ACIP is closely monitoring clinical trials in children and adolescents and will consider recommendations for use when a COVID-19 vaccine is authorized for use in persons aged <16 years.

Acknowledgments

Voting members of the Advisory Committee on Immunization Practices: Robert L. Atmar, Baylor College of Medicine; Kevin A. Ault, University of Kansas Medical Center; Lynn Bahta, Minnesota Department of Health; Henry Bernstein, Zucker School of Medicine at Hofstra/Northwell Cohen Children's Medical Center; Sharon E. Frey, Saint Louis University Medical School; Paul Hunter, City of Milwaukee Health Department; Veronica V. McNally, Franny Strong Foundation; Katherine A. Poehling, Wake Forest School of Medicine; Pablo J. Sanchez, The Research Institute at Nationwide Children's Hospital; Peter Szilagyi, University of California, Los Angeles. Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group: Edward Belongia, Center for Clinical Epidemiology & Population Health, Marshfield Clinic Research Institute; Dayna Bowen Matthew, George Washington University Law School; Oliver Brooks, National Medical Association; Matthew Daley, Institute for Health Research, Kaiser Permanente Colorado; Jillian Doss-Walker, Indian Health Service; Marci Drees, Society for Healthcare Epidemiology of America; Jeffrey Duchin, Infectious Diseases Society of America; Doran Fink, Food and Drug Administration; Sandra Fryhofer, American Medical Association; Jason M. Goldman, American College of Physicians; Michael Hogue, American Pharmacists Association; Denise Jamieson, American College of Obstetricians and Gynecologists; Jeffery Kelman, Centers for Medicare & Medicaid; David Kim, U.S. Department of Health and Human Services; Kathy Kinlaw, Center for Ethics, Emory University; Susan Lett, Council of State and Territorial Epidemiologists; Kendra McMillan, American Nurses Association; Kathleen Neuzil, Center for Vaccine Development and Global Health, University of Maryland School of Medicine; Sean O'Leary, American Academy of Pediatrics; Christine Oshansky, Biomedical Advanced Research and Development Authority; Stanley Perlman, Department of Microbiology and Immunology, University of Iowa; Marcus Plescia, Association of State and Territorial Health Officials; Chris Roberts, National Institutes of Health; William Schaffner, National Foundation for Infectious Diseases; Rob Schechter, Association of Immunization Managers; Kenneth Schmader, American Geriatrics Society; Bryan Schumacher, Department of Defense; Jonathan Temte, American Academy of Family Physicians; Matthew Tunis, National Advisory Committee on Immunization Secretariat, Public Health Agency of Canada; Thomas Weiser, Indian Health Service; Matt Zahn, National Association of County and City Health Officials; Rachel Zhang, Food and Drug Administration.

Corresponding author: Kathleen Dooling, vic9@cdc.gov.

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.

References

- Food and Drug Administration. COVID-19 vaccines. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2020. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' interim recommendation for allocating initial supplies of COVID-19 vaccine—United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1857–9. PMID:33301429 https://doi.org/10.15585/mmwr.mm6949e1
- Cybersecurity and Infrastructure Security Agency. Guidance on essential critical infrastructure workers: version 4.0. Washington, DC: US Department of Homeland Security, Cybersecurity and Infrastructure Security Agency; 2020. https://www.cisa.gov/publication/ guidance-essential-critical-infrastructure-workforce
- 4. National Academies of Sciences, Engineering, and Medicine. Framework for equitable allocation of COVID-19 vaccine. Washington, DC: National Academies of Sciences, Engineering, and Medicine; 2020. https://www. nationalacademies.org/our-work/a-framework-for-equitable-allocationof-vaccine-for-the-novel-coronavirus#sectionPublications
- Bui DP, McCaffrey K, Friedrichs M, et al. Racial and ethnic disparities among COVID-19 cases in workplace outbreaks by industry sector— Utah, March 6–June 5, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1133–8. PMID:32817604 https://doi.org/10.15585/mmwr. mm6933e3
- Waltenburg MA, Victoroff T, Rose CE, et al.; COVID-19 Response Team. Update: COVID-19 among workers in meat and poultry processing facilities—United States, April–May 2020. MMWR Morb Mortal Wkly Rep 2020;69:887–92. PMID:32644986 https://doi. org/10.15585/mmwr.mm6927e2
- CĎC. Coronavirus disease 2019 (COVID-19): CDC COVID data tracker. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://covid.cdc.gov/covid-data-tracker
- 8. CDC. COVID-NET: laboratory-confirmed COVID-19-associated hospitalizations. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://gis.cdc.gov/grasp/COVIDNet/COVID19 3.html
- CDC. Weekly updates by select demographic and geographic characteristics: provisional death counts for coronavirus disease 2019 (COVID-19). Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/nchs/nvss/vsrr/covid_ weekly/index.htm#AgeAndSex
- Ko J, Danielson M, Town M, et al. Risk factors for coronavirus disease 2019 (COVID-19)—associated hospitalization: COVID-19—Associated Hospitalization Surveillance Network and Behavioral Risk Factor Surveillance System. Clin Infect Dis 2020. E-pub September 18, 2020. PMID:32945846 https://doi.org/10.1093/cid/ciaa1419
- McClung N, Chamberland M, Kinlaw K, et al. The Advisory Committee on Immunization Practices' ethical principles for allocating initial supplies of COVID-19 vaccine—United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1782–6. PMID:33237895 https://doi. org/10.15585/mmwr.mm6947e3
- CDC. COVIDView: a weekly surveillance summary of U.S. COVID-19 activity. Atlanta, GA: US Department of Health and Human Services, CDC; 2020. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/ covidview/index.html

¹CDC COVID-19 Response Team; ²Epidemic Intelligence Service, CDC; ³General Dynamics Information Technology, Falls Church, Virginia; ⁴Stanford University School of Medicine, Stanford, California; ⁵Vanderbilt University School of Medicine, Nashville, Tennessee; ⁶Arkansas Department of Health; ⁷University of Washington, Seattle, Washington.

Erratum

Vol. 69, No. 39

In the report, "COVID-19 Trends Among School-Aged Children — United States, March 1-September 19, 2020," the percentage of school-aged children with underlying conditions was calculated using school-aged children for whom one or more underlying conditions was reported as the denominator. Information on underlying conditions is not reported for the vast majority (approximately 80%) of school-aged children included in CDC's National Notifiable Diseases Surveillance System, so using the total population as the denominator to calculate the percent of children with underlying conditions would substantially underestimate the prevalence of underlying conditions. To correct this, the percentage of school-aged children with underlying conditions was recalculated using school-aged children for whom underlying condition status was known as the denominator (i.e., a "yes" or "no" on case report form, excluding "unknown" and no information).

On page 1410, in the first paragraph, the seventh sentence should have read "Underlying conditions were more common among school-aged children with severe outcomes related to COVID-19: among school-aged children who were hospitalized, admitted to an intensive care unit (ICU), or who died, 23%, 38%, and 33%, respectively, had at least one underlying condition.

On page 1412, in the second column, the first paragraph should have read "Among school-aged children with COVID-19, data about underlying conditions were reported for 59,851 (22%). At least one underlying condition was reported for 17,319 (29%) of those with known underlying condition status, including 11,333 adolescents and 5,986 younger children. Among those with reported data about underlying conditions, chronic lung disease, including asthma, was most commonly reported (7%), followed by disability^{†††} (1%), immunosuppressive conditions (0.9%), diabetes (0.8%), psychological conditions (0.7%), cardiovascular disease (0.6%), and severe obesity (0.5%). At least one underlying condition was reported for 23% of school-aged children who were hospitalized for COVID-19, 38% of those admitted to an ICU, and 33% of those who died."

On page 1412, there were multiple errors in the Table for the "Underlying conditions" section. Corrections to Table footnotes are bolded. The corrected Table is as follows:

TABLE. Demographic characteristics and underlying conditions among school-aged children aged 5–11 years and 12–17 years* with positive test results for SARS-CoV-2 (N = 233,474) — United States, March 1–September 19, 2020

		Age group, no. (%)	
Characteristic	All (N = 277,285)	5–11 yrs (n = 101,503)	12–17 yrs (n = 175,782)
Sex [†]			
Female	140,755 (50.8)	50,096 (49.4)	90,659 (51.6)
Male	136,530 (49.2)	51,407 (50.6)	85,123 (48.4)
Median age, yrs	13	8	15
Symptom status			
Yes	161,751 (58.3)	56,917 (56.1)	104,834 (59.6)
No	12,806 (4.6)	5,985 (5.9)	6,821 (3.9)
Missing/Unknown	102,728 (37.0)	38,601 (38.0)	64,127 (36.5)
Race/Ethnicity§			
Hispanic/Latino	67,275 (41.7)	27,539 (45.9)	39,736 (39.2)
White, non-Hispanic	52,229 (32.4)	15,503 (25.8)	36,726 (36.2)
Black, non-Hispanic	27,963 (17.3)	11,315 (18.8)	16,648 (16.4)
A/PI, non-Hispanic	4,541 (2.8)	1,932 (3.2)	2,609 (2.6)
AI/AN, non-Hispanic	3,044 (1.9)	1,342 (2.2)	1,702 (1.7)
Multiracial/Other race	6,335 (3.9)	2,421 (4.0)	3,914 (3.9)
Unknown [¶]	115,898 (N/A)	41,451 (N/A)	74,447 (N/A)
Underlying conditions			
Known underlying condition status**	59,851 (21.6)	21,505 (21.2)	38,346 (21.8)
Any underlying condition	17,319 (28.9)	5,986 (27.8)	11,333 (29.6)
Chronic lung disease ^{††}	4,214 (7.0)	1,441 (6.7)	2,773 (7.2)
Disability ^{§§}	714 (1.2)	251 (1.2)	463 (1.2)
Immunosuppression	526 (0.9)	193 (0.9)	333 (0.9)
Diabetes mellitus	476 (0.8)	88 (0.4)	388 (1.0)
Psychological/psychiatric	445 (0.7)	60 (0.3)	385 (1.0)
Cardiovascular disease	363 (0.6)	128 (0.6)	235 (0.6)
Current/Former smoker ^{¶¶}	334 (0.6)	11 (0.1)	323 (0.8)
Severe obesity (BMI ≥40)	315 (0.5)	70 (0.3)	245 (0.6)
Chronic kidney disease	116 (0.2)	47 (0.2)	69 (0.2)
Hypertension	94 (0.2)	13 (0.1)	81 (0.2)
Autoimmune	87 (0.1)	16 (0.1)	71 (0.2)
Chronic liver disease	64 (0.1)	14 (0.1)	50 (0.1)
Substance abuse/use	34 (0.1)	0 (0.0)	34 (0.1)
Other***	10,907 (18.2)	4,009 (18.6)	6,898 (18.0)
Outcome			
Hospitalized ^{†††}	3,240 (1.2)	1,021 (1.0)	2,219 (1.3)
ICU admission ^{§§§}	404 (0.1)	145 (0.1)	259 (0.1)
Died ^{¶¶¶}	51 (<0.1)	20 (<0.1)	31 (<0.1)

 $\textbf{Abbreviations:} \ A/PI = A sian/Pacific \ Islander; \ AI/AN = American \ Indian/Alaska \ Native; \ BMI = body \ mass \ index; \ COVID-19 = coronavirus \ disease \ 2019; \ N/A = not \ available.$

^{*} Age was missing for 1.4% of all persons with positive test results; the proportion aged 5–17 years cannot be determined.

[†] Among **242,259** persons aged 5–17 years with COVID-19, sex was missing, unknown, or other for **8,785** (**3.6%**).

[§] Persons for whom ethnicity was missing (i.e., not reported as either "Hispanic" or "non-Hispanic") were categorized has having missing race/ethnicity.

Missing data were excluded from the denominator for calculating percentage of each racial/ethnic group. Missing rates did not differ by age group. Multiracial/other race includes persons reported as American Indian/Alaskan Native, Native Hawaiian or other Pacific Islander, multiracial, and persons of another race without further specification.

^{**} Status of underlying conditions known for 59,851 school-aged children: 21,505 aged 5–11 years and 38,346 aged 12–17 years. Status was classified as "known" if any of the following conditions were reported as present or absent: diabetes mellitus, hypertension, severe obesity (BMI ≥40 kg/m²), cardiovascular disease, chronic kidney disease, chronic liver disease, chronic lung disease, immunocompromising condition, autoimmune condition, disability, psychological/psychiatric condition, current or former smoker, substance abuse or use, and other underlying medical condition not otherwise specified. Those with known underlying condition status were used as the denominator for the remaining underlying conditions in the table.

^{††} Chronic lung disease includes asthma, emphysema, and chronic obstructive pulmonary disease (COPD).

⁵⁵ Disability includes neurologic and neurodevelopmental disorders (e.g., seizure disorders, autism spectrum disorders, and developmental delay), intellectual and physical disabilities, vision or hearing impairment, genetic disorders and inherited metabolic disorders, and blood disorders (e.g., sickle cell disease and hemophilia).

[¶] Checked the box on the case report form for either "current smoker" or "former smoker."

^{***} Other includes conditions not listed elsewhere, conditions with no specific autoimmune etiology, endocrine disorders other than diabetes (e.g., polycystic ovarian disease, hypothyroidism, and hyperthyroidism), gastrointestinal disorders (e.g., gastritis or gastresophageal reflux), obstructive sleep apnea, allergies/atopy, anemia (etiology not specified), history of cancer in remission, and other conditions that did not fall under the specified categories.

^{§\$\$} ICU admission status. 5–11 years: missing/unknown = 90,405 (89.0%); 12–17 years: missing/unknown = 154,662 (88.0%).

¹¹¹ Mortality status. 5–11 years: missing/unknown = 47,006 (46.3%); 12–17 years: missing/unknown = 83,479 (47.5%).

Errata

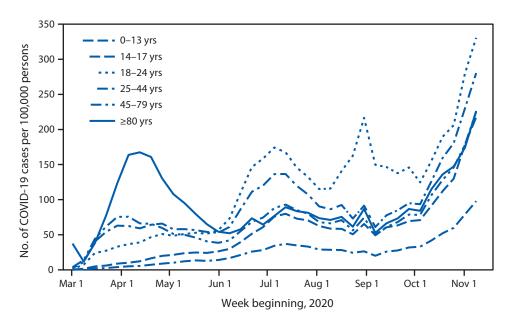
Vol. 69, No. 47

In the report "Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020," on p. 1777, the sixth footnote should have read "†† https://usafacts.org/visualizations/coronavirus-covid-19-spread-map. **Accessed August 31, 2020.**"

Vol. 62, No. RR-1

In the MMWR Recommendations and Reports "Methodology of the Youth Risk Behavior Surveillance System — 2013," the Republic of the Marshall Islands and the Republic of Palau were erroneously referred to as U.S. territories. Throughout the report, all references to "territories" should have read "territorial" should have read "territorial and freely associated state."

COVID-19 Incidence,* by Age Group[†] — United States, March 1–November 14, 2020[§]



Abbreviation: COVID-19 = coronavirus disease 2019.

During late March–late May, COVID-19 incidence was highest among adults aged ≥80 years, with a peak in incidence in the week beginning April 12. In June, incidence increased in all age groups, with the most rapid rate of increase and highest overall incidence among young adults aged 18–24 years; the rate in this group continues to be the highest among all age groups. Incidence steadily increased among children and adolescents (aged 0–17 years). The incidence in high school–aged persons (aged 14–17 years) was markedly higher than that in younger children by early July, then decreased before increasing in September. During late September–early October, weekly incidence decreased among young adults aged 18–24 years only, then continued to steadily increase among all age groups through November 14.

Source: CDC COVID-19 case-level report forms, March 1-November 14, 2020.

Reported by: Lindsey M. Duca, PhD, eocevent331@cdc.gov; Likang Xu, MD; Sandy F. Price; Catherine A. McLean, MD.

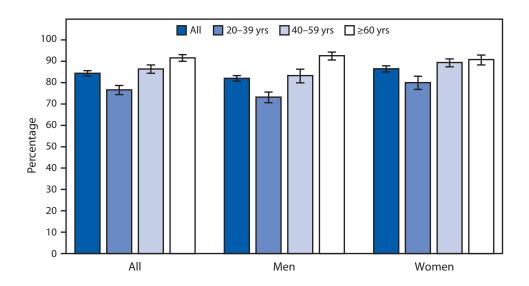
^{*} Incidence = cases per 100,000 calculated using 2019 U.S. Census population.

[†] Age data for COVID-19 cases are based on case report forms submitted by state and territorial jurisdictions for confirmed and probable cases. Reporting for some jurisdictions is incomplete. Age is missing for 1% of case reports.

[§] Data are provisional and subject to change.

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Adults Aged ≥20 Years Consuming Breakfast on a Given Day, by Sex and Age — United States, 2015–2018



^{*} Percentages are based on reporting breakfast as the eating occasion for a food or beverage during the in-person 24-hour dietary recall; 95% confidence intervals are indicated with error bars.

During 2015–2018, 84.4% of adults aged \geq 20 years consumed breakfast on a given day, with the percentage increasing with age, from 76.6% among adults aged 20–39 years, to 86.4% among adults aged 40–59 years, and 91.6% among those aged \geq 60 years. A higher percentage of women consumed breakfast compared with men among all adults \geq 20 years (86.5% versus 82.0%), those aged 20–39 years (80.0% versus 73.2%), and those aged 40–59 years (89.4% versus 83.3%). No significant differences were observed by sex for adults aged \geq 60 years (90.8% women and 92.6% men).

Source: Terry, AL, Wambogo E. National Health and Nutrition Examination Survey, Dietary Data, 2015–2018; https://www.cdc.gov/nchs/nhanes/index.htm.

Reported by: Ana Terry, MS, auc5@cdc.gov, 301-458-4227; Edwina Wambogo, PhD.

Morbidity and Mortality Weekly Report

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR* at https://www.cdc.gov/mmwr/index.html.

Readers who have difficulty accessing this PDF file may access the HTML file at https://www.cdc.gov/mmwr/index2020.html. Address all inquiries about the MMWR Series, including material to be considered for publication, to Executive Editor, MMWR Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to mmwrq@cdc.gov.

All material in the MMWR Series is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated. MMWR and Morbidity and Mortality Weekly Report are service marks of the U.S. Department of Health and Human Services.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to MMWR readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in MMWR were current as of the date of publication.

ISSN: 0149-2195 (Print)