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COVID-19 Self-Test Data: Challenges and Opportunities — United States, October 31, 2021–June 11, 2022

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Self-tests* to detect current infection with SARS-CoV-2, the virus that causes COVID-19, are valuable tools that guide individual decision-making and risk reduction† (*1*–*3*). Increased self-test use (*4*) has likely contributed to underascertainment of COVID-19 cases (*5*–*7*), because unlike the requirements to report results of laboratory-based and health care provider–administered point-of-care COVID-19 tests,§ public health authorities do not require reporting of self-test results. However, self-test instructions include a recommendation that users report results to their health care provider so that they can receive additional testing and treatment if clinically indicated.¶ In addition, multiple manufacturers of COVID-19 self-tests have developed websites or companion mobile applications for users to voluntarily report self-test result data. Federal agencies use the data reported to manufacturers, in combination with manufacturing supply chain information, to better understand self-test availability and use. This report summarizes data voluntarily reported by users of 10.7 million self-tests from four manufacturers during October 31, 2021–June 11, 2022, and compares these self-test data with data received by CDC for 361.9 million laboratory-based and point-of-care tests performed during the same period. Overall trends in reporting volume and percentage of positive results, as well as completeness of reporting demographic variables, were similar

* The first self-test was authorized by the Food and Drug Administration (FDA) for emergency use in December 2020. As of May 2022, FDA had authorized 20 self-tests (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests). Self-tests are also referred to as home tests, at-home tests, or over-the-counter tests. Self-test data reflect primarily antigen test results but can include nucleic acid amplification test (NAAT) results.

† https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

§ Laboratory-based and point-of-care NAAT and antigen test results were identified and classified based on Logical Observation Identifiers Names and Codes identifiers. Laboratory-based and point-of-care test data include NAAT results; setting type for NAAT administration cannot be distinguished based on available data. Point-of-care test result data also include antigen tests administered in settings operating under a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver. Reporting of all NAAT results is required of facilities with CLIA certification to perform moderate- or high-complexity tests; however, reporting of negative results for point-of-care antigen test results is no longer required, which might artificially inflate percent positivity calculations. https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/HHS-Laboratory-Reporting-Guidance-508.pdf

¶ As part of their Emergency Use Authorization request submission to FDA, self-test manufacturers were requested to describe how all test users could report all test results to public health and other authorities to whom reporting was required, in accordance with local, state, and federal requirements. In addition, some state and local jurisdictions also established mechanisms for persons to voluntarily report self-test results.

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across test types. However, the limited amount and quality of data reported from self-tests currently reduces their capacity to augment existing surveillance. Self-tests provide important risk-reduction information to users, and continued development of infrastructure and methods to collect and analyze data from self-tests could improve their use for surveillance during public health emergencies.

CDC analyzed COVID-19 self-test result data voluntarily reported by users of tests produced by four manufacturers** to describe available data and related metrics compared with those from COVID-19 laboratory-based and point-of-care nucleic acid amplification tests (NAATs) and point-of-care antigen tests reported by states and territories through the COVID-19 Electronic Laboratory Reporting (CELR) data system.†† Positive NAAT results are considered confirmatory laboratory evidence for SARS-CoV-2 infection, and are the main test type used to track national and local community transmission levels (*8*). Positive point-of-care antigen test results meet the case definition for probable SARS-CoV-2 infection and are used less frequently for national surveillance. Data were analyzed for tests conducted during October 31, 2021–June 11, 2022, to assess the following metrics: 1) weekly testing volume (number of test results reported); 2) 7-day average percentage of positive test results (the number of positive tests reported divided by total tests reported within a 7-day period); and 3) overall completeness of reporting of critical demographic variables (age, sex, and race or ethnicity). CDC does not receive information on patients' actual name, address, telephone number, or email for test results; however, completeness of self-test obfuscated values (i.e., the fields are coded as having information but the values [e.g., name] are not provided) was able to be assessed based on data obtained during May 25–June 3, 2022.§§ This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶¶

During October 2021–May 2022, the four manufacturers produced 393.4 million self-tests, representing 15.3% of all

** The four manufacturers send individual self-test result data voluntarily reported by customers to the Association of Public Health Laboratories Informatics Messaging Services platform via ReportStream, and deidentified versions of the data are then made available to CDC within HHS Protect. https://reportstream.cdc.gov/; https://public-data-hub-dhhs.hub.arcgis.com/

†† https://www.cdc.gov/elr/index.html

§§ CDC does not receive information on patient's actual name, address, telephone number or email for laboratory-based tests, point-of-care tests, or self-tests. Patient contact information is made available on nearly all laboratory-based test and point-of-care test results because the fields are mandated for reporting; however, these data are only made available to local and state public health agencies to support case investigations and are not included in the data sent to CDC via the COVID-19 Electronic Laboratory Reporting system. Self-test users can include personal identifiable information when they submit results to manufacturers; however, these fields are obfuscated for CDC use (i.e., the field is coded as having information but the value [e.g., name] is not provided).

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

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self-tests produced for the United States during this period.*** During October 31, 2021–June 11, 2022, users voluntarily reported results of 10,673,837 self-tests through the four manufacturers' websites or companion mobile applications compared with results of 276,257,710 laboratory-based and point-of-care NAATs and 85,670,213 point-of-care antigen tests reported through the CELR system. For all test types, the peak reported test volume occurred during the week ending January 8, 2022 (Figure 1). During the weeks ending November 6, 2021, and April 23, 2022, the volume of reported laboratory-based and point-of-care NAAT results ranged from 1,947 to 14 times that of self-reported test results, respectively. During the same period, trends in percentages of positive test results were similar across test types; the highest percentage of positive laboratory-based and point-of-care NAAT results (29.1%) and self-tests (17.3%) occurred during the week ending January 8, 2022, and for point-of-care antigen tests (19.8%), occurred during the week ending January 1, 2022 (Figure 2).

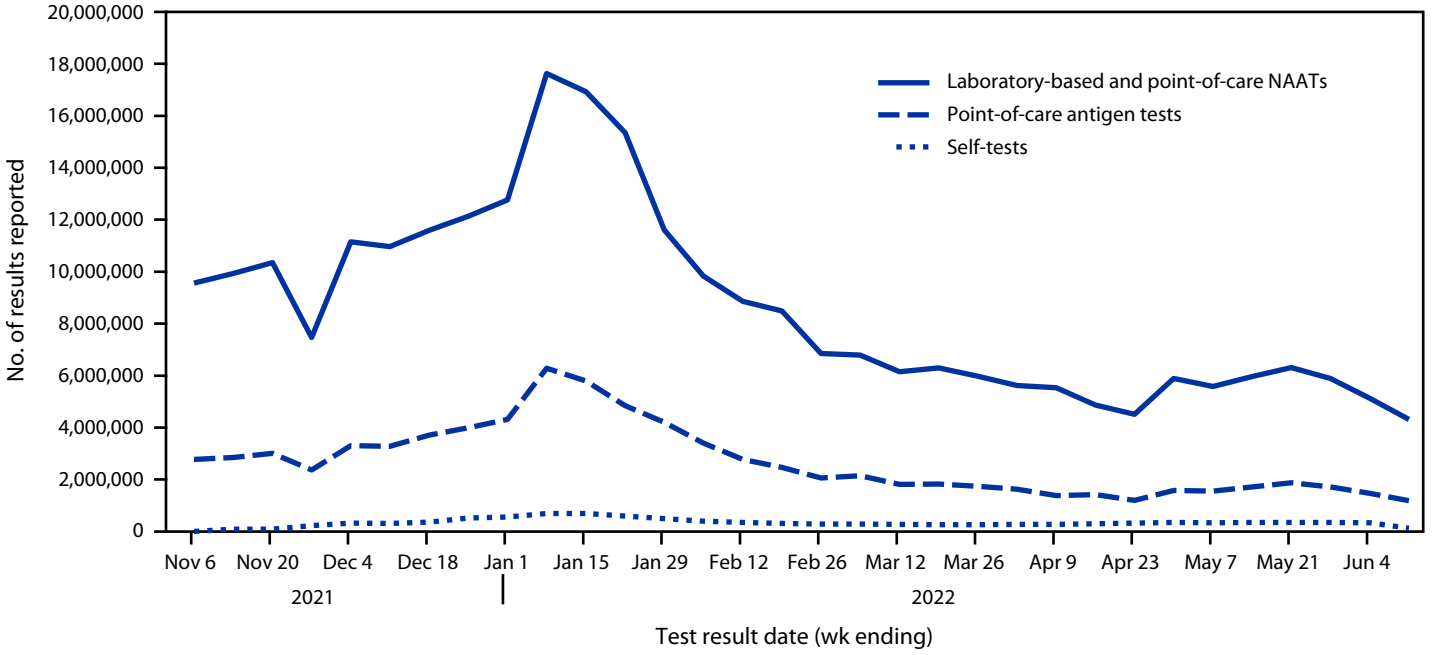
During October 31, 2021–June 11, 2022, completeness of reporting of demographic information varied across test types and was similar to, but generally higher for laboratory-based and point-of-care tests than for self-tests (Table). For self-test results reported during May 25–June 3, 2022, obfuscated values (i.e., the fields are coded as having information but the values [e.g., name] are not provided) for the customer's name (first and last) were included in 24.8% of reported self-test results, address was included in 9.8%, telephone number in 17.2%, and email address in 26.6%.

*** Data on self-test production (defined as the number of tests developed and available for U.S. distribution), overall and for the four manufacturers included in this analysis, were provided by the Office of the Assistant Secretary for Preparedness and Response. Combined monthly production totals for the four manufacturers (other manufacturers), in millions were October 2021: 22.3 (29.9); November 2021: 30.9 (81.0); December 2021: 40.6 (230.7); January 2022: 48.4 (356.8); February 2022: 65.5 (920.7); March 2022: 60.3 (358.6); April 2022: 57.4 (106.8); and May 2022: 68.0 (98.9).

Discussion

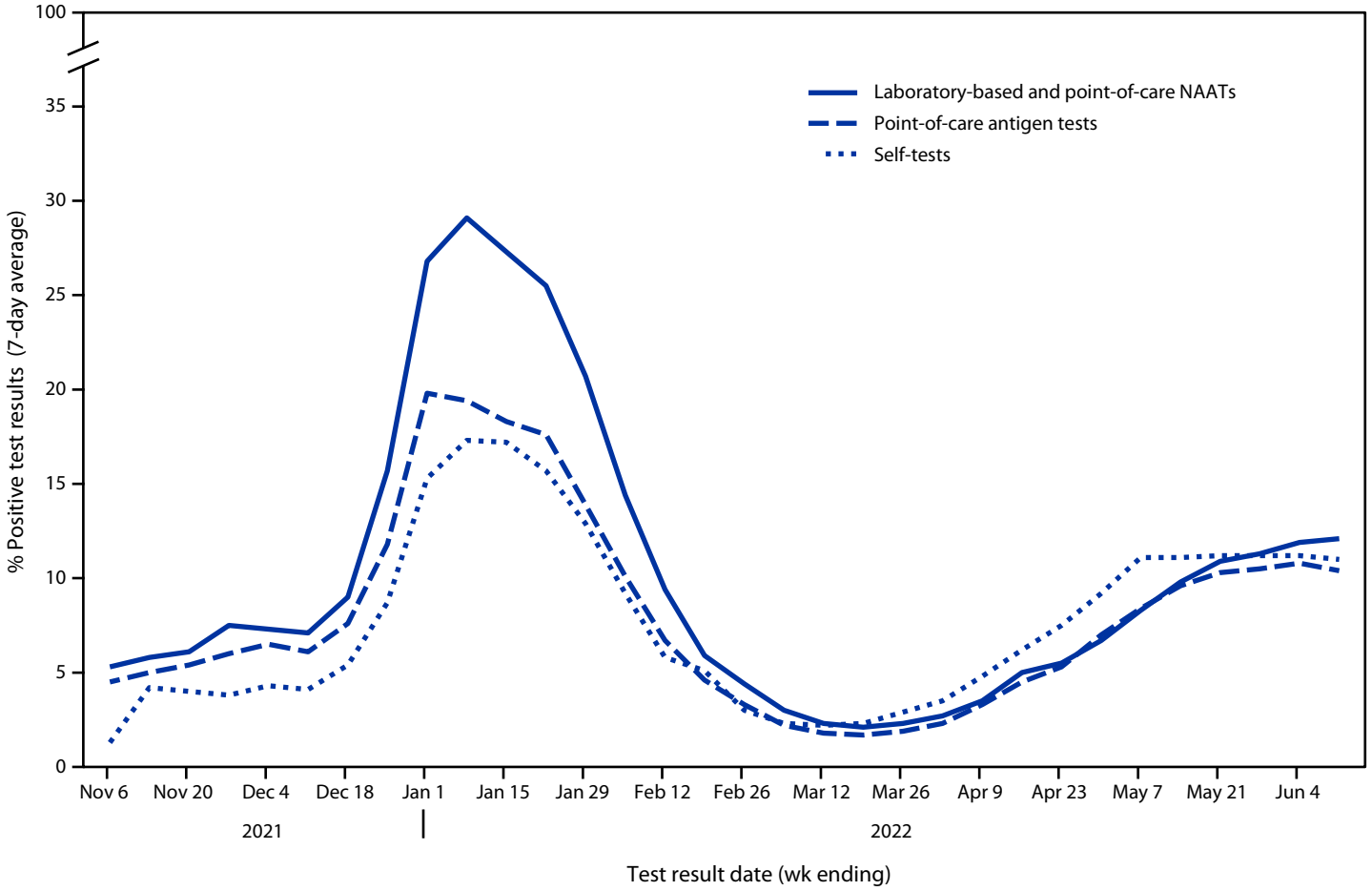
During October 2021–May 2022, approximately 393 million self-tests were produced by the four manufacturers assessed in this study. Although not all self-tests produced by these manufacturers were distributed, purchased, and used, the 10.7 million results voluntarily reported by users and made available for public health surveillance likely reflect a small fraction of the number of self-tests used. This finding indicates that throughout the COVID-19 pandemic, including during the Omicron variant surge period (December 2021–February 2022) covered by this analysis (*6*,*7*), underascertainment of cases has occurred (*5*). Underascertainment might be

FIGURE 1. Weekly number of reported results for COVID-19 self-tests,* point-of-care antigen tests, and laboratory-based and point-of-care nucleic acid amplification tests — United States, October 31, 2021–June 11, 2022



Abbreviation: NAAT = nucleic acid amplification test.
* Self-tests reflect primarily antigen test results but can include NAAT results.

FIGURE 2. Seven-day average percentage of positive test results reported for COVID-19 self-tests,* point-of-care antigen tests, and laboratory-based and point-of-care nucleic acid amplification tests — United States, October 31, 2021–June 11, 2022



Abbreviation: NAAT = nucleic acid amplification test.
* Self-tests reflect primarily antigen test results but can include NAAT results.

attributed to multiple factors, including the lack of formal mechanisms to enable reporting of self-test results to public health authorities and persons with mild or no symptoms not seeking testing or health care.

Self-tests provide another option for persons seeking accessible testing and remain an important tool to guide individual decision-making and risk reduction. Mandating reporting of all self-test results to public health authorities is not practical and could negatively affect acceptability and use of self-tests, which would be detrimental to minimizing disease spread. Although the increase in self-testing (*4*) might result in underascertainment of total case counts, this analysis indicates that the NAAT data captured via CELR, combined with case data, remain robust and continue to track trends in community transmission.[†††] In addition, persons with more severe disease are probably more likely to receive a NAAT when seeking care in outpatient or inpatient settings, and national surveillance primarily focuses on these cases. Furthermore, other types of surveillance data provide insights into aspects of disease burden such as demands on health care systems, highly or disproportionately affected populations, and severity indicators. Therefore, even without self-testing result data being formally included in national surveillance efforts, the integrated, whole-of-government surveillance activity for the COVID-19 pandemic[§§§] remains strong, incorporating data from various sources, including case surveillance, laboratory testing, syndromic surveillance, genomics testing, hospitalizations, health care use, supply chain capacities, school data, wastewater surveillance, vital statistics, and vaccination.

[†††] https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

[§§§] https://covid.cdc.gov/covid-data-tracker; https://data.cdc.gov/browse?tags = covid-19; https://www.healthdata.gov/browse?tags = hhs+covid-19

TABLE. Completeness of reporting demographic fields for COVID-19 self-test, point-of-care antigen test, and laboratory-based and point-of-care nucleic acid amplification test results — United States, October 31, 2021–June 11, 2022*

Demographic field	% of records with complete information		
	Self-tests†	Point-of-care antigen tests	Laboratory-based and point-of-care NAATs
Age	83.1	98.9	97.7
Sex	86.2	92.5	95.4
Race or ethnicity	43.0	58.4	53.2
Name (first and last)*	24.8	NA	NA
Address*	9.8	NA	NA
Telephone no.*	17.2	NA	NA
Email*	26.6	NA	NA

Abbreviations: NA = not available; NAAT = nucleic acid amplification test.

* CDC does not receive information on patient's actual name, address, telephone number, or email for laboratory-based tests, point-of-care tests, or self-tests. Patient contact information is made available on nearly all laboratory-based test and point-of-care test results because the fields are mandated for laboratory reporting; however, these data are only made available to local and state public health agencies to support case investigations and are not included in the data sent to CDC via the COVID-19 Electronic Laboratory Reporting system. Self-test users can include personal identifiable information when they submit results to manufacturers; however, these fields are obfuscated for CDC use (i.e., the field is coded as having information but the value [e.g., name] is not provided). Data for obfuscated patient contact information data elements for self-test results were only available for analysis during May 25, 2022–June 3, 2022.

† Self-tests reflect primarily antigen test results but can include NAAT results.

Current limitations in self-test data reduce their usefulness to guide public health decision-making. Cases based solely on positive self-test results do not meet national guidance for confirmed or probable cases because self-tests are not administered by Clinical Laboratory Improvement Amendments (CLIA)-certified providers (*8*). The quality of the specimen, execution of the self-test, result produced, and person tested are unverified in most instances; therefore, reported interpretation of results cannot be confirmed. Moreover, in contrast to NAATs, self-test specimens cannot be submitted for culturing and viral isolate characterization to identify or describe the prevalence of variants. Voluntary reporting is often anonymous and lacks information (e.g., telephone number) necessary for action, including deduplication, case investigation, or contact tracing. Finally, because of the similarity in trends for percentage of positive test results and demographic completeness across test types, self-test results are currently unlikely to enhance the ability to understand disease transmission trends.

Despite these limitations, public health experts need to continue evaluating self-test data to understand how they can be incorporated into future surveillance models. Additional analyses can explore several factors: how communities are using and reporting self-tests, equitable access to self-tests, what factors drive decisions to report results, and representativeness of findings; how often positive self-test results lead to isolation, pursuit of treatment, or confirmation of result with laboratory-based testing; and to what degree self-testing is replacing testing in more traditional settings.

Anticipating the potential importance of self-test data for public health and the growing demand to shift testing outside of care and to individual persons, federal agencies have been building relationships with test manufacturers to enable data transmission for public health use. For example, CDC, through partnerships with the U.S. Digital Service, the National Institutes of Health, the Administration for Strategic Preparedness and Response, and the Association of Public Health Laboratories, worked with manufacturers to advise on data to be collected and supported development of data reporting and data transportation capabilities and sharing of self-test data for broad public health use. In addition, the National Institutes of Health, through their RADx Mobile Application Reporting through Standards (MARS) program, is focusing on leveraging data standards to enhance data harmonization, capture, transmission, and reporting for self-tests for clinical and public health use.¶¶¶ Furthermore, certain

Summary

What is already known about this topic?

COVID-19 self-test use has increased but reporting of results is not required.

What is added by this report?

During October 31, 2021–June 11, 2022, 10.7 million test results were voluntarily reported by users of four manufacturers' self-tests; during that period, 361.9 million laboratory-based and point-of-care test results were reported. Completeness of reporting demographic variables and trends in percent positivity were similar across test types.

What are the implications for public health practice?

Self-tests are a valuable risk-reduction tool that can guide individual actions, but they currently offer limited utility in enhancing public health surveillance. Laboratory-based and point-of-care test result data, in combination with other COVID-19 surveillance information, continue to provide strong situational awareness.

¶¶¶ https://www.nibib.nih.gov/covid-19/radx-tech-program/mars

jurisdictions are leveraging anonymous exposure notification systems that use voluntarily reported test result information, including for self-tests, to notify close contacts of potential COVID-19 exposures.

The findings in this report are subject to at least two limitations. First, self-test data were available from only four manufacturers and from users who voluntarily reported results, representing only approximately 3% of the total self-tests produced by these manufacturers and 0.4% produced by all manufacturers during the period; therefore, these data might not be representative of all self-tests used. Second, data completeness was based on presence of any value and not valid values, and personally identifiable information assessment only captured data for a short period; therefore, estimates provided might not represent overall data quality.

Established surveillance based on NAAT testing is in place that can monitor trends in the spread and effects of COVID-19 within communities. However, during the COVID-19 pandemic, self-tests have become an important public health tool to guide individual decision-making. Persons who use self-tests should be encouraged to report results to their health care providers, who can ensure that they receive additional testing, counselling, and medical care, as clinically indicated. Limitations in currently available self-test data limit their value for present public health COVID-19 surveillance. Continued development of infrastructure and methods to collect and analyze self-test data could improve their value for surveillance purposes during future public health emergencies.

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Vital Signs: Hepatitis C Treatment Among Insured Adults — United States, 2019–2020

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On August 9, 2022, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

Abstract

Introduction: Over 2 million adults in the United States have hepatitis C virus (HCV) infection, and it contributes to approximately 14,000 deaths a year. Eight to 12 weeks of highly effective direct-acting antiviral (DAA) treatment, which can cure ≥95% of cases, is recommended for persons with hepatitis C.

Methods: Data from HealthVerity, an administrative claims and encounters database, were used to construct a cohort of adults aged 18–69 years with HCV infection diagnosed during January 30, 2019–October 31, 2020, who were continuously enrolled in insurance for ≥60 days before and ≥360 days after diagnosis (47,687). Multivariable logistic regression was used to assess the association between initiation of DAA treatment and sex, age, race, payor, and Medicaid restriction status; adjusted odds ratios (aORs) and 95% CIs were calculated.

Results: The prevalence of DAA treatment initiation within 360 days of the first positive HCV RNA test result among Medicaid, Medicare, and private insurance recipients was 23%, 28%, and 35%, respectively; among those treated, 75%, 77%, and 84%, respectively, initiated treatment within 180 days of diagnosis. Adjusted odds of treatment initiation were lower among those with Medicaid (aOR = 0.54; 95% CI = 0.51–0.57) and Medicare (aOR = 0.62; 95% CI = 0.56–0.68) than among those with private insurance. After adjusting for insurance type, treatment initiation was lowest among adults aged 18–29 and 30–39 years with Medicaid or private insurance, compared with those aged 50–59 years. Among Medicaid recipients, lower odds of treatment initiation were found among persons in states with Medicaid treatment restrictions (aOR = 0.77; 95% CI = 0.74–0.81) than among those in states without restrictions, and among persons whose race was coded as Black or African American (Black) (aOR = 0.93; 95% CI = 0.88–0.99) or other race (aOR = 0.73; 95% CI = 0.62–0.88) than those whose race was coded as White.

Conclusions and Implications for Public Health Practice: Few insured persons with diagnosed hepatitis C receive timely DAA treatment, and disparities in treatment exist. Unrestricted access to timely DAA treatment is critical to reducing viral hepatitis–related mortality, disparities, and transmission. Treatment saves lives, prevents transmission, and is cost saving.

Introduction

Despite the availability of accurate diagnostic tests and an effective cure, approximately 2.2 million civilian, noninstutionalized adults had hepatitis C virus (HCV) infection in the United States during January 2017–March 2020,[†] and incidence continues to rise, particularly among younger adults and in association with injection drug use (*1*,*2*). Untreated, hepatitis C can lead to advanced liver disease, liver cancer, and death (*3*). Hepatitis C treatment with direct-acting antiviral (DAA) agents is recommended for all persons with HCV infection with few exceptions (e.g., persons with a very limited life expectancy and children aged <3 years) (*4*).

[*] These authors contributed equally to this report.

[†] The January 2017–March 2020 estimate was obtained from the National Health and Nutrition Examination Survey (NHANES) (https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?cycle=2017-2020). The NHANES national probability sample includes the noninstitutionalized, civilian population of the United States; because it excludes certain populations known to have high hepatitis C prevalence from its sampling frame, NHANES underestimates the true prevalence of hepatitis C in the United States. During 2013–2016, researchers estimated that an additional 0.25 million persons in high-risk population groups unaccounted for by NHANES data were infected. https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates-press-release.html

Hepatitis C treatment saves lives, prevents transmission, and is cost saving (*5*–*8*). Short course, safe, well-tolerated, oral-only hepatitis C treatment results in a cure in ≥95% of cases (*9*). However, only an estimated 1.2 million persons initiated hepatitis C treatment with DAA agents in the United States during 2014–2020 (*10*), far below the number needed to achieve national hepatitis C elimination goals (*11*). Further, the number of persons treated was highest in 2015 and declined to its lowest level in 2020 (*10*); approximately 14,200 hepatitis C–related deaths were reported in the United States in 2019 (*2*). This analysis used a large national health care claims database to assess hepatitis C treatment among persons with diagnosed HCV infection by sex, age, race, insurance type (i.e., private, Medicaid, and Medicare), and by state Medicaid treatment restrictions.

Methods

Deidentified data came from HealthVerity, a nationwide administrative claims and encounters database containing longitudinal person-level enrollment records, laboratory test results, and prescription information.[§] The retrospective cohort in this study included approximately 2 million persons from all 50 states and the District of Columbia enrolled in private insurance plans, Medicare Advantage, or Medicaid managed care who had received a test for HCV infection and had ≥1 day of enrollment in either private insurance, Medicaid, or Medicare coverage (Supplementary Table, https://stacks.cdc.gov/view/cdc/119619). HealthVerity claims capture complete health care use and enrollment records across physician outpatient visits, diagnostic centers, and pharmacies. Enrollment, laboratory test, and pharmacy claims databases were linked using HealthVerity's person-level deterministic proprietary matching algorithm.

An analytic cohort of patients with hepatitis C (those who received at least one positive HCV RNA test result during January 30, 2019–October 31, 2020) was created by selecting from among patients aged 18–69 years who received any HCV test. The earliest date of receipt of a positive HCV RNA test result that occurred within the selected time frame was defined as the index HCV RNA–positive test date. Eligible persons had continuous enrollment in medical and pharmacy plans for ≥60 days before and ≥360 days after the index RNA-positive test date, and no evidence of DAA treatment during the 60 days preceding the index HCV RNA test date. Initiation of DAA treatment was defined as receipt of any prescription using the Food and Drug Administration and American Association for the Study of Liver Diseases/Infectious Diseases Society of America National Drug Codes definition.[¶] For persons with a DAA treatment pharmacy claim, the first DAA prescription date was assigned as the index DAA treatment date. The interval from the positive index RNA test result to DAA treatment date for the treatment cohort was defined as the difference between the index HCV RNA–positive test date and the index DAA prescription fill date. Initiation of DAA treatment prevalence was calculated as the percentage of eligible patients who initiated DAA treatment within 360 days of the index RNA-positive test date. The primary outcome for analysis was receipt of a DAA pharmacy claim during the 360-day follow-up period. Covariates included sex (i.e., female or male), age group (i.e., 18–29, 30–39, 40–49, 50–59, and 60–69 years), race (i.e., White, Black, Asian, or other race), and insurance type (i.e., private, Medicaid managed care, and Medicare Advantage). Ethnicity was only available for 39% of persons and was not included in the primary analyses. Medicaid treatment restrictions were defined as state Medicaid programs imposing any of three restrictions before authorization of DAA treatment: presence of liver fibrosis meeting fibrosis stage criteria, mandated sobriety or abstinence from alcohol or drugs (≥1 month), or requirement for prescription by or in consultation with a specialist. State-level Medicaid treatment restrictions data were obtained from HepVu,[**] an online platform used to visualize data and disseminate information on the U.S. hepatitis epidemic. State-level restriction was defined as the presence of one or more restrictions at the time of patient index HCV RNA–positive test date. Data were excluded from this analysis for persons who had positive HCV RNA test results but were missing sex, age, or state of residence (0.4%).

DAA treatment initiation was assessed using point estimates and 95% CIs; a Wald chi-square test of independence was used to compare baseline characteristics by treatment status. Multivariable logistic regression models were used to quantify the association between the covariates and HCV DAA treatment, adjusting for sex, age group, race, insurance type, and Medicaid treatment restrictions status; aORs and 95% CIs were calculated with $p<0.05$ considered statistically significant. Sensitivity analyses were conducted to assess potential effects of missing ethnicity data, alternative codings for race, and impact of state Medicaid treatment restrictions. Analyses were conducted using Azure Databricks (web version; Databricks) and RStudio (version 4.1; RStudio). This activity was reviewed by CDC and conducted consistent with applicable federal law and CDC policy.[††]

Results

During January 30, 2019–October 31, 2020, among 81,913 persons who had at least one positive HCV RNA test result,

[§] https://healthverity.com/solutions/healthverity-marketplace/

[¶] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

[**] https://hepvu.org/hepatitis-c-treatment-restrictions-2/

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

47,687 (58%) met inclusion criteria (Supplementary Table, https://stacks.cdc.gov/view/cdc/119619). Medicaid managed care covered 37,877 (79%) persons who had a positive HCV RNA test result (Table 1). DAA treatment initiation within 360 days of receipt of a positive HCV RNA test result among persons continuously enrolled in Medicaid, Medicare, and private insurance was 23%, 28%, and 35%, respectively (Figure 1). Among patients who received treatment, 84% of private insurance recipients initiated DAA treatment within 180 days of index HCV RNA–positive test date, compared with 75% of Medicaid and 77% of Medicare recipients.

Comparison of DAA treatment initiation by age group and insurance type showed that treatment initiation prevalence was lower among both Medicaid and private insurance recipients aged 18–29 years (17% and 23%, respectively), compared with that among these recipients aged 50–59 years (28% and 42%, respectively) (Figure 2). Compared by insurance type, the odds of DAA treatment initiation were lowest among persons aged 18–29 and 30–39 years with Medicaid (aOR = 0.52 and 0.68, respectively) and among the same age groups for those with private insurance (0.42 and 0.62, respectively), and those aged 30–39 years with Medicare (0.56), compared with persons aged 50–59 years (Table 2).

Assessment of DAA treatment initiation by race and insurance type found that among Medicaid recipients, treatment initiation was lowest among persons of other races (20%) and those missing race information (19%) (Figure 2). Among private insurance recipients, treatment initiation was higher in all race groups, but was lowest among persons with missing race information (32%). In adjusted analyses, DAA treatment initiation was similar across most racial groups, except persons with missing race information, who had a lower prevalence of DAA treatment initiation relative to White persons for all insurance types (Table 2). In addition, both Medicaid recipients who reported Black or other race had lower prevalences of treatment initiation relative to White Medicaid recipients (aOR = 0.93 and 0.73, respectively); among Medicare recipients, Asian persons had higher rates of treatment initiation relative to White persons (aOR = 1.56). Male sex was consistently associated with lower treatment initiation among Medicaid, Medicare, and private insurance recipients (aOR = 0.85, 0.79, and 0.90, respectively).

In a model including variables for sex, age group, race, and insurance type, persons with hepatitis C with Medicaid and Medicare had lower odds of initiating DAA treatment than did those with private insurance (aOR = 0.54; 95% CI = 0.51–0.57

TABLE 1. Characteristics of patients with hepatitis C,* by insurance provider — HealthVerity, United States, 2019–2020†

Characteristic	Medicaid§		Medicare¶		Private	
	No. of unique patients with HCV RNA test†	No. (%) with positive HCV RNA test result**	No. of unique patients with HCV RNA test†	No. (%) with positive HCV RNA test result**	No. of unique patients with HCV RNA test†	No. (%) with positive HCV RNA test result**
Total	**88,490**	**37,877 (42.8)**	**11,583**	**3,218 (27.8)**	**32,559**	**6,592 (20.2)**
Sex						
Female	42,585	15,812 (37.1)	4,842	1,177 (24.3)	15,270	2,384 (15.6)
Male	45,905	22,065 (48.1)	6,741	2,041 (30.3)	17,289	4,208 (24.3)
Age group, yrs						
18–29	13,735	5,690 (41.4)	97	28 (28.9)	3,918	722 (18.4)
30–39	21,734	10,674 (49.1)	449	174 (38.8)	5,208	1,140 (21.9)
40–49	14,961	6,683 (44.7)	816	269 (33.0)	5,114	1,041 (20.4)
50–59	22,335	8,909 (39.9)	2,536	696 (27.4)	9,193	1,831 (19.9)
60–69	15,725	5,921 (37.7)	7,685	2,051 (26.7)	9,096	1,858 (20.4)
Race						
White	54,009	24,374 (45.1)	6,417	1,778 (27.7)	15,378	3,276 (21.3)
Black	19,346	7,666 (39.6)	3,164	879 (27.8)	5,817	1,169 (20.1)
Asian	2,651	934 (35.2)	317	95 (30.0)	1,131	151 (13.4)
Other	2,297	841 (36.6)	281	72 (25.6)	2,059	383 (18.6)
Missing	10,187	4,062 (39.9)	1,404	394 (28.1)	8,174	1,613 (19.7)
State Medicaid treatment restrictions††						
No	44,239	17,083 (38.8)	—	—	—	—
Yes§§	44,251	20,794 (47.0)	—	—	—	—

Abbreviation: HCV = hepatitis C virus.

* Persons with hepatitis C are patients with a positive HCV RNA test result.

† Continuous enrollment in medical and pharmacy plans for ≥60 days before and ≥360 days after the RNA-positive index date during January 30, 2019–October 31, 2020.

§ Medicaid managed care.

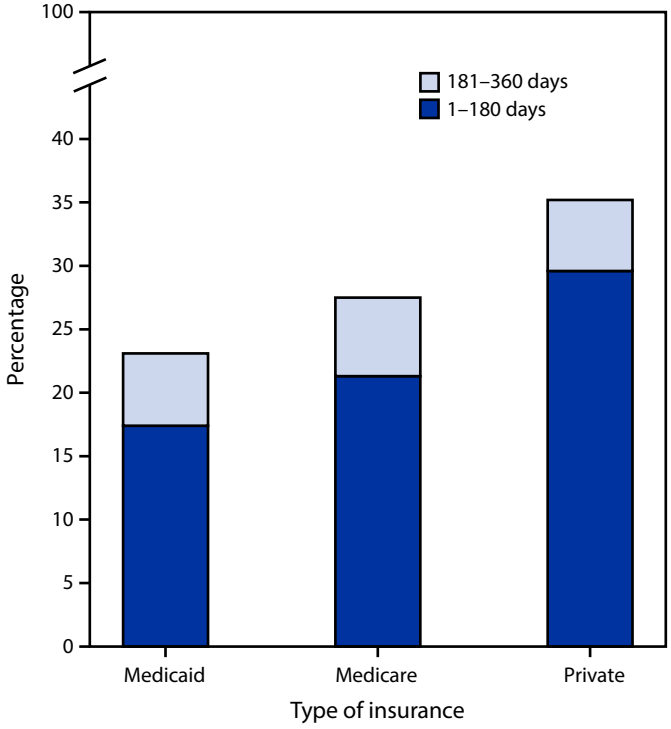
¶ Medicare Advantage programs.

** Data spans December 1, 2018–October 31, 2021. Continuous enrollment in medical and pharmacy plans for ≥60 days before and ≥360 days after the RNA-positive index date during January 30, 2019–October 31, 2020.

†† Data restricted to Medicaid recipients only.

§§ Living in a state with a Medicaid liver fibrosis or sobriety requirement (≥1 month of abstinence from alcohol or drugs) or prescriber restriction.

FIGURE 1. Percentage of adults with hepatitis C initiating direct-acting antiviral treatment within 360 days of diagnosis, by number of days after diagnosis and insurance type — United States, 2019–2020



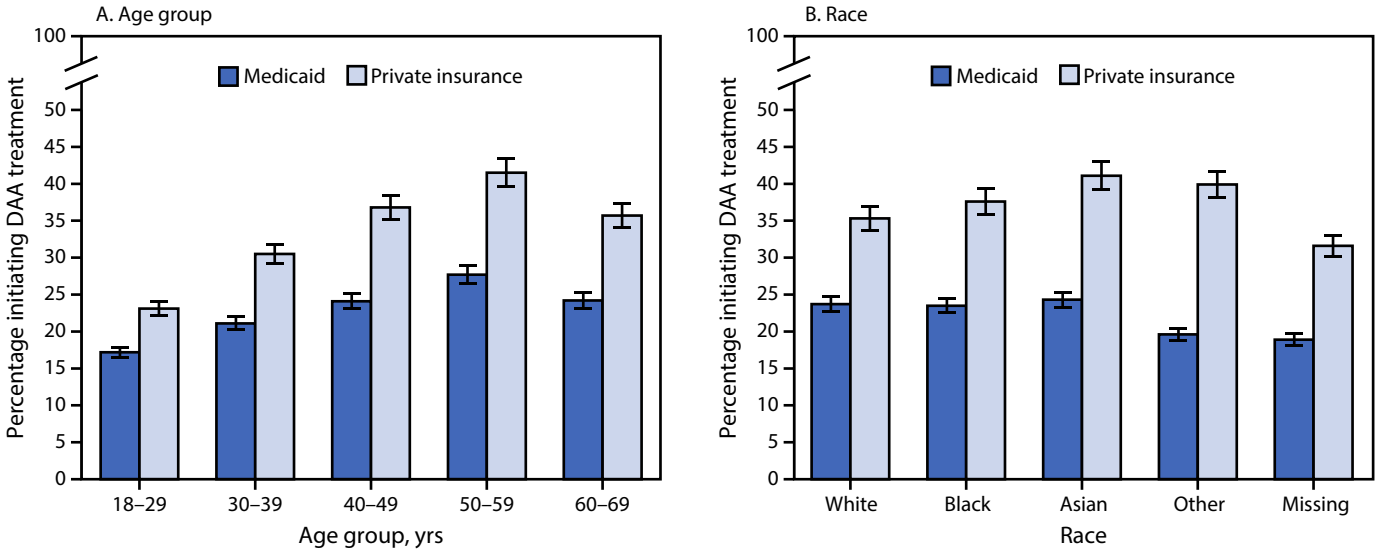
and aOR = 0.62; 95% CI = 0.56–0.68, respectively). Among Medicaid recipients, persons in states with Medicaid treatment restrictions had lower odds of receiving treatment than did those living in states without restrictions (aOR = 0.77).

Discussion

Among adults aged 18–69 years with diagnosed HCV infection and continuous insurance coverage, approximately one third of those with private insurance and one quarter of Medicaid and Medicare recipients initiated DAA treatment within 360 days of diagnosis. Highly effective DAA treatment is recommended for persons with hepatitis C (*4*) and is curative in ≥95% of cases. Treatment saves lives, prevents ongoing transmission, and is cost saving *(5–8),* yet too few persons are receiving timely treatment (*8,12–14*), which could lead to both further progression of disease for the person infected with HCV as well as ongoing transmission to other persons.

Medicaid and Medicare recipients with hepatitis C were 46% and 38% less likely, respectively, to receive timely treatment compared with those with private insurance. Further, Medicaid recipients with diagnosed hepatitis C in states with Medicaid treatment restrictions were 23% less likely to receive timely treatment than were those living in states without restrictions. Medicare provides health insurance for persons aged ≥65 years living in the United States and persons with disabilities, and Medicaid provides health insurance for eligible adults and children in low-income households. Persons with

FIGURE 2. Percentage of adults* with hepatitis C initiating direct-acting antiviral treatment, by insurance type, age group (A), and race (B) — United States, 2019–2020



Abbreviation: DAA = direct-acting antiviral.
* With 95% CIs shown by error bars.

low income experience social determinants of health that lead to negative health outcomes, including delays in timely treatment for health conditions (*14*). In general, Medicaid recipients have fewer financial resources and are more likely to be affected by social determinants of health, which further increases the likelihood of negative health outcomes associated with hepatitis C (*11*).

Although marketplace competition has reduced the net cost of DAAs, in 2014 initial costs for a course of all oral treatments exceeded $90,000, resulting in many insurers establishing restrictions to access (*14*). Current costs are considerably lower; however, Medicaid remains the least likely insurer to cover hepatitis C treatment. Treating all eligible patients without restriction would result in substantially reducing downstream negative clinical outcomes, decreasing the proportion of total costs attributable to future care, and producing considerable cost savings (14). Further, whereas hepatitis C treatment eligibility restrictions have become less stringent in some states, others maintain limitations on access to DAAs, including liver fibrosis qualifications, sobriety requirements, or medical specialist prescribing requirements. Removing these eligibility restrictions is necessary, but not sufficient. Addressing other barriers, including burdensome preauthorization requirements as well as integrating routine screening and treatment into primary care and other settings where persons with hepatitis C receive services, could also increase treatment coverage (*15*–*17*).

DAA treatment initiation was lowest among adults aged 18–29 and 30–39 years. These groups also have the highest rates of incident HCV infection, often in association with injection drug use, and the largest number of newly reported chronic infections (2). Early hepatitis C treatment prevents disease progression, limits future morbidity and mortality, and reduces health care costs by preventing cases of cirrhosis, liver transplantations, and hepatocellular carcinoma (*12*–*14*). Treatment of persons with ongoing transmission risk has important benefits beyond those to the person infected because with each successfully treated person, the number of persons able to transmit disease declines (*6*).

Medicaid recipients of other races were up to 27% less likely to initiate timely DAA treatment than White Medicaid recipients. The reasons for racial disparities in treatment initiation among continuously enrolled Medicaid recipients are unclear but might involve health system barriers associated with patient access, provider availability, quality of care, patient distrust, stigma, or language and cultural factors (*18*,*19*). The provision of culturally competent and timely hepatitis C treatment for racial and ethnic minority groups is essential to reducing existing disparities in hepatitis C–associated outcomes, including higher mortality among American Indian or Alaskan Native, Black, and Hispanic or Latino persons (8.63, 5.44, and 3.84 per 100,000 population, respectively) compared with that among White persons (3.08) (*2*,*11*,*16*,*19*).

TABLE 2. Adjusted odds* of initiation of direct-acting antiviral treatment of hepatitis C cases, by characteristic, insurance provider, and state Medicaid treatment restrictions — HealthVerity, United States, 2019–2020†

Characteristic	Multivariable aOR (95% CI)		
	Medicaid§	Medicare¶	Private
Sex			
Female	Ref	Ref	Ref
Male	0.85 (0.81–0.89)	0.79 (0.67–0.93)	0.90 (0.81–0.99)
Age group, yrs			
18–29	0.52 (0.49–0.57)	0.56 (0.21–1.50)	0.42 (0.35–0.51)
30–39	0.68 (0.64–0.73)	0.56 (0.39–0.88)	0.62 (0.53–0.73)
40–49	0.83 (0.77–0.89)	0.77 (0.56–1.07)	0.82 (0.70–0.96)
50–59	Ref	Ref	Ref
60–69	0.84 (0.79–0.91)	1.06 (0.87–1.28)	0.85 (0.80–0.90)
Race			
White	Ref	Ref	Ref
Black	0.93 (0.88–0.99)	1.03 (0.86–1.24)	1.08 (0.93–1.81)
Asian	0.99 (0.85–1.16)	1.56 (1.01–2.40)	1.30 (0.93–1.81)
Other	0.73 (0.62–0.88)	1.11 (0.67–1.89)	1.17 (0.95–1.46)
Missing	0.73 (0.67–0.79)	0.74 (0.57–0.96)	0.83 (0.73–0.95)
State Medicaid treatment restrictions**			
No	Ref	—	—
Yes††	0.77 (0.74–0.81)	—	—

Abbreviations: aOR = adjusted odds ratio; Ref = referent group.

* All models adjusted for sex, age group, and race. The Medicaid sample was also adjusted for Medicaid treatment restrictions. 95% CIs that exclude 1 were considered statistically significant.

† Continuous enrollment in medical and pharmacy plans for ≥60 days before and ≥360 days after the RNA-positive index date during January 30, 2019–October 31, 2020.

§ Medicaid managed care.

¶ Medicare Advantage programs.

** Analysis restricted to Medicaid recipients only.

†† Living in a state with a Medicaid liver fibrosis or sobriety requirement (≥1 month of abstinence from alcohol or drugs) or prescriber restrictions.

Summary

What is already known about this topic?

Direct-acting antiviral (DAA) treatment is recommended for nearly all persons with hepatitis C and cures ≥95% of cases. Treatment saves lives, prevents transmission, and is cost saving.

What is added by this report?

Treatment rates are low overall and vary by age and insurance payor. DAA treatment is lowest among young adults aged 18–29 years and Medicaid recipients, and within Medicaid, among persons reporting Black or other race and persons in states with treatment restrictions.

What are the implications for public health practice?

Timely initiation of DAA treatment, regardless of insurance type, is critical to reducing viral hepatitis–related mortality, disparities, and transmission.

Across insurance types, ≥75% of persons treated initiated treatment within the first 180 days after diagnosis. The smaller percentage of persons treated within 180 days after diagnosis might indicate lack of access to a hepatitis C treatment provider, insurance denial, or loss to follow-up. Treatment coverage can be increased by providing integrated care, patient navigation, and care coordination (*15*). The introduction of simplified hepatitis C treatment algorithms reducing the number of laboratory tests and in-person visits can facilitate patient-centered treatment (*20*).

The findings in this report are subject to at least five limitations. First, HealthVerity data might not be representative of DAA treatment patterns across the United States because of the sample characteristics of the payors and providers for whom they process data. Second, information on patients who are uninsured or incarcerated were not included; in addition, these data do not include persons who received care through the Veterans Health Administration. Third, the analytic cohort was conservatively defined, only including persons continuously enrolled for ≥60 days before and ≥360 days after the date of the positive index HCV RNA test result, which likely overestimates treatment initiation among all persons with hepatitis C HCV infection. Fourth, ethnicity data were missing for 61%, and race data for 13%, of the analytic cohort, which prevented examination of other potential treatment disparities. Finally, these data do not allow determination of whether absence of claims for treatment was the result of patient nonadherence, clinicians not prescribing DAAs, insurance providers not authorizing treatment, or prohibitive costs associated with copayments and deductibles. Further studies are needed to understand these barriers better.

Interventions to increase access to hepatitis C treatment with DAA agents include removing policies limiting patient eligibility based on fibrosis stage or sobriety, requiring treatment through specialists, and requirement for preauthorization (*11*,*17*). Universal hepatitis C screening coupled with simplified treatment protocols should be integrated into primary care and other settings serving persons with hepatitis C, and the number of primary care providers treating hepatitis C expanded, especially Medicaid providers serving populations disproportionately affected by hepatitis C. Increasing access to hepatitis C treatment to all populations, regardless of insurance type, is essential to reducing viral hepatitis–related disparities and achieving hepatitis C elimination.

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Morbidity and Mortality Weekly Report

Epidemiologic and Clinical Characteristics of Monkeypox Cases — United States, May 17–July 22, 2022

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Monkeypox, a zoonotic infection caused by an orthopoxvirus, is endemic in parts of Africa. On August 4, 2022, the U.S. Department of Health and Human Services declared the U.S. monkeypox outbreak, which began on May 17, to be a public health emergency (*1*,*2*). After detection of the first U.S. monkeypox case), CDC and health departments implemented enhanced monkeypox case detection and reporting. Among 2,891 cases reported in the United States through July 22 by 43 states, Puerto Rico, and the District of Columbia (DC), CDC received case report forms for 1,195 (41%) cases by July 27. Among these, 99% of cases were among men; among men with available information, 94% reported male-to-male sexual or close intimate contact during the 3 weeks before symptom onset. Among the 88% of cases with available data, 41% were among non-Hispanic White (White) persons, 28% among Hispanic or Latino (Hispanic) persons, and 26% among non-Hispanic Black or African American (Black) persons. Forty-two percent of persons with monkeypox with available data did not report the typical prodrome as their first symptom, and 46% reported one or more genital lesions during their illness; 41% had HIV infection. Data suggest that widespread community transmission of monkeypox has disproportionately affected gay, bisexual, and other men who have sex with men and racial and ethnic minority groups. Compared with historical reports of monkeypox in areas with endemic disease, currently reported outbreak-associated cases are less likely to have a prodrome and more likely to have genital involvement. CDC and other federal, state, and local agencies have implemented response efforts to expand testing, treatment, and vaccination. Public health efforts should prioritize gay, bisexual, and other men who have sex with men, who are currently disproportionately affected, for prevention and testing, while addressing equity, minimizing stigma, and maintaining vigilance for transmission in other populations. Clinicians should test patients with rash consistent with monkeypox,† regardless of whether the rash is disseminated or was preceded by prodrome. Likewise, although most cases to date have occurred among gay, bisexual, and other men who have sex with men, any patient with rash consistent with monkeypox should be considered for testing. CDC is continually evaluating new evidence and tailoring response strategies as information on changing case demographics, clinical characteristics, transmission, and vaccine effectiveness become available.§

On June 3, 2022, CDC released a case report form for health departments to report monkeypox cases. Data collected include possible exposures during the 3 weeks preceding symptom onset, symptoms during the illness course, and distribution of rash, defined as at least one lesion on the skin or mucous membranes. To describe epidemiologic and clinical characteristics, CDC analyzed case report form data for probable or confirmed cases¶ initially reported through July 22, 2022; to allow for reporting delay, data received through July 27 were included. Analyses were restricted to cases for which relevant data were available. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.**

During May 17–July 22, 2022, a total of 2,891 U.S. monkeypox cases were reported by 43 states, Puerto Rico, and DC; the number of reported cases increased rapidly during

* These authors contributed equally to this report.

† https://www.cdc.gov/poxvirus/monkeypox/symptoms.html

§ https://www.cdc.gov/poxvirus/monkeypox/index.html

¶ A probable case was defined as illness for which there was no suspicion of other recent orthopoxvirus exposure and one of the following: 1) detection of orthopoxvirus DNA by polymerase chain reaction testing of a clinical specimen, 2) evidence of orthopoxvirus antigen using immunohistochemical staining or visualization by electron microscopy, or 3) demonstration of detectable levels of antiorthopoxvirus immunoglobulin M antibody during the 4–56 days after rash onset. A confirmed case was defined as 1) the presence of *Monkeypox virus* DNA by polymerase chain reaction testing or Next-Generation sequencing of a clinical specimen or 2) isolation of *Monkeypox virus* in culture from a clinical specimen.

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

this time (Figure). Case report forms including, at minimum, age and gender identity were received for 1,195 (41%) cases; these cases are described in this report. Median age was 35 years (IQR = 30–41 years). Nearly all (99%) persons with case report forms available were men (cisgender and transgender) (Table 1). Among 1,054 cases for which race and ethnicity were reported, 41% occurred among White persons, 28% among Hispanic persons, and 26% among Black persons. Based on information available in case report forms, the percentage of cases among Black persons increased from 12% (29 of 248) during May 17–July 2 to 31% (247 of 806) during July 3–22, and the percentage among Hispanic persons decreased from 33% (82 of 248) to 27% (214 of 806) and among White persons from 49% (121 of 248) to 38% (307 of 806).

Among 241 cases (20%) with reported classification by health departments as being travel-associated or locally acquired, 178 (74%) were classified as locally acquired. The percentage of locally acquired cases increased from 51% (33 of 65) during May 17–July 2 to 82% (145 of 175) during July 3–22.

Among 358 (30%) men (cisgender and transgender) with information on recent sexual behaviors and gender of sex partners available, 337 (94%) reported sex or close intimate contact with a man during the 3 weeks before symptom onset; 16 (4%) reported no such contact. Among 291 men who reported information about their male sexual partners during the 3 weeks preceding symptom onset, 80 (27%) reported one partner, 113 (40%) reported two to four partners, 42 (14%) reported five to nine partners, and 56 (19%) reported 10 or more partners. Among 86 men with information reported, 33 (38%) reported group sex, defined as sex with more than two persons, at a festival, group sex event, or sex party.

The most frequently reported signs and symptoms included rash (100%), fever (63%), chills (59%), and lymphadenopathy (59%) (Table 2). Reported rectal symptoms included purulent or bloody stools (21%), rectal pain (22%), and rectal bleeding (10%). Among 291 persons with available information about their first symptoms, 58% reported at least one prodromal symptom[††]; for the 42% of patients without prodromal symptoms, illness began with a rash.

Rash was most frequently reported on the genitals (46%), arms (40%), face (38%), and legs (37%); among 718 persons with monkeypox who reported body regions with rash, 238 (33%) reported rash in one region, 126 (18%) in two regions, 98 (14%) in three regions, and 256 (36%) in four or more regions. Among 104 persons with information on the number of lesions, 88% of cases involved fewer than 50 lesions.

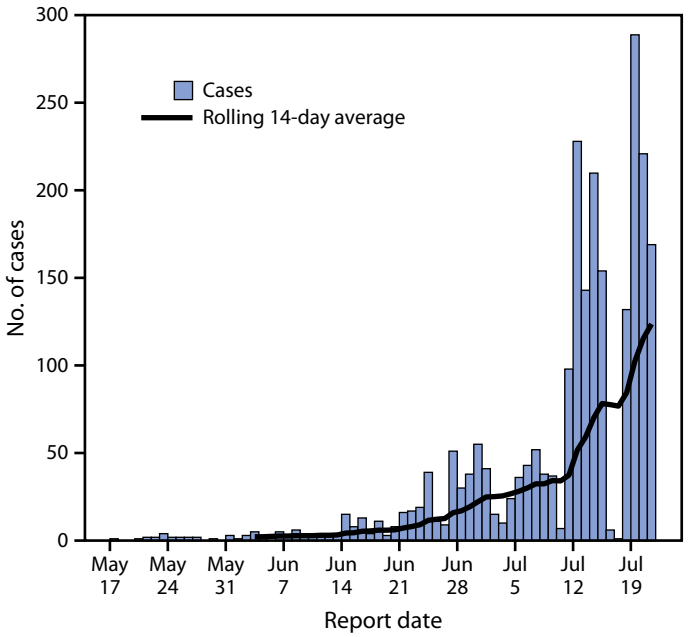
[††] Prodrome defined as at least one of the following: fever, myalgias, malaise, headaches, lymphadenopathy, or chills occurring as first symptom, not accompanied by a rash.

Among 334 persons with data available on HIV status, 136 (41%) had HIV infection. Among 954 persons with hospitalization data available, 77 (8%) patients were hospitalized because of their illness. No deaths were reported. Among 339 persons with vaccination status available, 48 (14%) reported previous receipt of smallpox vaccine, including 11 (23%) who received 1 of 2 JYNNEOS doses during the current outbreak, 11 (23%) who received pre-exposure prophylaxis at an unknown time before the current outbreak, and 26 (54%) who did not provide information about when vaccine was administered. Among the recently vaccinated persons with monkeypox, at least one experienced symptoms >3 weeks after their first JYNNEOS dose.

Discussion

Current findings indicate that community transmission of monkeypox is widespread and is disproportionately affecting gay, bisexual, and other men who have sex with men; this is consistent with data reported from other countries (*3*). Public health efforts to slow monkeypox transmission among gay, bisexual, and other men who have sex with men require addressing challenges that include homophobia, stigma, and discrimination. Although the largest proportion of cases have occurred in White persons, Black and Hispanic persons, who represent approximately one third (34%) of the general population (*4*), accounted for more than one half (54%) of

FIGURE. Monkeypox cases, by report date* — United States, May 17–July 22, 2022



* Includes either the positive laboratory test report date, CDC call center reporting date, or date of case data entry into CDC's emergency response common operating platform.

monkeypox cases in persons for whom information on race and ethnicity is available; further, the proportion of cases among Black persons has increased during recent weeks. Ensuring equity in approaches to monkeypox testing, treatment, and prevention is critical, and taking actions to minimize stigma related to monkeypox can reduce barriers to seeking care and prevention. The data presented in this report provide insights into early transmission; however, ongoing surveillance is essential to monitor future transmission trends and assess the impacts among different communities.

These data can guide clinical considerations for evaluating persons for monkeypox. Typically, monkeypox begins with a febrile prodrome, which might include malaise, chills, headache, or lymphadenopathy, followed by a disseminated rash that often includes the palms and soles (*5*). Although most cases in this report included these features, 42% of persons did not report prodromal symptoms, and 37% did not report fever by the time of interview. Genital rash, although reported in fewer than one half of cases, was common; 36% of persons developed rash in four or more body regions. Other recent reports describe similar clinical characteristics (*6*,*7*). Clinicians should be vigilant for patients with rash consistent with monkeypox, regardless of whether the rash is disseminated or was preceded by prodrome. Likewise, although most cases to date have occurred among gay, bisexual, and other men who have sex with men, any patient, regardless of sexual or gender identity, with rash consistent with monkeypox should be considered for testing because close physical contact with an infectious person or exposure to contaminated materials such as clothing or bedding can result in transmission.

A substantial proportion of monkeypox cases have been reported among persons with HIV infection, and efforts are underway to characterize monkeypox clinical outcomes among these persons. Recent reports have found that concurrent sexually transmitted infections were common in persons with monkeypox (*3*,*7*). Clinicians and health officials implementing monkeypox education, testing, and prevention efforts should also incorporate recommended interventions for other conditions occurring among gay and bisexual men, including HIV infection, sexually transmitted infections, substance use, and viral hepatitis[§§] (*8*).

On May 23, 2022, CDC launched an emergency response for monkeypox. This response includes educating providers and the public, expanding laboratory testing, outlining prevention strategies, and promoting the use of medical countermeasures for treatment and postexposure prophylaxis. CDC is supporting state, tribal, local, and territorial health departments through guidance and technical assistance. Testing capacity was rapidly expanded through CDC's Laboratory Response Network and commercial laboratories, with national capacity estimates of 80,000 tests per week by July 18.[¶¶]

Because of long-standing investments in medical countermeasures for potential smallpox events, licensed vaccines and therapeutics for monkeypox are held in the U.S. Department of Health and Human Services Strategic National Stockpile. A national vaccine strategy was developed to equitably expand vaccination in areas experiencing high numbers of monkeypox cases and contacts. Two vaccines are available in the United States.[***] As of August 3, more than 1 million doses of JYNNEOS,

Summary

What is already known about this topic?

A global monkeypox outbreak began in 2022.

What is added by this report?

Among U.S. monkeypox cases with available data, 99% occurred in men, 94% of whom reported recent male-to-male sexual or close intimate contact; racial and ethnic minority groups appear to be disproportionately affected. Clinical presentations differed from typical monkeypox, with fewer persons experiencing prodrome and more experiencing genital rashes.

What are the implications for public health practice?

Public health efforts should prioritize gay, bisexual, and other men who have sex with men, who are currently disproportionately affected, for prevention and testing, address equity, and minimize stigma, while maintaining vigilance for transmission in other populations. Clinicians should test persons with rash consistent with monkeypox, regardless of whether the rash is disseminated or was preceded by prodrome.

TABLE 1. Characteristics of persons with monkeypox — United States, May 17–July 22, 2022

Characteristic (no. with available information)	No. (%)*
Total	**1,195 (100)**
Gender identity (1,195)	
Man	1,178 (98.7)
Transgender man	3 (0.3)
Woman	5 (0.4)
Transgender woman	5 (0.4)
Prefer not to answer	4 (0.3)
Missing	0 (—)
Race and ethnicity (1,054)	
Asian, non-Hispanic	48 (4.6)
Black, non-Hispanic	276 (26.2)
White, non-Hispanic	428 (40.6)
Hispanic	296 (28.1)
Multiple races, non-Hispanic	6 (0.6)
Missing	141

* Percentages calculated using nonmissing data.

[§§] https://www.cdc.gov/msmhealth/index.htm

[¶¶] https://www.hhs.gov/about/news/2022/06/22/hhs-expanding-monkeypox-testing-capacity-five-commercial-laboratory-companies.html

[***] https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

TABLE 2. Symptoms and rash among persons with monkeypox — United States, May 17–July 22, 2022

Characteristic	Ever experienced during illness* (N = 1,007)			Initially experienced† (N = 461)		
	No. (%)§			No. (%)§		
	Yes	No	No. missing	Yes	No	No. missing
Symptoms						
Rash¶	1,004 (100.0)	0 (—)	3	121 (41.6)	170 (58.4)	170
Fever	596 (63.3)	345 (36.7)	66	120 (41.2)	171 (58.8)	170
Chills	550 (59.1)	381 (40.9)	76	48 (16.5)	243 (83.5)	170
Lymphadenopathy	545 (58.5)	387 (41.5)	75	23 (7.9)	268 (92.1)	170
Malaise	531 (57.1)	399 (42.9)	77	24 (8.2)	267 (91.8)	170
Myalgia	507 (55)	415 (45)	85	13 (4.5)	278 (95.5)	170
Headache	469 (50.8)	454 (49.2)	84	27 (9.3)	264 (90.7)	170
Rectal pain	201 (21.9)	715 (78.1)	91	0 (—)	291 (100.0)	170
Pus or blood in stools	184 (20.5)	713 (79.5)	110	0 (—)	291 (100.0)	170
Abdominal pain	96 (11.5)	742 (88.5)	169	1 (0.3)	290 (99.7)	170
Rectal bleeding	90 (10.0)	810 (90.0)	107	0 (—)	291 (100.0)	170
Tenesmus	90 (10.0)	809 (90.0)	108	2 (0.7)	289 (99.3)	170
Vomiting or nausea	83 (9.2)	817 (90.8)	107	0 (—)	291 (100.0)	170
Rash sites						
Genitals	333 (46.4)	385 (53.6)	289	214 (55.7)	170 (44.3)	77
Arms	284 (39.6)	434 (60.4)	289	20 (5.2)	364 (94.8)	77
Face	276 (38.4)	442 (61.6)	289	94 (24.5)	290 (75.5)	77
Legs	265 (36.9)	453 (63.1)	289	18 (4.7)	366 (95.3)	77
Perianal	225 (31.3)	493 (68.7)	289	86 (22.4)	298 (77.6)	77
Mouth, lips, or oral mucosa	179 (24.9)	539 (75.1)	289	99 (25.8)	285 (74.2)	77
Palms of hands	157 (21.9)	561 (78.1)	289	13 (3.4)	371 (96.6)	77
Trunk	156 (21.7)	562 (78.3)	289	14 (3.6)	370 (96.4)	77
Neck	130 (18.1)	588 (81.9)	289	33 (8.6)	351 (91.4)	77
Head	97 (13.5)	621 (86.5)	289	8 (2.1)	376 (97.9)	77
Soles of feet	77 (10.7)	641 (89.3)	289	1 (0.3)	383 (99.7)	77

* Symptoms experienced up until the time of interview.
† Symptoms reported by persons with monkeypox as their first symptoms during their illness or the body location where rash first appeared.
§ Percentages calculated using nonmissing data.
¶ Rash includes at least one lesion affecting the skin or mucous membranes.

a nonreplicating, live virus vaccine (https://www.fda.gov/media/131078/download) had been allocated to jurisdictions, and approximately 14,700 courses of oral tecovirimat (TPOXX) had been distributed to jurisdictions and providers.

The findings in this report are subject to at least three limitations. First, this analysis includes only 41% of U.S. monkeypox cases reported through July 22 and might not be representative of all cases. Jurisdictions with high numbers of cases without submitted case report forms were more racially and ethnically diverse according to U.S. Census Bureau data; therefore, persons from racial and ethnic minority groups might be more disproportionately affected than indicated by these data. Second, even on submitted case report forms, data for variables such as timing of vaccination, sexual behaviors, HIV status, reason for hospitalization, and whether cases were travel-associated were frequently missing; data might also not reflect symptoms or outcomes occurring after the interview. Finally, persons with monkeypox who have mild symptoms might be less likely to seek care or initiate testing and could be underrepresented in this analysis.

CDC is continually evaluating new evidence and tailoring response strategies as information on changing case demographics, clinical characteristics, transmission, and vaccine effectiveness become available. Public health efforts should prioritize gay, bisexual, and other men who have sex with men, who are currently disproportionately affected for prevention and testing, address equity, and minimize stigma, while maintaining vigilance for transmission in other populations. Clinicians should test persons with rash consistent with monkeypox, regardless of whether the rash is disseminated or was preceded by prodrome.

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Interim Guidance for Prevention and Treatment of Monkeypox in Persons with HIV Infection — United States, August 2022

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Monkeypox virus, an orthopoxvirus sharing clinical features with smallpox virus, is endemic in several countries in Central and West Africa. The last reported outbreak in the United States, in 2003, was linked to contact with infected prairie dogs that had been housed or transported with African rodents imported from Ghana (*1*). Since May 2022, the World Health Organization (WHO) has reported a multinational outbreak of monkeypox centered in Europe and North America, with approximately 25,000 cases reported worldwide; the current outbreak is disproportionately affecting gay, bisexual, and other men who have sex with men (MSM) (*2*). Monkeypox was declared a public health emergency in the United States on August 4, 2022.[†] Available summary surveillance data from the European Union, England, and the United States indicate that among MSM patients with monkeypox for whom HIV status is known, 28%–51% have HIV infection (*3*–*10*). Treatment of monkeypox with tecovirimat as a first-line agent is available through CDC for compassionate use through an investigational drug protocol. No identified drug interactions would preclude coadministration of tecovirimat with antiretroviral therapy (ART) for HIV infection. Pre- and postexposure prophylaxis can be considered with JYNNEOS vaccine, if indicated. Although data are limited for monkeypox in patients with HIV, prompt diagnosis, treatment, and prevention might reduce the risk for adverse outcomes and limit monkeypox spread. Prevention and treatment considerations will be updated as more information becomes available.

Background

Signs and Symptoms: Classically, monkeypox occurs in three stages. After an incubation period of approximately 1–2 weeks, a prodrome, characterized by fever and lymphadenopathy occurs, which is followed by the onset of a deep-seated vesicular or pustular rash that often begins centrally and spreads to the limbs (*11*). Transmission of monkeypox can occur through direct contact with the infectious rash, scabs, or body fluids, through respiratory secretions during prolonged face-to-face contact or intimate physical contact, or through touching items, such as clothing or linens, that previously touched a patient's infectious rash or body fluids.[§] Patients are considered contagious until the scabs have crusted over and fallen off and a fresh layer of intact skin has formed underneath.

Reports from the current outbreak suggest transmission patterns and clinical manifestations might not follow the classic presentation of monkeypox (*5*–*10*). Although any person can acquire monkeypox, epidemiologic data indicate that transmission is currently most intense among interconnected networks of sexually active MSM, with transmission occurring primarily through intimate skin-to-skin contact during sex (*6*). Prodrome or systemic symptoms do not always occur or precede the rash. Mucosal involvement occurs in approximately 40% of cases, including genital, perianal, and oropharyngeal lesions (*5*). Genital and perianal lesions can be associated with severe and painful proctitis, urethritis, phimosis, and balanitis. Oropharyngeal symptoms, including symptoms resulting from tonsillitis and epiglottitis, can be associated with pain or difficulty swallowing.

Treatment: There are no Food and Drug Administration (FDA)–approved treatments for monkeypox. However, drugs that are approved for treatment of smallpox and cytomegalovirus might have activity against *Monkeypox virus*. Tecovirimat is an antiviral medication available in oral and intravenous formulations. Animal studies have shown that tecovirimat is effective in treating orthopoxvirus-induced disease (*12*). Data are not available on the effectiveness of tecovirimat in treating monkeypox in humans; however, a case report from the United Kingdom suggested that tecovirimat might shorten the duration of illness and of viral shedding (*13*). Human clinical trials indicate that the drug is safe and tolerable with only minor side effects (*14*). Randomized controlled trials in humans are underway to further assess safety as well as efficacy in treating monkeypox. Tecovirimat is available from the Strategic National Stockpile (SNS) and is administered under an expanded access (i.e., compassionate use) Investigational New Drug (EA-IND) protocol held by CDC.[¶]

Other treatments that can be considered in severe cases include vaccinia immune globulin intravenous (VIGIV), cidofovir, and brincidofovir. Cidofovir and brincidofovir have proven activity against poxviruses in in vitro and animal studies, but only cidofovir is currently available either commercially or from the SNS. VIGIV is available from the SNS and is administered under an EA-IND protocol for monkeypox. At

[*] These authors contributed equally to this report.
[†] https://www.washingtonpost.com/health/2022/08/04/monkeypox-public-health-emergency-united-states-becerra/
[§] https://www.cdc.gov/poxvirus/monkeypox/transmission.html
[¶] https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

this time, it is unknown whether a person with severe monkeypox will benefit from treatment with VIGIV, cidofovir, or brincidofovir because effectiveness data are not available.

Pre- and Postexposure Prophylaxis: The only form of preexposure prophylaxis available or authorized for monkeypox is vaccination, which currently is recommended for persons at risk for occupational exposure to orthopoxviruses, such as laboratory personnel performing diagnostic testing for *Monkeypox virus* and members of health care worker response teams designated by appropriate public health and antiterror authorities (*15*). Routine immunization of all health care workers against smallpox or monkeypox is not currently recommended.**

Postexposure prophylaxis can be considered after exposure to monkeypox.†† Although the use of smallpox vaccines for postexposure prophylaxis has not been studied in the context of monkeypox outbreaks, early administration of vaccines (≤4 days after exposure) might prevent monkeypox, and later use (5–14 days after exposure) might decrease the severity of monkeypox if infection occurs (*16*,*17*). Vaccination given after the onset of signs or symptoms of monkeypox is not expected to provide benefit.§§

Two vaccines are licensed by FDA for the prevention of orthopoxvirus infections. JYNNEOS is a live virus vaccine that uses nonreplicating modified vaccinia Ankara (MVA) which is licensed for prevention of smallpox and monkeypox in adults aged ≥18 years (*18*). Because JYNNEOS contains replication-deficient MVA, it does not present a risk for disseminated infection, autoinoculation, or transmission to others (*15*). JYNNEOS vaccine is administered as a series of two doses given 28 days apart (*18*). ACAM2000 is a replication-competent live vaccinia virus vaccine licensed for prevention of smallpox that is administered as a single dose (*19*). ACAM2000 was derived from Dryvax, the vaccine used in the eradication of smallpox (*19*).

Monkeypox in Persons with HIV Infection

Clinical Presentation and Outcomes: It is currently not known whether HIV infection affects a person's risk for acquiring monkeypox. MSM with HIV infection are at present disproportionately represented among monkeypox cases. However, ascertaining the relative roles that exposure and biologic risks play in this disproportionality is challenging. Sexual behavior that confers risk for HIV acquisition also increases risk for acquiring other sexually transmitted infections (STIs) leading to a similar disproportionate overrepresentation of MSM with HIV among STI cases (*20*); risk for monkeypox through sexual contact is likely similarly increased. Although it is possible that poorly controlled HIV would increase risk for monkeypox after exposure, evidence from other diseases suggests that persons with HIV infection who are receiving ART and have robust CD4 counts are not at increased risk for most infections, including opportunistic infections, and therefore might not be at increased risk for monkeypox after exposure.¶¶

Available data indicate that persons with advanced and uncontrolled HIV infection might be at higher risk for severe or prolonged monkeypox disease following infection. In a 2017–2018 case series describing 122 Nigerian patients with monkeypox caused by the same strain responsible for the current outbreak, four of the seven deaths occurred among persons with untreated advanced HIV infection; however, information about the overall proportion of patients with HIV infection was not available, precluding the ability to determine whether this mortality was disproportionately large (*21*). A second 2017–2018 series of 40 monkeypox cases, also from Nigeria, included nine persons with HIV infection for whom clinical data relevant to HIV status were provided; CD4 cell counts ranged from 20 to 357 per μL, and most patients had either failed ART or had newly diagnosed HIV infection, suggesting a lack of viral suppression. Two of nine patients with HIV in that case series died. Compared with other patients with monkeypox, those with HIV infection had higher rates of secondary bacterial infection, more prolonged illness (and thereby also longer period of infectiousness), as well as a higher likelihood of having a confluent or partially confluent rash rather than discrete lesions (*22*). In contrast, recent reports from European countries where most patients are receiving effective ART have noted no deaths or evident excess in hospitalizations among persons with HIV infection and monkeypox to date (*3*,*4*,*6*). In addition, WHO has stated that a more severe disease course has not been reported in persons with HIV infection who are receiving ART and have a robust immune system (*23*), a finding supported by recent large cohort studies (*5*,*7*,*8*).

Management of patients with HIV infection and monkeypox: ART and opportunistic infection prophylaxis should be continued in all persons with HIV infection who acquire monkeypox (Table 1). Treatment interruption might lead to rebound HIV viremia that could complicate the management of monkeypox, including worsening illness severity.*** Persons receiving ART for HIV pre-exposure prophylaxis or postexposure prophylaxis should likewise continue taking these medications. Persons with newly diagnosed HIV infection at

** https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html
†† https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html
§§ https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

¶¶ https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/introduction
*** https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/discontinuation-or-interruption

TABLE 1. Recommendations for management of persons with HIV infection and monkeypox — United States, August 2022

Patient group and treatment	Recommendations/Precautions	Availability/Effectiveness in treating monkeypox
HIV management for persons with monkeypox		
Known HIV infection	Continue ART and opportunistic infection prophylaxis as indicated	NA
Newly diagnosed HIV	Begin ART as soon as possible	NA
HIV pre-exposure prophylaxis	Continue treatment or start, as indicated	NA
HIV postexposure prophylaxis	Continue treatment or start, as indicated	NA
Monkeypox management for persons with HIV*		
Tecovirimat (TPOXX, ST-246)	Review potential interactions with ART	Available from SNS Oral and intravenous formulations available
Cidofovir (Vistide)	Contraindicated if serum creatinine >1.5 mg/dL	Available from SNS Effectiveness in treating monkeypox unknown
Brincidofovir (CMX001, Tembexa)	Might cause increases in serum transaminases and bilirubin	Not available from SNS Effectiveness in treating monkeypox unknown
Vaccinia immune globulin intravenous	Might be considered in severe cases	Available from SNS Effectiveness in treating monkeypox unknown
Monkeypox pre-exposure prophylaxis†		
JYNNEOS§ vaccine (2-dose, nonreplicating live vaccinia virus vaccine)	Safety and immunogenicity similar in persons with and without HIV infection	Licensed for prevention of orthopoxvirus infections, including monkeypox¶
Monkeypox postexposure prophylaxis†		
JYNNEOS§ vaccine (2-dose, nonreplicating live vaccinia virus vaccine)	Safety and immunogenicity similar in persons with and without HIV infection	Limited available data. If administered ≤4 days after exposure, might prevent infection; administration ≥5 days after exposure might decrease severity of disease if infection occurs.

Abbreviations: ART = antiretroviral therapy; FDA = Food and Drug Administration; NA = not applicable; SNS = Strategic National Stockpile.
* https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html
† ACAM2000 is a replication-competent vaccina virus vaccine that is licensed for prevention of smallpox. ACAM2000 should not be used in persons with HIV infection, regardless of immune status. https://www.fda.gov/media/75792/download
§ https://www.fda.gov/media/131078/download
¶ https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

the time of monkeypox diagnosis should commence ART as soon as possible, in consultation with an expert in HIV care, if needed. Monkeypox diagnosis has been reported concurrent with diagnosis of acute HIV infection and other STIs, highlighting the importance of testing for these infections when monkeypox is suspected or diagnosed (*24*).

Treatment of monkeypox should be considered among persons with HIV infection, taking into account disease severity, degree of immunosuppression, or vulnerable sites of infection (e.g., the genitals or anus).††† Tecovirimat is the first-line medication recommended for treatment of monkeypox, including among persons with HIV infection. Clinically relevant interactions among tecovirimat, cidofovir, and brincidofovir and certain ARTs are known and should be considered when selecting treatment (Table 2). However, none of the identified drug interactions should preclude coadministration of tecovirimat and antiretroviral therapy. Cidofovir is contraindicated in patients with serum creatinine >1.5 mg/dL because of the associated nephrotoxicity. There are no specific contraindications for use of VIGIV among persons with HIV infection.

Considerations for vaccination: The safety and immunogenicity of JYNNEOS have been specifically evaluated in persons with HIV infection. Clinical trials demonstrate that JYNNEOS is well-tolerated with similar immunogenicity and rates of adverse events in persons with HIV infection with CD4 cell counts of 200–750 per μL and persons without HIV infection (*25*,*26*). In persons with HIV infection with a prior diagnosis of AIDS who were virologically suppressed and had CD4 counts of 100–500 per μL, there were no serious safety concerns and the vaccine appeared efficacious based on immunogenicity at standard dosing (*27*). However, immunogenicity among persons with HIV infection who have CD4 cell counts <100 per μL or who are not virologically suppressed is not known.

Because ACAM2000 contains a replication-competent, attenuated strain of vaccinia virus, severe localized or systemic complications of ACAM2000 (e.g., progressive vaccinia) can occur in persons with weakened immune systems, including from HIV infection (*15*).

Interim Guidance

Providers should consider both viral suppression and CD4 count in weighing the risk for severe monkeypox-associated outcomes for any patient with HIV infection. Although severe outcomes have been observed in persons with inadequately treated HIV infection who have CD4 counts ≤350 per μL and

††† https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

TABLE 2. Treatments for monkeypox and clinically relevant drug interactions with antiretroviral therapies

Monkeypox treatment	ART	Mechanism	Clinical comments
Tecovirimat	Doravirine (DOR) Rilpivirine (RPV) Maraviroc (MVC)	Induction of CYP3A4	Consultation with local pharmacists is suggested. Interaction may result in a reduction in NNRTI and MVC levels. Per Liverpool HIV interactions database, dose increases could be considered for these antiretroviral medications during therapy and for 2 wks after completion of tecovirimat therapy.* However, based on evidence graded very low quality and the short treatment course of tecovirimat, some experts believe neither dose adjustments nor additional ART are needed.†
	Long-acting cabotegravir/RPV	Induction of CYP3A4	Consultation with local pharmacists is suggested. Interaction might result in a reduction in RPV levels. Per Liverpool HIV interactions database, consider addition of oral RPV 25mg once daily (or the patient's prior ART regimen) during treatment with tecovirimat and for approximately 2 wks after the end of treatment could be considered.* However, some experts believe no additional therapy is necessary during tecovirimat treatment.† Initiation of long-acting cabotegravir/RPV should be avoided during tecovirimat therapy and for 2 wks after conclusion of tecovirimat.§
Cidofovir	Tenofovir disoproxil fumarate (TDF)	Nephrotoxicity; probenecid might inhibit excretion of TDF	Coadministration of cidofovir and TDF is not recommended. If concomitant use of TDF and nephrotoxic agents is unavoidable, renal function should be monitored closely. Probenecid might increase serum levels of TDF. Consider use of tenofovir alafenamide (TAF) in place of TDF and monitor for renal adverse events.
	Zidovudine (AZT)	Probenecid increases drug concentration of AZT	Probenecid substantially increases AZT plasma levels, and if coadministered AZT should either be temporarily discontinued or decreased by 50% on the day of cidofovir-probenecid administration to avoid AZT-induced hematological toxicity.
Brincidofovir	Cobicistat (COBI) Fostemsavir (FTR) Protease Inhibitors (class)	Inhibition of OATP1B1, OATP1B3	If concomitant use with brincidofovir is necessary, increase the monitoring for adverse reactions associated with brincidofovir (i.e., elevations in transaminases and bilirubin, diarrhea, or other gastrointestinal adverse events) and postpone the dosing of these antiretrovirals for ≥3 hrs after brincidofovir administration.
	Tenofovir disoproxil fumarate (TDF)	Nephrotoxicity	If concomitant use of TDF and nephrotoxic agents is unavoidable, renal function should be monitored closely.
	Zidovudine (AZT)	Possible reduced renal secretion of AZT	When brincidofovir is coadministered to patients being treated with AZT, they should be closely monitored for AZT-induced hematological toxicity.
Vaccinia immune globulin intravenous	No known or anticipated interactions with antiretroviral therapy	—	—

Abbreviations: ART = antiretroviral therapy; CYP = cytochrome P450; NNRTI = non-nucleoside reverse transcriptase inhibitors; OATP = organic anion transporting polypeptide.
* https://hiv-druginteractions.org/checker
† https://cdn.hivguidelines.org/wp-content/uploads/20220715134949/NYSDOH-AI-ARVs-and-Treatments-for-Severe-Monkeypox_7-15-2022_HG.pdf
§ https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212888s005s006lbl.pdf

Summary

What is already known about this topic?

A multinational monkeypox outbreak disproportionately affecting men who have sex with men, including persons with HIV infection, is ongoing worldwide.

What is added by this report?

CDC has developed clinical considerations for prevention and treatment of monkeypox in persons with HIV infection, including pre-exposure and postexposure prophylaxis with JYNNEOS vaccine, treatment with tecovirimat, and infection control.

What are the implications for public health practice?

Persons with advanced HIV might be at increased risk for severe monkeypox. Postexposure prophylaxis and antiviral treatments are available for persons with HIV infection. Prompt diagnosis and treatment and enhanced prevention efforts might reduce the risk for severe outcomes.

are likely not virologically suppressed, currently available data are insufficient to define actionable thresholds (*21*,*22*). Until more is known, clinicians should exercise clinical judgement assessing the extent of immunosuppression from HIV and from any other sources, and the relationship of the patient's immunosuppression to the risk for severe monkeypox illness.

When vaccination is used for prevention of monkeypox in persons with HIV infection, JYNNEOS is preferred over ACAM2000. Based on current recommendations from ACIP, ACAM2000 is contraindicated for persons with HIV infection because of the risk for severe adverse effects resulting from the spread of vaccinia virus (*15*). If high-risk exposures cannot be avoided, immunocompromised persons may receive JYNNEOS in consultation with their health care provider after careful consideration of the risks and benefits (*15*). Clinical efficacy (vaccine effectiveness) of JYNNEOS against monkeypox is unknown, including among persons with HIV infection. Other therapies,

including tecovirimat and VIGIV, can be considered for monkeypox postexposure prophylaxis on an individual case-by-case basis, in cases of known high-risk exposure to a confirmed or probable case of infection and clinical conditions that necessitate an alternative option to postexposure vaccination, such as advanced HIV. The efficacy of these therapies as monkeypox postexposure prophylaxis is unknown.

Persons with and without HIV infection should follow the same guidance to protect themselves from monkeypox. Primary prevention of monkeypox includes isolating persons with infection from other persons and their pets, avoiding close contact and sexual activity (including oral, anal, and vaginal sex or sharing of sex toys) with persons with infection, and postexposure vaccination. Persons identified as close contacts of persons with monkeypox should follow any additional guidance from their state or local health department.

Discussion

Persons with advanced HIV infection or who are not virologically suppressed with ART might be at increased risk for severe disease related to monkeypox. Postexposure prophylaxis and antiviral treatments are available for persons exposed to *Monkeypox virus* or with monkeypox. Vaccination with JYNNEOS is considered safe for persons with HIV infection. Drug interactions between ART and tecovirimat do not preclude coadministration if antiviral therapy for monkeypox is indicated. Prevention and treatment considerations will be updated as more information becomes available.

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Notes from the Field

School-Based and Laboratory-Based Reporting of Positive COVID-19 Test Results Among School-Aged Children — New York, September 11, 2021–April 29, 2022

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By April 29, 2022, a total of 702,686 COVID-19 cases were reported among children and adolescents aged 5–17 years in the state of New York.* Pediatric COVID-19 cases and hospitalizations increased during the 2021–22 school year, driven by transmission of the Omicron variant† (*1*). In late 2021, during the surge in Omicron BA.1 variant cases, state§ and federal¶ authorities expanded access to self-administered, at-home rapid antigen tests, which can increase a person's knowledge of their COVID-19 status and guide risk-reduction behaviors. New York government agencies sent millions of these tests to schools for distribution to teachers, students, and staff members. Because results of self-administered, at-home tests are not captured by electronic laboratory reporting (in contrast to health care provider–administered tests at a physician's office or laboratory that are reported through electronic health records or other means), expanded use of these tests might affect interpretation of trends in reported COVID-19 cases; however, this has yet to be assessed** (*2*). Furthermore, understanding changes in testing behavior before and after the Omicron variant surge might help public health officials better use available COVID-19 data to guide future policy.

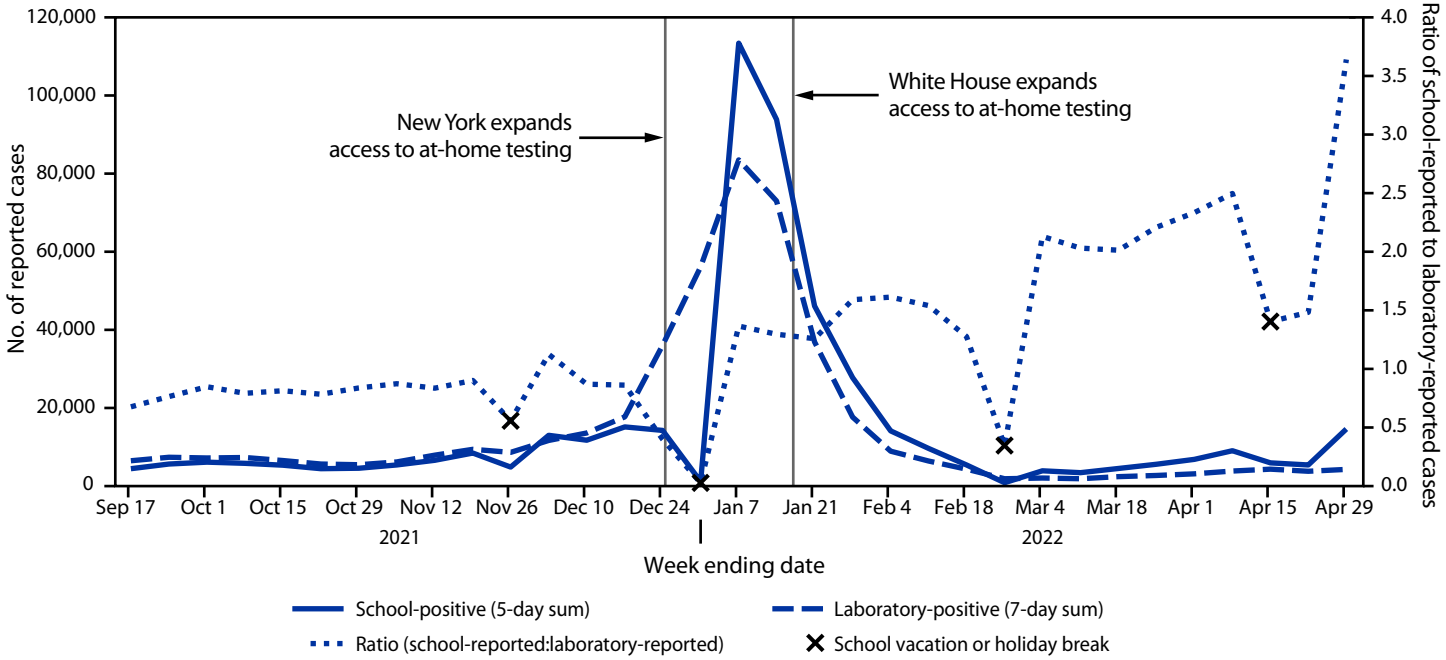
COVID-19 case data from two independently operating New York State Department of Health systems were compared before and after expansion of at-home testing: 1) laboratory-reported data†† for children and adolescents aged 5–17 years and 2) a kindergarten through grade 12 (K–12) school-based system§§ for reporting positive results from all testing sources¶¶ (*3*). Laboratory-reported data include results of school-administered tests (which are required to be reported) but exclude results from self-administered, at-home tests. School-reported data include positive results reported to the state from any test source, including those from clinical settings, school-based testing programs, and self-administered, at-home tests. Case totals for both data sets*** and the ratio of school-reported to laboratory-reported cases were calculated weekly during September 11, 2021–April 29, 2022, and compared. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.†††

During the September 11–17, 2021, school week, among 6,928 New York schools, 5,201 (75.1%) reported to the school-based system; by the April 23–29, 2022, school week, 5,274 (76.1%) schools reported (weekly median = 80.7%; IQR = 76.1%–81.7%). During the entire analysis period, 477,538 student cases were reported to the K–12 school-based system, and 464,421 cases in children and adolescents aged 5–17 years were reported by laboratories§§§; the overall ratio of school-reported to laboratory-reported cases was 1.03. During September 11–December 31, 2021, the ratio of school-reported to laboratory-reported cases was stable and near 1.0 (median = 0.82; IQR = 0.73–0.85) (Figure). From the January 1–7 to the April 29, 2022, school week, during and following state and federal expansion of at-home testing, the

* https://coronavirus.health.ny.gov/covid-19-data-new-york
† https://coronavirus.health.ny.gov/pediatric-covid-19-update-january-21-2022
§ https://www.governor.ny.gov/news/video-audio-photos-rush-transcript-governor-hochul-announces-comprehensive-winter-surge-plan
¶ https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/
** https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html
†† Laboratories in New York state report results from both reverse transcription–polymerase chain reaction and antigen tests.

§§ Since September 2020, all K–12 schools have been required to submit data on the number of students, teachers, and staff members who have reported receiving positive COVID-19 test results by 5:00 p.m. each day (excluding weekends, vacation breaks, and unexpected closures). https://schoolcovidreportcard.health.ny.gov/
¶¶ Schools report any notification of positive test results to the New York State Department of Health from a variety of sources, including school-based testing programs, results from community-based diagnostic and at-home testing reporting by families and providers, and notifications from a local health department as part of contact tracing efforts.
*** The number of school-reported cases is typically higher on Mondays because of the cumulative caseload from the preceding weekend. Therefore, 5-day weekly sums for schools were compared with 7-day weekly sums for laboratories, (e.g., Monday, September 13, 2021–Friday September 17, 2021, for school-reported data and Saturday, September 11, 2021–Friday, September 17, 2021, for laboratory-reported data). Both data sets are statewide and include New York City.
††† 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.
§§§ Laboratories in New York state are required to submit COVID-19 test results only if they receive specimens for testing. In 2021, the compliance rate for all laboratory facilities was 95.6%.

FIGURE. School-reported* and laboratory-reported† COVID-19 cases — New York, September 11, 2021–April 29, 2022



* School-reported data include positive results from any test source, reported through the New York state COVID-19 report card system for children in kindergarten through grade 12.

† Laboratory-reported data include positive results of SARS-CoV-2 reverse transcription–polymerase chain reaction and antigen tests conducted at laboratories or physician offices, reported through electronic health records or other means.

ratio of school-reported to laboratory-reported cases increased 167%, from 1.36 to 3.64 (median = 1.58; IQR = 1.36–2.13).

These findings are subject to at least three limitations. First, because school-reported data include some students aged <5 years or >17 years, and not all children and adolescents aged 5–17 years attend schools that reported cases, school-reported and laboratory-reported case data were not directly comparable. Second, these results might reflect both underreporting of infection and increased detection because of at-home test use. Finally, results from school-aged children and adolescents are not representative of those from the general population.

The changing relationship between school-reported and laboratory-reported data, during a period of stable school reporting, suggests a decline in the capture of positive laboratory test result data for children and adolescents aged 5–17 years following the expansion of at-home testing. Throughout the pandemic, public health programs have relied on laboratory-reported data to guide risk communication; underestimation of cases based on these data could affect interpretations of epidemic trends and metrics derived from them, including community COVID-19 incidence. This analysis suggests that methods of capturing data on results from self-administered, at-home tests can augment laboratory-reported data to provide a more complete picture of positive COVID-19 test results within communities. Jurisdictions that prioritize both at-home COVID-19 testing and comprehensive epidemiologic monitoring of the COVID-19 pandemic might consider implementing reporting systems that operate alongside electronic laboratory reporting. As the pandemic has evolved, however, the level of vaccine- and infection-derived immunity has increased in the population; thus, prioritization of reducing medically significant illness and minimizing strain on the health care system has increased.¶¶¶ Health officials and the public should consider current information about COVID-19 cases and hospitalizations in the community, as well as the potential for strain on the local health system, when making decisions about community prevention strategies and individual behaviors.****

¶¶¶ https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/indicators-monitoring-community-levels.html

**** https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html

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Notes From the Field

Overdose Deaths Involving Eutylone (Psychoactive Bath Salts) — United States, 2020

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Synthetic cathinones (known as psychoactive bath salts) are a class of potent central nervous stimulants that mimic the effects produced by cocaine, methamphetamine, and methylenedioxymethamphetamine (MDMA; known as ecstasy). Synthetic cathinones have been sold as MDMA (*1*), distributed as nondrug products (e.g., bath salts) to conceal their sale as an illicit drug and also sold as illicit drug products.* From 2017 to 2021, the supply of eutylone† (a synthetic cathinone) rapidly increased in the United States. During January–June 2017, eutylone was detected in fewer than 10 drug items such as powders, capsules, or tablets obtained through law enforcement activities such as drug seizures, arrests, or undercover buys and tested; during January–June 2021, eutylone was detected in 8,379 drug items, making it the seventh most identified drug during this period (*2*). Public alerts have been issued and include concern about elevated overdose risk associated with eutylone being sold as MDMA§ (*1*). Little is known about the relative potencies and pharmacological profile of synthetic cathinones compared with MDMA, and using counterfeit tablets potentially increases the risk for overdose; however, additional investigation is needed.

CDC, through the State Unintentional Drug Overdose Reporting System (SUDORS), funds 47 states and the District of Columbia¶ to enhance postmortem toxicology testing and abstract comprehensive data from death certificates and medical examiner or coroner reports, including toxicology reports, for drug overdose deaths of unintentional and undetermined intent. This report describes overdose deaths in which the medical examiner or coroner determined that eutylone contributed to the death (eutylone-involved deaths), submitted to SUDORS by 43 states and the District of Columbia with data for January–June 2020, July–December 2020, or both.** For three states (Alabama, South Carolina, and Wisconsin), data from the death certificate only were analyzed. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.††

During 2020, 343 eutylone-involved deaths were reported by 22 of 44 SUDORS jurisdictions, with 259 (75.5%) concentrated in two southern states§§ (Florida [182] and Maryland [77]). Eutylone-involved deaths commonly co-involved illicitly manufactured fentanyls (IMFs)¶¶ (which include both illicitly manufactured fentanyl and fentanyl analogs) (77.3%), and cocaine or methamphetamine (53.1%) (Table). Among 183 (53.4%) of 343 eutylone-involved deaths with medical examiner or coroner reports available (from 41 of 44 jurisdictions),*** 23 (12.6%) had negative MDMA toxicology findings but evidence of MDMA use before the overdose or a history of MDMA use.††† One of the 23 deaths was in a person who had a history of cathinone use.

In 2020, most eutylone-involved deaths occurred within two states in the South, the region with the most eutylone

* https://www.dea.gov/sites/default/files/2020-06/Bath%20Salts-2020.pdf

† https://www.deadiversion.usdoj.gov/drug_chem_info/eutylone.pdf

§ https://www.npsdiscovery.org/wp-content/uploads/2020/03/Public-Alert_Eutylone_Benzylone_NPS-Discovery_033120.pdf; https://cdn.ymaws.com/www.fadaa.org/resource/resmgr/files/resource_center/trend_alert_4__eutylone_fada.pdf; https://cdn.who.int/media/docs/default-source/essential-medicines/unedited-advance-copy-44th-ecdd-critical-review-report-eutylone.pdf?sfvrsn=ca370181_3&download=true

¶ https://www.cdc.gov/drugoverdose/fatal/sudors.html

** *January–December 2020:* Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, and West Virginia; *January–June 2020:* Wisconsin; *July–December 2020:* Alabama, Hawaii, Iowa, Louisiana, and South Carolina.

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

§§ U.S. Census Bureau regions were used to stratify jurisdictions into geographic regions (https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf). Analyses of overdose characteristics included the following 44 jurisdictions: eight of nine in the Northeast region; 10 of 12 in the Midwest region; 16 of 17 in the South region; and 10 of 13 in the West region.

¶¶ Fentanyl was classified as likely illicitly manufactured using toxicology, scene, and witness evidence. When evidence was insufficient to classify fentanyl as illicit or prescription, it was classified as illicit because most fentanyl overdose deaths involve illicit fentanyl. All fentanyl analogs except alfentanil, remifentanil, and sufentanil (which have legitimate human medical use) were included as IMFs.

*** Alabama, South Carolina, and Wisconsin were not included. Only 26 of 182 eutylone-involved deaths in Florida had a medical examiner report at the time of this analysis and thus are not representative of Florida eutylone-involved deaths.

††† Two authors reviewed narrative information abstracted from medical examiner or coroner reports for evidence of decedent using MDMA before the overdose (i.e., witness reported MDMA use by decedent before overdose symptoms) or a history of MDMA use (i.e., decedent was known by family to use MDMA frequently).

TABLE. Demographic and other characteristics of drug overdose deaths involving eutylone (N = 343), by co-involvement with opioids — State Unintentional Drug Overdose Reporting System, United States,* 2020

Characteristic	No. (%) of eutylone-involved deaths		
	Total deaths	Deaths involving any opioid	Deaths not involving any opioid
Total	**343 (100.0)**	**283 (100.0)**	**60 (100.0)**
Sex†			
Male	246 (71.7)	203 (71.7)	43 (71.7)
Female	97 (28.3)	80 (28.3)	17 (28.3)
Age group, yrs†			
15–24	24 (7.0)	20 (7.1)	4 (6.7)
25–34	130 (37.9)	111 (39.2)	19 (31.7)
35–44	102 (29.7)	83 (29.3)	19 (31.7)
45–54	57 (16.6)	45 (15.9)	12 (20.0)
≥55	30 (8.7)	24 (8.5)	6 (10.0)
Race and ethnicity§			
White, non-Hispanic	161 (46.9)	144 (50.9)	17 (28.3)
Black, non-Hispanic	115 (33.5)	78 (27.6)	37 (61.7)
Other, non-Hispanic	8 (2.3)	8 (2.8)	0 (—)
Hispanic	37 (10.8)	34 (12.0)	3 (5.0)
Unknown/Missing	22 (6.4)	19 (6.7)	3 (5.0)
U.S. Census Bureau region of the state†,¶			
Northeast	14 (4.1)	10 (3.5)	4 (6.7)
Midwest	12 (3.5)	9 (3.2)	3 (5.0)
South	314 (91.5)	261 (92.2)	53 (88.3)
West	3 (0.9)	3 (1.1)	0 (—)
Drugs involved in overdose**			
Any opioid	283 (82.5)	283 (100.0)	—††
IMFs	265 (77.3)	265 (93.6)	—††
Heroin	39 (11.4)	39 (13.8)	—††
Prescription opioid	39 (11.4)	39 (13.8)	—††
Other stimulants, not eutylone†	191 (55.7)	164 (58.0)	27 (45.0)
Cocaine or methamphetamine§	182 (53.1)	159 (56.2)	23 (38.3)
Methamphetamine†	54 (15.7)	43 (15.2)	11 (18.3)
Cocaine§	147 (42.9)	133 (47.0)	14 (23.3)
No opioid or other stimulant	33 (9.6)	—††	33 (55.0)
Benzodiazepines†	48 (14.0)	44 (15.5)	4 (6.7)
Total eutylone-involved deaths in 41 jurisdictions§§ with medical examiner/coroner data¶¶	**183 (100.0)**	**151 (100.0)**	**32 (100.0)**
Evidence of current or past MDMA use§	23 (12.6)	10 (6.6)	13 (40.6)
Evidence of MDMA use before overdose§	13 (7.1)	4 (2.6)	9 (28.1)
History of chronic MDMA use†	15 (8.2)	8 (5.3)	7 (21.9)

Abbreviations: IMF = illicitly manufactured fentanyl; MDMA = methylenedioxymethamphetamine.

* Forty-four jurisdictions provided data: Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin. Data only from the death certificate were analyzed for three states: Alabama, South Carolina, and Wisconsin.

† No significant difference between eutylone-involved deaths with and without opioids was found using Fisher's exact test ($p>0.05$).

§ A significant difference between eutylone-involved deaths with and without opioids was found using Fisher's exact test ($p<0.05$). Test excluded missing values.

¶ U.S. Census Bureau regions were used to stratify jurisdictions into geographic regions. https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf

** A drug overdose can involve multiple drugs such as IMF, eutylone, and cocaine. Consequently, specific drug percentages when summed will exceed 100%.

†† By definition, this category will be zero. For example, eutylone-involved deaths with no opioid co-involvement did not have any opioids (e.g., IMF, heroin, and prescription) involved in the overdose.

§§ Did not include Alabama, South Carolina, or Wisconsin. Only 26 of the 182 eutylone-involved deaths in Florida had a coroner or medical examiner report at the time of this analysis and thus are not representative of Florida eutylone-involved deaths.

¶¶ Two authors reviewed narrative information abstracted from medical examiner or coroner reports for evidence of decedent using MDMA before the overdose (i.e., witness reported MDMA use by decedent before overdose symptoms) or a history of MDMA use (i.e., decedent was known by family to use MDMA frequently).

drug reports by law enforcement in both 2019 and 2020 (*2*). Rapid increases in drug products containing eutylone (*2*), coupled with the concentration of eutylone-involved deaths in a few states, warrant enhanced surveillance for new outbreaks in other states involving emerging or known synthetic cathinones, including eutylone. Starting in late 2021, the World Health Organization Expert Committee on Drug Dependence reviewed and then recommended legally regulating the international distribution of eutylone; subsequently, the United Nations Commission on Narcotics Drugs internationally scheduled eutylone with enforcement beginning on November 23, 2022.§§§ International scheduling of eutylone might be contributing to its replacement with a newer synthetic cathinone with sharp increases in N,N-dimethylpentylone and declines in eutylone reported in 2022.¶¶¶

Understanding whether eutylone exposure is intended or unintended (i.e., via adulterated substances) can guide prevention efforts. Consistent with previously reported unintentional exposure among persons using MDMA (*1*), approximately one in 10 eutylone-involved deaths in this report had evidence of current or past MDMA use but no toxicology finding of MDMA. Common co-involvement of IMFs in eutylone-involved deaths is consistent with the increased prevalence of concurrent use of IMFs with illicit stimulants (*3*). However, infrequent documentation of purposeful cathinone use in eutylone-involved deaths might indicate unintended exposures and needs further investigation. One half of eutylone-involved deaths co-involved cocaine or methamphetamine, which heightens fatal overdose risk because of the cumulative effects of multiple stimulants. This high level of co-involvement could be related to unintentional exposure or part of an increasing trend to co-use multiple stimulants such as methamphetamine and cocaine (*4*). Risk for unintentional eutylone exposure might be mitigated by 1) increasing knowledge about synthetic cathinones, including eutylone, among persons using MDMA and other drugs with eutylone, 2) supporting rapid dissemination of results from enhanced toxicology testing of illicit drug products, including those sold as MDMA, and 3) broadly increasing availability and access to harm reduction strategies.

§§§ https://www.who.int/publications/i/item/9789240042834; https://www.unodc.org/LSS/Announcement/Details/a56e0bd9-0da5-4152-a34d-7cff7746bf50

¶¶¶ https://www.npsdiscovery.org/wp-content/uploads/2022/07/2022-Q2_NPS-Stimulants-and-Hallucinogens_Trend-Report.pdf

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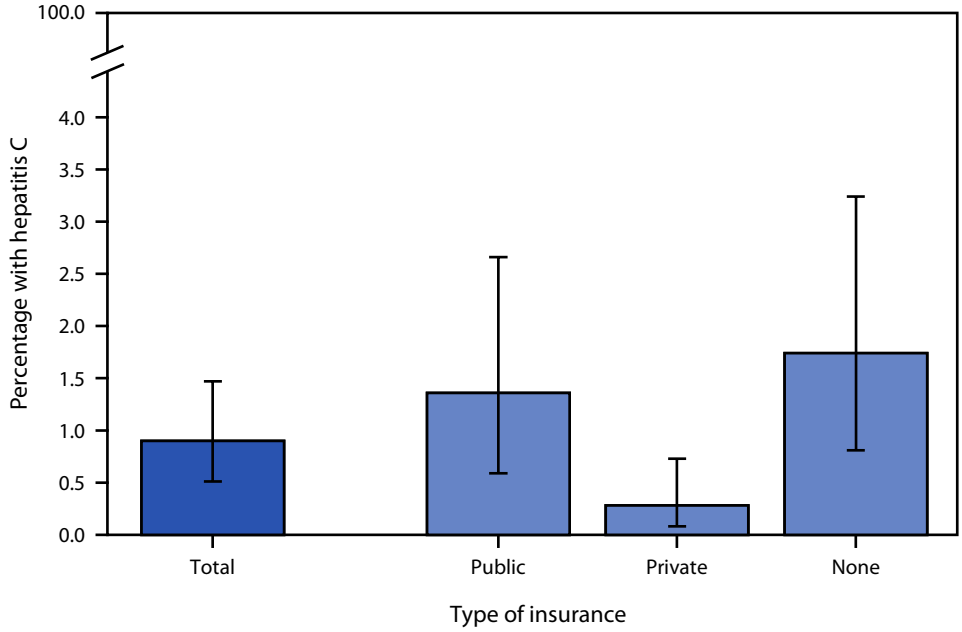
QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Adults† Aged ≥18 Years with Current Hepatitis C Virus Infection,§ by Health Insurance Coverage¶ — National Health and Nutrition Examination Survey, United States, January 2017–March 2020



Abbreviation: NHANES = National Health and Nutrition Examination Survey.

* With 95% CIs indicated by error bars.

† Based on a representative sample of the civilian, noninstitutionalized U.S. population. NHANES data collection was halted in March 2020 because of the COVID-19 pandemic. Data collected during January 2019–March 2020 were combined with data from the 2017–2018 NHANES to form a nationally representative sample of NHANES January 2017–March 2020 prepandemic data. https://www.cdc.gov/nchs/data/series/sr_02/sr02-190.pdf

§ Current hepatitis C virus infection was based on the detection of viral RNA in serum. During January 2017–March 2020 an estimated 2.2 million U.S. adults aged ≥18 years were infected with hepatitis C virus.

¶ The public insurance category includes adults who reported having Medicare, Medicaid, Medigap, Children's Health Insurance Program, state-sponsored or other government health plans. Private insurance includes adults who did not report having any public insurance but did have some form of private insurance.

During January 2017–March 2020, an estimated 0.9% of U.S. adults aged ≥18 years had current hepatitis C virus infection. The percentage of adults with current hepatitis C virus infection was greater among those with no insurance (1.7%) or public insurance (1.4%), compared with those with private insurance (0.3%).

Source: National Health and Nutrition Examination Survey, January 2017–March 2020. https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?cycle=2017-2020

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