Preventable Deaths During Widespread Community Hepatitis A Outbreaks — United States, 2016–2022

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Abstract

Hepatitis A is acquired through the fecal-oral route and is preventable by a safe and effective vaccine. Although hepatitis A is generally mild and self-limited, serious complications, including death, can occur. Since 2016, widespread hepatitis A outbreaks have been reported in 37 U.S. states, primarily among persons who use drugs and those experiencing homelessness. Nearly twice as many hepatitis A–related deaths were reported during 2016–2022 compared with 2009–2015. CDC analyzed data from 27 hepatitis A outbreak-affected states* that contributed data during August 1, 2016–October 31, 2022, to characterize demographic, risk factor, clinical, and cause-of-death data among 315 outbreak-related hepatitis A deaths from those states. Hepatitis A was documented as an underlying or contributing cause of death on 60% of available death certificates. Outbreak-related deaths peaked in 2019, and then decreased annually through 2022. The median age at death was 55 years; most deaths occurred among males (73%) and non-Hispanic White persons (84%). Nearly two thirds (63%) of decedents had at least one documented indication for hepatitis A vaccination, including drug use (41%), homelessness (16%), or coinfection with hepatitis B (12%) or hepatitis C (31%); only 12 (4%) had evidence of previous hepatitis A vaccination. Increasing vaccination coverage among adults at increased risk for infection with hepatitis A virus or for severe disease from infection is critical to preventing future hepatitis A–related deaths.

Introduction

Hepatitis A virus (HAV) infections are acquired through fecal-oral transmission. Although hepatitis A is generally mild and self-limited, serious complications, including death, can occur (1,2). Hepatitis A is preventable by a highly effective and safe vaccine (3). Since 2016, hepatitis A outbreaks associated with person-to-person transmission have been reported in 37 states, involving approximately 44,900 cases,

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* The following 27 states contributed data for the analysis: Arizona, Arkansas, California, Colorado, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and West Virginia.

27,450 hospitalizations, and 423 deaths as of October 6, 2023 (4,5). These outbreaks have disproportionately affected persons who use drugs and persons experiencing homelessness, who might be at increased risk for HAV infection because of poor hygiene practices, lack of access to sanitation, or crowded living conditions (3). Nearly twice as many deaths involving hepatitis A in the United States occurred during 2016–2022 compared with 2009–2015 (6).

Methods

Deidentified demographic, risk factor, and clinical data from state outbreak databases, along with place and cause of death data from death certificates, were requested for all hepatitis A outbreak–related deaths from the 32 state health departments that publicly reported at least one outbreak-related death during August 1, 2016–October 31, 2022. All hepatitis A cases met the Council of State and Territorial Epidemiologists' hepatitis A surveillance case definition (7). Risk factors were self-reported during the exposure period (15–50 days before symptom onset). Outbreak-related deaths were defined as deaths that state health departments determined were attributable to hepatitis A. Death certificate data were reviewed to determine if hepatitis A was listed as 1) a cause of death (listed anywhere in the chain of events that directly caused death) or 2) a significant condition contributing to death. The analysis was conducted using SAS software (version 9.4;

SAS Institute). This activity was reviewed by CDC, deemed not research, and conducted consistent with applicable federal law and CDC policy.[†]

Results

CDC analyzed data from 27 (84%) states contributing data, among the 32 outbreak-affected states that had publicly reported at least one hepatitis A outbreak-related death. These 27 states accounted for 315 outbreak-related deaths, approximately 75% of publicly reported hepatitis A outbreak-related deaths (approximately 71% of publicly reported hepatitis A outbreak-related cases) at the time of the request for data. Deaths occurred during September 13, 2016–June 20, 2022 (Figure), most among males (73%) and non-Hispanic White persons (84%); the median age at death was 55 years (Table 1). Outbreak-related deaths peaked in 2019, and then decreased annually through 2022. The median interval between symptom onset and date of death was 17 days. Among decedents, 91% were hospitalized, 77% had jaundice, and one (<1%) underwent liver transplantation; among the 218 hospitalized decedents with available information, the median length of hospitalization was 7 days (IQR = 4–14 days). Drug use was the most commonly reported risk factor for HAV infection (41%), followed by homelessness or unstable housing (16%).

[†] 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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FIGURE. Date of hepatitis A outbreak–related deaths* — 27 U.S. states, August 1, 2016–October 31, 2022
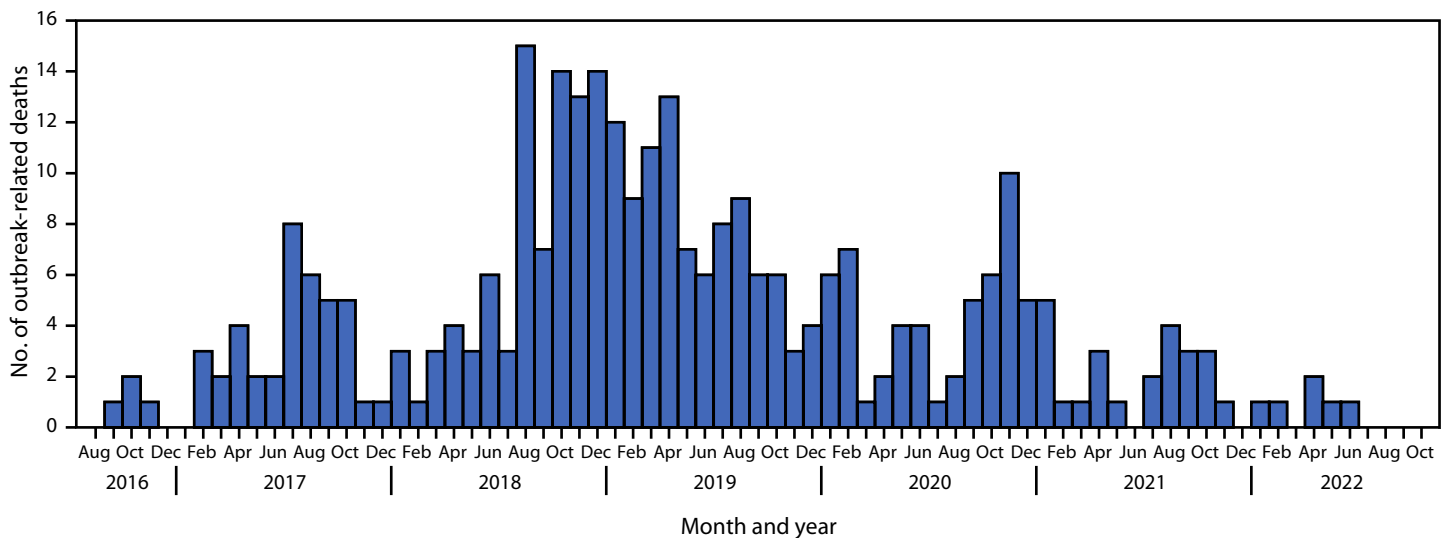
* Among 306 outbreak-related deaths for which the date of death was known.

Coinfection with hepatitis C (31%) was more prevalent than was coinfection with hepatitis B (12%). Only 12 decedents (4%) had evidence of previous hepatitis A vaccination; 63% had at least one documented indication for vaccination according to recommendations of the Advisory Committee on Immunization Practices (*3*).

Death certificate data were provided by 25 (93%) of 27 states for 272 (86%) decedents (Table 2). Hepatitis A was not listed on 108 (40%) of the death certificates. Among the 164 (60%) death certificates with hepatitis A documented, hepatitis A was listed as a cause of death on 142 (87%) and as a significant condition contributing to death on 26 (16%).

Discussion

Data from 27 states were analyzed to characterize the epidemiology of 315 hepatitis A outbreak–related deaths during August 1, 2016–October 31, 2022. Deaths occurred predominantly among males, non-Hispanic White persons, and persons aged ≥50 years. Nearly two thirds of decedents had at least one documented indication for hepatitis A vaccination, including drug use, homelessness, or coinfection with hepatitis B virus or hepatitis C virus; however, only 12 decedents had evidence of previous hepatitis A vaccination, indicating substantial missed opportunities to prevent hepatitis A deaths. Lack of stable housing and substance use disorder are commonly associated with viral hepatitides (*3,4*) and interact to increase disease incidence and health disparities. Although hepatitis A is usually a self-limited and preventable disease, it can have lethal consequences when introduced into populations with limited access to preventive care, unstable housing situations, inadequate access to sanitary services, or coexisting liver disease.

These findings underscore the importance of integrated, comprehensive services, including vaccination, harm reduction, substance use disorder treatment, and hygiene and sanitation, to improve the health of medically underserved populations.

Among 272 outbreak-related decedents with available death certificate data, hepatitis A was listed as a cause of death or significant condition contributing to death on only 60% of death certificates, suggesting a substantial underestimation of hepatitis A mortality related to the outbreaks associated with person-to-person transmission in U.S. national vital statistics data. The 60% reporting rate for hepatitis A outbreak–related deaths is substantially higher than reporting rates for hepatitis B and hepatitis C; in previous death certificate analyses of cohorts of patients with chronic hepatitis B and chronic hepatitis C, only 19% of decedents had hepatitis B or hepatitis C reported on their death certificates (*8,9*).

Limitations

The findings in this report are subject to at least five limitations. First, states did not use a standardized hepatitis A–related death definition, which might have resulted in differential classification of deaths as being related to hepatitis A. Second, death from hepatitis A is not a reportable condition and health departments might not have identified all outbreak-related hepatitis A deaths. Third, risk factor data were self-reported and subject to social desirability and recall biases and missingness. Consequently, information about additional decedents with indications for hepatitis A vaccination was unavailable. Fourth, vaccination information was missing for nearly one half of decedents; however, HAV infection after vaccination or appropriately timed postexposure prophylaxis is rare given the

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TABLE 1. Characteristics of persons whose death was related to a hepatitis A outbreak — 27 U.S. states,* August 1, 2016–October 31, 2022[†]

Characteristic (no. with available data)	No. (%)
Total no. of reported hepatitis A outbreak–related deaths	315
Death date range (306)	Sep 13, 2016–Jun 20, 2022
Year of death (306)	
2016	4 (1.3)
2017	39 (12.7)
2018	86 (28.1)
2019	94 (30.7)
2020	53 (17.3)
2021	24 (7.8)
2022	6 (2.0)
Interval between symptom onset and death, days, median (IQR) (306)[§]	17.0 (9.0–33.0)
Sex	
Female	85 (27.0)
Male	230 (73.0)
Age group at death, yrs (314)	
0–19	0 (—)
20–29	12 (3.8)
30–39	27 (8.6)
40–49	62 (19.8)
50–59	97 (30.9)
≥60	116 (36.9)
Median age at death, yrs (range) (314)	55 (24–96)
Race and ethnicity	
American Indian or Alaska Native, non-Hispanic	3 (1.0)
Black or African American, non-Hispanic	15 (4.8)
White, non-Hispanic	265 (84.1)
Hispanic or Latino	13 (4.1)
Multiple races, non-Hispanic	2 (0.6)
Unknown	17 (5.4)
Jaundice or scleral icterus	
Yes	242 (76.8)
No	52 (16.5)
Unknown	21 (6.7)
Hospitalized	
Yes	288 (91.4)
Length of hospitalization, days, median (IQR) (218)	7.0 (4.0–14.0)
No	24 (7.6)
Unknown	3 (1.0)
Liver transplant	
Yes	1 (0.3)
No	134 (42.5)
Unknown	180 (57.1)
Hepatitis A vaccination status	
Ever vaccinated (≥1 dose)[¶]	12 (3.8)
Unvaccinated	146 (46.4)
Unknown	157 (49.8)
Risk factors**	
Any drug use	
Yes	128 (40.6)
No	113 (35.9)
Unknown	74 (23.5)
Injection drug use	
Yes	76 (24.1)
No	140 (44.4)
Unknown	99 (31.4)

Characteristic (no. with available data)	No. (%)
Noninjection drug use	
Yes	77 (24.4)
No	123 (39.1)
Unknown	115 (36.5)
Experiencing homelessness or unstable housing	
Yes	50 (15.9)
No	217 (68.9)
Unknown	48 (15.2)
Male-to-male sexual contact (230)[††]	
Yes	7 (3.0)
No	91 (39.6)
Unknown	132 (57.4)
International travel	
Yes	2 (0.6)
No	200 (63.5)
Unknown	113 (35.9)
Incarcerated	
Yes	9 (2.9)
No	160 (50.8)
Unknown	146 (46.4)
Epidemiologically linked[§§]	
Yes	30 (9.5)
No	99 (31.4)
Unknown	186 (59.1)
Coinfection	
Hepatitis B	
Yes	37 (11.7)
No	231 (73.3)
Unknown	47 (14.9)
Hepatitis C	
Yes	97 (30.8)
No	179 (56.8)
Unknown	39 (12.4)
HIV	
Yes	0 (—)
No	140 (44.4)
Unknown	175 (55.6)

* The following 27 states contributed data for the analysis: Arizona, Arkansas, California, Colorado, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and West Virginia.

[†] Missing data were categorized as unknown for the purpose of the analysis.

[§] When symptom onset date was not available, date of collection of the specimen that tested positive for hepatitis A virus immunoglobulin M antibodies was used as a proxy for symptom onset date.

[¶] Characteristics related to hepatitis A vaccination status of those reported as "ever vaccinated" were not available (the number of hepatitis A vaccine doses received, whether the hepatitis A vaccine doses were self-reported or confirmed in a state immunization information system, and the timing of doses). These do not necessarily represent instances of hepatitis A vaccine failure (e.g., they could represent instances of postexposure prophylaxis having been administered outside the recommended 14-day window when it is effective).

** Risk factors were ascertained during the exposure period (15–50 days before symptom onset).

[††] Restricted to males.

[§§] Contact (e.g., household or sexual) with a laboratory-confirmed hepatitis A case 15–50 days before symptom onset.

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TABLE 2. Death certificate analysis of hepatitis A outbreak–related deaths — 25 U.S. states,* August 1, 2016–October 31, 2022

Characteristic (no. with available data)	No. (%)
Death certificate available (315)[†]	
Yes	272 (86.3)
No	22 (7.0)
Unknown	21 (6.7)
Hepatitis A status when death certificate was available (272)[§]	
Hepatitis A not listed on death certificate	108 (39.7)
Hepatitis A listed on death certificate	164 (60.3)
Hepatitis A listed as a cause of death (164)[¶]	142 (86.6)
Hepatitis A listed as a significant condition contributing to death (164)[¶]	26 (15.9)
Place of death (272)[§]	
Inpatient facility	226 (83.1)
Hospice facility	16 (5.9)
Decedent's home	13 (4.8)
Other	8 (2.9)
Emergency department or outpatient facility	6 (2.2)
Nursing home or long-term care facility	3 (1.1)

* The following 25 states contributed death certificate data for the analysis: Arizona, Arkansas, California, Colorado, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, South Carolina, Tennessee, Texas, Utah, Washington (Seattle-King County only), and West Virginia.
[†] Calculated among all 315 hepatitis A outbreak–related deaths from 27 states.
[§] Calculated among 272 hepatitis A outbreak–related decedents from 25 states for whom death certificate data was available.
[¶] Categories are not mutually exclusive.

documented high immunogenicity of the vaccine (*3*). Finally, although the analysis captured nearly three quarters of publicly reported outbreak-related deaths, the results might not be generalizable to all outbreak-related deaths in the United States.

Implications for Public Health Practice

Hepatitis A is a vaccine-preventable disease; safe and highly effective vaccines have been available for decades (*3*). Substantial progress has been made in controlling the recent outbreaks through intensive efforts by health departments, including outreach through mobile vans and foot teams, nontraditional vaccination clinics in jails and homeless shelters, and partnerships with sheriffs' associations and other community-based partners to expand vaccination coverage. As of October 2023, 34 states have declared ends to their outbreaks; however, many susceptible adults, particularly among persons who use drugs, persons experiencing homelessness, and persons with chronic liver disease, remain at increased risk for HAV infection or severe disease from HAV infection (*5,10*). Increased hepatitis A vaccination coverage is critical to maintain the progress that has been made and prevent future hepatitis A deaths.

Summary

What is already known about this topic?

Hepatitis A is a vaccine-preventable disease that typically causes mild, self-limited illness. Serious complications, including death, are rare, but are more frequent among older adults. Hepatitis A outbreaks associated with person-to-person transmission have been widespread in the United States since 2016.

What is added by this report?

During August 1, 2016–October 31, 2022, 27 U.S. states reported 315 hepatitis A outbreak–related deaths. Deaths peaked in 2019 and then decreased annually through 2022. Overall, 63% of decedents had at least one documented preexisting indication for hepatitis A vaccination.

What are the implications for public health practice?

Increased hepatitis A vaccination coverage, particularly among adults at increased risk for infection with hepatitis A virus or for severe disease from infection, is critical to preventing future hepatitis A deaths.

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Progress Toward Measles and Rubella Elimination — Indonesia, 2013–2022

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Abstract

In 2019, Indonesia and the other countries in the World Health Organization South-East Asia Region adopted the goal of measles and rubella elimination by 2023. This report describes Indonesia's progress toward measles and rubella elimination during 2013–2022. During this period, coverage with a first dose of measles-containing vaccine (MCV) decreased from 87% to 84%, and coverage with a second MCV dose decreased from 76% to 67%. After rubella vaccine was introduced in 2017, coverage with the first dose of rubella-containing vaccine increased approximately fivefold, from 15% in 2017 to 84% in 2022. During 2013–2021, annual reported measles incidence decreased by 95%, from 33.2 to 1.4 cases per million population, reported rubella incidence decreased 89%, from 9.3 to 1.0 cases per million population. However, a large surge in measles and rubella cases occurred in 2022, with a reported measles incidence of 29 cases per million and a reported rubella incidence of 3 per million, primarily related to disruption in immunization services caused by the COVID-19 pandemic. In 2022, approximately 26 million children (an estimated 73% of the target population) received a combined measles- and rubella-containing vaccine during supplementary immunization activities completed in 32 provinces. Progress toward measles and rubella elimination in Indonesia has been made; however, continued and urgent efforts are needed to restore routine immunization services that were adversely affected by the COVID-19 pandemic and close immunity gaps to accelerate progress toward measles and rubella elimination.

Introduction

Indonesia's immunization program currently targets a birth cohort of approximately 4.4 million children annually. In 1982, a first dose of measles-containing vaccine (MCV1) was introduced into the routine immunization program, administered to children at age 9 months; a second MCV dose (MCV2), administered to grade 1 elementary school children (aged 7 years) was introduced in 2003. In 2013, the age of MCV2 administration was changed to 18–24 months. An MCV dose is still given to grade 1 elementary school children and recorded as the third MCV dose. Two doses of rubella-containing vaccine (RCV) were introduced into the routine immunization program in 2017 as a combined measles- and rubella-containing vaccine (MRCV). The first RCV dose (RCV1) is administered at age 9 months (as MRCV1), and the second dose (RCV2) at age 18–24 months (as MRCV2).

In 2013, Indonesia, along with the other 10 countries of the World Health Organization (WHO) South-East Asia Region (SEAR),* adopted the goal of measles elimination and control of rubella and congenital rubella syndrome (CRS), a condition that can result in miscarriage, stillbirth, or a constellation of birth defects resulting from maternal infection with rubella virus during pregnancy† by 2020 (1). In 2019, this goal was revised to include the elimination of both measles and rubella§ by 2023 (2). In 2021, Indonesia adopted the National Strategic Plan for Measles-Rubella Elimination 2020–2024 (3). The main objectives of this strategy include 1) achieving and maintaining ≥95% coverage with the first and second doses of measles- and rubella-containing vaccine (MRCV1 and MRCV2, respectively) in every district through routine immunization and supplementary immunization activities (SIAs)¶; 2) achieving and maintaining sensitive and timely case-based measles-rubella and CRS surveillance systems; 3) building and maintaining an accredited measles and rubella laboratory network for case confirmation that covers all 38 provinces in Indonesia; 4) ensuring preparedness and rapid response to every measles or rubella outbreak; and 5) strengthening support and partnerships. This report describes Indonesia's progress toward measles and rubella elimination during 2013–2022.

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* Bangladesh, Bhutan, Burma, India, Indonesia, Maldives, Nepal, North Korea, Sri Lanka, Thailand, and Timor-Leste.

† Measles elimination is defined as the absence of endemic measles cases for ≥12 months in the presence of adequate surveillance. Rubella and congenital rubella syndrome control is defined as a 95% reduction in disease incidence from the 2013 level.

§ Rubella elimination is defined as the absence of endemic rubella cases for ≥12 months in the presence of adequate surveillance.

¶ In Indonesia, follow-up SIAs for measles and rubella conducted during 2013–2022 were carried out using two target age ranges. SIAs focused on all children and adolescents aged 9 months to <15 years and were conducted with the goal of eliminating susceptibility to measles and rubella in the general population. Other SIAs focused on children aged 9–59 months with the goal of eliminating any measles and rubella susceptibility that had accumulated in recent birth cohorts and of protecting the estimated 2%–5% of children who did not respond to the first measles vaccine dose.

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Methods

Administrative vaccination coverage (the number of vaccine doses administered divided by the estimated target population) is reported each year from all 7,252 districts in Indonesia to the national immunization program, where data are aggregated and reported to WHO and UNICEF through the electronic Joint Reporting Form (eJRF). WHO and UNICEF use reported administrative coverage, official estimates, and vaccination coverage survey data to generate annual estimates of national immunization coverage through routine immunization services; these estimates are used throughout this report (*4*). Measles and rubella cases are also reported to WHO and UNICEF through Indonesia's eJRF. Genotype data are reported to the WHO measles nucleotide surveillance (MeaNS) and rubella nucleotide surveillance (RubeNS) genetic databases. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[**]

[**] 45 C.F.R. part 46.102(I)(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.

Results

Immunization Activities

Routine immunizations. During 2013–2022, MCV1 coverage decreased approximately 3%, from 87% in 2013 to 84% in 2022; MCV2 coverage decreased approximately 12%, from 76% to 67% (Figure 1). RCV1 coverage increased from 15% in 2017 (the year RCV was introduced) to 84% in 2022 (Figure 2). During the COVID-19 pandemic, both measles and rubella vaccination coverage declined. In 2019, MCRV1 coverage was 88%; this declined to 76% in 2020 and to 72% in 2021. In 2019, MCRV2 coverage was 71%; this declined to 60% in 2020 and to 50% in 2021.

Supplementary immunization activities. In 2016, in response to measles outbreaks during 2014–2015, a nationwide follow-up measles SIA reached approximately 3.6 million children aged 9–59 months. In 2017 and 2018, as an integral component of RCV introduction, a MRCV SIA was conducted, reaching approximately 58 million children and adolescents aged 9 months to <15 years. In 2022, in response to the setbacks resulting from the COVID-19 pandemic, the

FIGURE 1. Number of reported measles cases,* estimated percentage of children who received their first and second dose of measles-containing vaccine,[†] and supplementary immunization activities, by year[§,¶,] — Indonesia, 2013–2022**
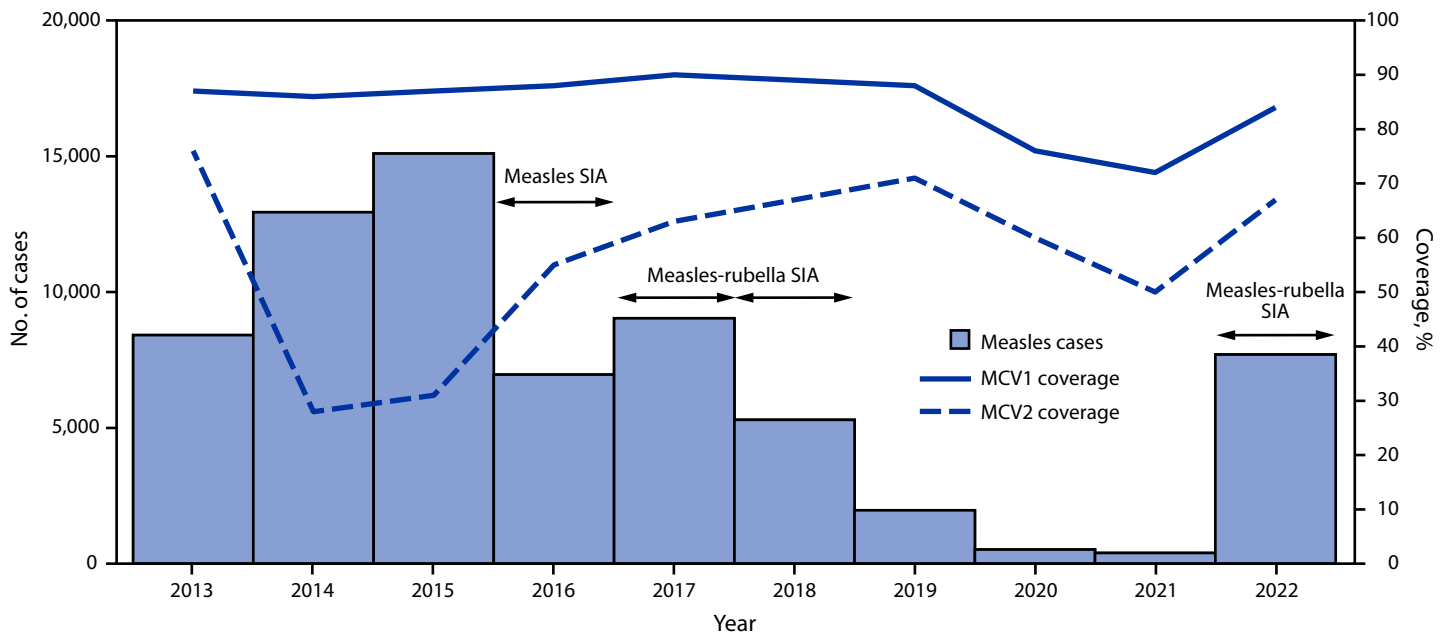
Abbreviations: MCV1 = first dose of measles-containing vaccine in routine immunization; MCV2 = second dose of measles-containing vaccine in routine immunization; SIA = supplementary immunization activity.
* Measles case data include laboratory-confirmed, epidemiologically linked, and clinically compatible cases and are reported through Indonesia's Electronic Joint Reporting Form.
[†] Vaccination coverage data were from World Health Organization and UNICEF estimates of national immunization coverage. https://cdn.who.int/media/docs/default-source/country-profiles/immunization/2023-country-profiles/immunization_idn_2023.pdf
[§] Measles SIA targeted children aged 9–59 months in 183 very high-risk districts; implemented during 2016–2017.
[¶] Measles-rubella SIA targeted children aged 9 months to <15 years; implemented in two phases: in 2017, the SIA was conducted in six provinces in Java Island, and in 2018, the SIA was conducted in the 28 remaining provinces.
[**] Measles-rubella SIA in 2022 targeted children of various ages, depending on the provincial-level risk. In five provinces, the SIA targeted children aged 9 months to <15 years; in 22 provinces, it targeted children aged 9 months to <12 years; and in the remaining five provinces, the SIA targeted children aged 9–59 months.

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Indonesian government sought to increase immunization coverage through Bulan Imunisasi Anak National (BIAN) or National Children Immunization Month,[††] reaching approximately 26 million children with MRCV. Due in part to this campaign, MRCV1 coverage increased from 72% in 2021 to 84% in 2022, and MRCV2 coverage increased from 50% in 2021 to 67% in 2022. In addition to BIAN, other efforts implemented by Indonesian government contributed to the increase in coverage, including expanding immunization activities to include children aged <5 years and search for unimmunized or partially immunized children in remote and high-risk areas, which are defined on the basis of population immunity, surveillance quality, and the presence of vulnerable groups, such as migratory populations.

[††] BIAN or Nationsl Chidren Immunization Month efforts included immunization activities (selectively giving ≥1 dose of measles-rubella containing vaccine to children aged 12–59 months who missed or had not received the appropriate number of measles and rubella doses) and an MR SIA targeting all children aged 9–59 months, regardless of previous vaccination status. BIAN was implemented in 32 of 34 provinces in Indonesia.

## Surveillance Activities and Measles and Rubella Incidence

Case-based measles and rubella surveillance was initiated in Indonesia in 2008[§§]; in 2019, this was transitioned to case-based fever and rash surveillance.[¶¶] The network of WHO-accredited laboratories for measles and rubella expanded from four in 2013 to seven in 2015. During 2018–2022, the discarded nonmeasles and nonrubella rate (NMNR),[***] a measure of surveillance sensitivity, approximately tripled, from 1.2 to 3.3 per 100,000 population (Table). The percentage of cases investigated within 48 hours of notification increased from 65% in 2018 to 74% in 2022. In 2022, 86% of suspected cases with adequate specimens were tested in a

[§§] For case-based measles and rubella surveillance, a suspected case was defined as fever and maculopapular rash with cough, coryza, or conjunctivitis, or any illness in a person that a clinician or health worker suspects to be measles infection.

[¶¶] For case-based acute fever and rash surveillance, a suspected case was defined as fever and maculopapular rash, or any illness in a person that a clinician or health worker suspects to be measles or rubella infection.

[***] A discarded case is defined as a suspected case that has been investigated and determined to be neither measles nor rubella by 1) laboratory testing in a proficient laboratory or 2) epidemiologic investigation with no linkage to another confirmed measles or rubella case.

FIGURE 2. Number of reported rubella cases,* estimated percentage of children who received their first dose of rubella-containing vaccine,[†] and supplementary immunization activities, by year[§,¶] — Indonesia, 2013–2022
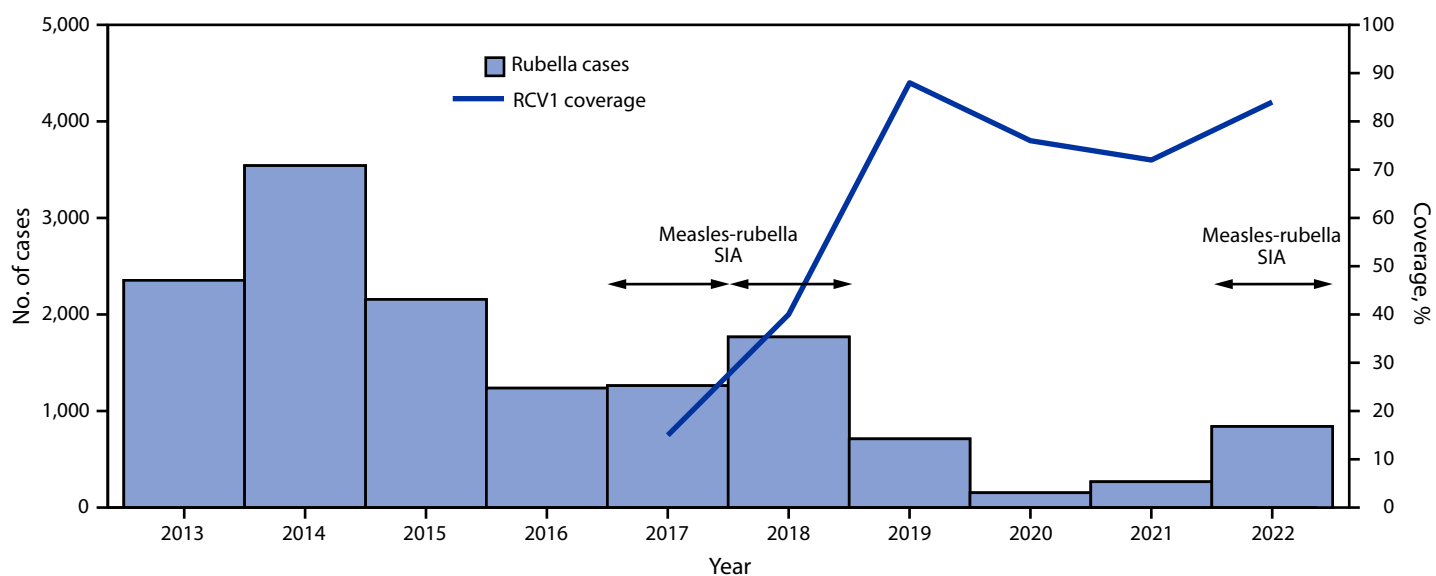
Abbreviations: RCV1 = first dose of rubella-containing vaccine in routine immunization; SIA = supplementary immunization activity.
* Rubella case data includes laboratory-confirmed and epidemiologically linked cases and are reported through Indonesia's Electronic Joint Reporting Form.
[†] Vaccination coverage data were from World Health Organization and UNICEF estimates of national immunization coverage (https://cdn.who.int/media/docs/default-source/country-profiles/immunization/2023-country-profiles/immunization_idn_2023.pdf); RCV1 was introduced into routine immunization in 2017.
[§] Measles-rubella SIA targeted children aged 9 months to <15 years; implemented in two phases: in 2017, the SIA was conducted in six provinces in Java Island, while in 2018, the SIA was conducted in the 28 remaining provinces.
[¶] Measles-rubella SIA in 2022 targeted children of various ages, depending on the provincial-level risk. In five provinces, the SIA targeted children aged 9 months to <15 years; in 22 provinces it targeted children aged 9 months to <12 years; and in the remaining five provinces, the SIA targeted children aged 9–59 months.

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TABLE. Reported number of measles and rubella cases, by case classification, age group, vaccination status, and surveillance indicator status — Indonesia, 2018–2022

Characteristic	Year, No. (%)				
	2018	2019	2020	2021	2022
Measles					
All cases, no.	**5,300**	**1,965**	**524**	**394**	**7,704**
Laboratory-confirmed*	861 (16)	639 (33)	310 (50)	132 (34)	4,844 (63)
Epidemiologically linked†	153 (3)	22 (1)	0 (0)	1 (0)	103 (1)
Clinically compatible§	4,286 (81)	1,304 (66)	214 (50)	261 (66)	2,757 (36)
Incidence¶	19.8	7.3	1.9	1.4	28.8
Measles genotypes (no.)	D8 (5)	—	—	—	D8 (54), B3 (47)
Age group of patients with laboratory-confirmed and epidemiologically linked measles					
<9 mos	64 (6)	20 (3)	11 (4)	7 (5)	484 (10)
9 mos–4 yrs	131 (13)	43 (6)	24 (8)	13 (10)	356 (7)
5–9 yrs	151 (15)	204 (31)	78 (25)	19 (14)	1,539 (31)
10–14 yrs	112 (11)	40 (6)	29 (9)	11 (8)	358 (7)
≥15 yrs	150 (15)	64 (10)	32 (10)	22 (17)	307 (7)
Unknown or missing	406 (40)	290 (44)	136 (44)	61 (46)	1,903 (38)
MCV doses received by patients with laboratory-confirmed or epidemiologically linked measles					
≥2	0 (—)	25 (4)	11 (5)	20 (15)	290 (6)
1	1 (—)	43 (6)	24 (8)	12 (9)	267 (5)
0	53 (5)	85 (13)	93 (30)	45 (34)	3,178 (64)
Unknown	960 (95)	508 (77)	182 (59)	56 (42)	1,212 (24)
Rubella					
All cases, no.	**1,767**	**713**	**155**	**268**	**839**
Laboratory-confirmed**	1,767 (100)	710 (100)	155 (100)	267 (100)	839 (100)
Epidemiologically linked††	0 (—)	3 (—)	0	1 (—)	0 (—)
Incidence¶	6.60	2.60	0.60	0.98	3.05
Rubella genotypes	NA	NA	NA	NA	NA
Age group of patients with laboratory-confirmed and epidemiologically linked rubella					
<9 mos	17 (1)	12 (2)	6 (4)	8 (3)	30 (4)
9 mos–4 yrs	48 (3)	73 (10)	25 (16)	35 (13)	98 (12)
5–9 yrs	364 (21)	93 (13)	25 (16)	39 (15)	151 (18)
10–14 yrs	347 (20)	66 (9)	13 (8)	25 (9)	68 (8)
≥15 yrs	388 (22)	76 (11)	22 (14)	28 (10)	133 (16)
Unknown or missing	603 (34)	393 (55)	64 (41)	133 (50)	359 (48)
RCV doses received by patients with laboratory-confirmed or epidemiologically linked rubella					
≥2	7 (0)	35 (5)	15 (10)	40 (15)	130 (15)
1	22 (1)	68 (10)	20 (13)	35 (13)	101 (12)
0	72 (4)	75 (11)	40 (26)	88 (33)	348 (41)
Unknown	1,666 (94)	535 (75)	80 (52)	105 (39)	260 (31)
Congenital rubella syndrome					
All suspected cases, no.	**275**	**664**	**457**	**916**	**1,026**
Laboratory-confirmed§§	89 (32)	35 (5)	10 (2)	29 (3)	25 (2)
Clinically compatible¶¶	99 (36)	176 (27)	100 (22)	200 (22)	148 (14)
Discarded***	87 (32)	453 (68)	347 (76)	687 (75)	853 (83)

See table footnotes on the next page.

WHO-accredited laboratory. However, only 43% of specimens were tested within 4 days of receipt by the laboratory, and 70% of laboratory results were submitted to the immunization program within 4 days of specimen receipt, potentially delaying public health action.

Sentinel CRS surveillance was initiated in 13 hospitals in Indonesia in 2015 and was expanded to 22 hospitals in 2022. During 2018–2022, the national reporting rate for suspected CRS cases (a marker of CRS surveillance sensitivity) increased 85% from 1.71 to 3.16 per 10,000 live births. In 2018, among 275 suspected CRS cases, 89 (32%) were

laboratory-confirmed, 99 (36%) were clinically confirmed as CRS, and 87 (32%) were discarded. In 2022, among 1,026 suspected CRS cases, 25 (2%) were laboratory-confirmed, 148 (14%) were clinically confirmed, and 853 (83%) were discarded. Despite the increase in the number of suspected cases, likely related to increased detection through increased surveillance sites, the percentage of laboratory or clinically confirmed CRS cases decreased, likely representing a decline in CRS incidence following introduction of RCV.

During 2013–2022, measles incidence decreased from 33.2 cases per million population to a low of 1.4 in 2021 but

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TABLE. (*Continued*) Reported number of measles and rubella cases, by case classification, age group, vaccination status, and surveillance indicator status — Indonesia, 2018–2022

Characteristic	Year, No. (%)				
	2018	2019	2020	2021	2022
Surveillance and program implementation					
Provinces with case-based fever and rash surveillance[†††]	34 (100)	34 (100)	34 (100)	34 (100)	34 (100)
WHO-accredited measles and rubella laboratories, no.	7	7	7	7	7
Provinces completing measles-rubella SIA	28 (80)	0 (—)	0 (—)	0 (—)	34 (100)
Surveillance performance indicators					
No. of discarded NMNR cases[§§§]	3,065	5,099	2,188	2,269	9,149
No. of discarded NMNR cases per 100,000 population, national level (target: ≥2)	1.2	1.0	0.8	0.8	3.3
Districts with NMNR discard rate ≥2	71 (14)	123 (24)	42 (8)	73 (14)	230 (45)
% of suspected cases adequately investigated ≤48 hrs of notification (target: ≥80)	65	62	60	71	74
% of suspected cases with adequate specimens[¶¶¶] tested for measles and rubella in a proficient laboratory[****] (target: ≥80)	96	94	91	92	86
% of samples tested ≤4 days of specimen receipt in laboratory (target: ≥80)[††††]	86	66	64	84	43
% of results received by program ≤4 days of specimen receipt (target: ≥80)[§§§§]	83	63	57	83	70
% of surveillance units reporting weekly to national level on time (target: ≥80)	47	40	77	70	89

Abbreviations: IgM = immunoglobulin M; MCV = measles-containing vaccine; NA = not available; NMNR = nonmeasles, nonrubella; RCV = rubella-containing vaccine; SIA = supplementary immunization activity; WHO = World Health Organization.

* Defined as a case that meets the suspected case definition and is laboratory-confirmed (serologically or virologically) as measles.
† Defined as a case that meets the suspected case definition, which is found as part of a laboratory-confirmed measles outbreak investigation but does not have a laboratory specimen collected.
§ Defined as a case that meets the suspected case definition without an adequate laboratory specimen collected and without epidemiological linkage to another laboratory-confirmed communicable disease.
¶ Cases per 1 million population.
** Defined as a case that meets the suspected case definition and is laboratory-confirmed as rubella.
†† Defined as a case that meets the suspected case definition, which is found as part of a laboratory-confirmed rubella outbreak investigation but does not have a laboratory specimen collected.
§§ Defined as a case that meets the suspected case definition and is laboratory-confirmed as congenital rubella syndrome.
¶¶ Defined as a case that meets the suspected case definition and the clinically compatible case definition but does not have an adequate laboratory specimen collected.
*** Defined as a case that meets the suspected case definition but does not meet the clinically compatible case definition or has negative laboratory testing for congenital rubella syndrome.
††† Case-based fever and rash surveillance identifies suspected cases as illness in any person with fever and maculopapular (nonvesicular) rash or in any person in whom a clinician suspects measles or rubella infection.
§§§ Suspected cases that have been investigated and discarded as not measles or rubella by 1) laboratory result negative for measles and rubella through serum sample testing in a proficient laboratory and 2) no epidemiological linkage to another measles or rubella case.
¶¶¶ Serum specimen collected ≤28 days (for serology) and throat or urine samples collected ≤7 days (for virology) after rash onset.
**** A WHO-accredited laboratory that has an established quality assurance program or one with oversight by a WHO-accredited laboratory.
†††† Samples tested for measles and rubella IgM ≤4 days after sample receipt by laboratory.
§§§§ Laboratory results for measles and rubella IgM received by program ≤4 days after sample receipt by laboratory.

sharply increased to 28.8 in 2022 (Table). In 2022, 88% of patients with laboratory-confirmed or epidemiologically linked measles had received no MCV doses or had an unknown vaccination history. After the introduction of RCV and a wide age-range MRCV SIA, rubella incidence declined from 9.3 cases per million in 2013 to a low of 0.6 in 2020 but increased to 3.1 in 2022. Similar to what was observed with measles surveillance, 72% of persons with laboratory-confirmed or epidemiologically linked rubella had received no RCV doses or had unknown vaccination history.

Measles virus genotypes detected and reported included D8 in 2018 and 2022 and B3 in 2022. No rubella virus genotypes were detected or reported (Table).

Discussion

During 2013–2022, Indonesia implemented substantial efforts toward measles and rubella elimination, including introducing RCV and conducting a wide age-range MRCV SIA. During 2013–2019, MCV1 coverage was stable (86%–90%); MCV2 coverage declined during 2014–2015, likely because of a change in age of administration in 2013, followed by an increase in coverage during 2016–2019. After introduction of RCV in 2017, RCV1 coverage increased steadily through 2019. However, the COVID-19 pandemic resulted in substantial declines in both coverage with MCV1, MCV2, and RCV1 and in sensitivity of measles and rubella (MR) surveillance during 2020–2021, because of temporary closing of immunization posts, movement restrictions, and repurposing of immunization and surveillance staff to COVID-19 activities. Similar COVID-19 pandemic-related setbacks were seen in other WHO SEAR countries (5,6).

Existing immunity gaps, widened by immunization coverage setbacks during the COVID-19 pandemic, led to substantial increases in the number of measles and rubella cases in 2022

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Summary

What is already known about this topic?

In 2019, Indonesia and the other countries in the World Health Organization South-East Asia Region adopted the goal of measles and rubella elimination by 2023.

What is added by this report?

During 2013–2021, measles and rubella incidence declined by 95% and 89%, respectively. However, in 2022, measles and rubella incidence significantly increased compared with 2021 because of disruption in surveillance and immunization services caused by the COVID-19 pandemic, leading to gaps in immunity.

What are the implications for public health practice?

Indonesia has made substantial progress toward measles and rubella elimination. To achieve elimination, urgent efforts are needed to restore immunization services adversely affected by the COVID-19 pandemic, close immunity gaps, and enhance surveillance.

compared with 2021. This is consistent with an independent review of progress toward measles and rubella elimination in WHO SEAR during October–November 2021, which concluded that Indonesia would not achieve measles and rubella elimination by 2023 (7).

In 2022, recovery efforts were accelerated with BIAN immunization activities. MRCV1 and MRCV2 coverage rates have rebounded to levels approaching those achieved in 2019. Despite this improvement, to accelerate progress toward elimination, Indonesia will need to continue to intensify efforts to enhance MR surveillance and close immunity gaps among eligible children through SIAs, with a particular focus in districts with low coverage (8).

Limitations

The findings in this report are subject to at least three limitations. First, coverage estimates based on administrative data might be inaccurate because of errors in recording doses administered or in estimating the target population. Second, surveillance data might underestimate actual disease incidence because surveillance sensitivity was low: children who had measles or rubella might not have been brought in for care, not all cases in patients who sought care might have received a proper diagnosis, and some diagnosed cases might not have been reported. Finally, few specimens were submitted for sequencing, so genotype data might not reflect predominant circulating genotypes.

Implications for Public Health Practice

COVID-19 caused substantial setbacks to Indonesia's MR elimination program. In 2022, intensified efforts to increase immunization coverage and improve MR surveillance sensitivity resulted in program recovery. Indonesia's large annual birth cohort represents an important opportunity to prevent illness and death from measles and rubella viruses. Urgent actions are still needed to accelerate progress toward MR elimination, including vaccinating all eligible children and optimizing surveillance sensitivity.

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

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Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2023

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Abstract

COVID-19 vaccines protect against severe COVID-19–associated outcomes, including hospitalization and death. As SARS-CoV-2 has evolved, and waning vaccine effectiveness has been noted, vaccine formulations and policies have been updated to provide continued protection against severe illness and death from COVID-19. Since September 2022, bivalent mRNA COVID-19 vaccines have been recommended in the United States, but the variants these vaccines protect against are no longer circulating widely. On September 11, 2023, the Food and Drug Administration (FDA) approved the updated (2023–2024 Formula) COVID-19 mRNA vaccines by Moderna and Pfizer-BioNTech for persons aged ≥12 years and authorized these vaccines for persons aged 6 months–11 years under Emergency Use Authorization (EUA). On October 3, 2023, FDA authorized the updated COVID-19 vaccine by Novavax for use in persons aged ≥12 years under EUA. The updated COVID-19 vaccines include a monovalent XBB.1.5 component, which is meant to broaden vaccine-induced immunity and provide protection against currently circulating SARS-CoV-2 XBB-sublineage variants including against severe COVID-19–associated illness and death. On September 12, 2023, the Advisory Committee on Immunization Practices recommended vaccination with updated COVID-19 vaccines for all persons aged ≥6 months. These recommendations will be reviewed as new evidence becomes available or new vaccines are approved and might be updated.

Introduction

By the end of 2022, COVID-19 vaccines had prevented 18.5 million COVID-19 hospitalizations and 3.2 million COVID-19 deaths in the United States (*1*). As SARS-CoV-2 has evolved, and waning vaccine effectiveness (VE) has been observed, vaccine formulations and policies have been updated to provide continued protection against severe COVID-19–associated illness and death. On September 11,

2023, the Food and Drug Administration (FDA) authorized the updated (2023–2024 Formula) COVID-19 mRNA vaccines by Moderna and Pfizer-BioNTech for use in persons aged 6 months–11 years under Emergency Use Authorization (EUA) and approved the updated Moderna and Pfizer-BioNTech COVID-19 vaccines for persons aged ≥12 years (*2*). On October 3, 2023, FDA authorized the updated Novavax COVID-19 vaccine for use in persons aged ≥12 years under EUA (*2*). The updated COVID-19 vaccines include a monovalent XBB.1.5 component and are meant to broaden vaccine-induced immunity and provide increased protection (compared with protection from earlier vaccines that might have waned) against currently circulating SARS-CoV-2 XBB-sublineage variants, which, by September 2, 2023, accounted for >99% of sequenced SARS-CoV-2 specimens in the United States.* As of September 11, 2023, bivalent mRNA COVID-19 vaccines (based on the ancestral SARS-CoV-2 strain and BA.4/BA.5 variants) are no longer authorized for use in the United States, and as of October 3, 2023, original monovalent Novavax COVID-19 vaccines (based on the ancestral SARS-CoV-2 strain) are no longer authorized for use in the United States. On September 12, 2023, the Advisory Committee on Immunization Practices (ACIP) recommended vaccination with the updated COVID-19 vaccine for all persons aged ≥6 months. These recommendations will be reviewed as new evidence becomes available or new vaccines are approved and might be updated.

Background

Although severe COVID-19 is now less prevalent in the United States than during previous years, it continues to cause significant morbidity and mortality in this country. Currently, older adults (aged ≥65 years) and infants aged <6 months are at highest risk for COVID-19–associated hospitalization. During January 1–August 26, 2023, COVID-19–associated hospitalization rates among adults aged ≥75 years were two to three times as high as those among the next youngest age group

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* https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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(adults aged 65–74 years). Rates among infants aged <6 months are similar to those among adults aged 65–74 years (*3*).

Nevertheless, persons aged 6 months–64 years, including those with no underlying medical conditions, remain at risk for severe COVID-19. Rates of COVID-19–associated hospitalization are currently lowest among children and adolescents aged 5–17 years. However, among persons in this age group who were hospitalized with COVID-19 during January–June 2023, 23% of those aged 5–11 years and 34% of those aged 12–17 years had no underlying medical conditions. During January 2022–June 2023, among children and adolescents aged ≤17 years who died during a COVID-19 hospitalization, 50% had no underlying condition. During January 1–July 22, 2023, a total of 28,128 persons, including 26 aged <1 year, 18 aged 1–4 years, 36 aged 5–19 years, 451 aged 20–44 years, 2,821 aged 45–64 years, and 24,776 aged ≥65, died from COVID-19, as evidenced by COVID-19 being listed as the underlying cause of death on the death certificate.[†]

Post–COVID-19 conditions contribute to COVID-19–related morbidity among all age groups. The prevalence of ongoing symptoms ≥3 months after COVID-19 illness ranged from <1% among persons aged <18 years to 5% among those aged 35–49 years. During June 7–19, 2023, approximately one in four adults with post–COVID-19 conditions reported significant activity limitations (*4*).

Members of racial and ethnic minority groups continue to be disproportionately affected by COVID-19–associated hospitalization (*5*). Higher prevalences of underlying conditions in some racial and ethnic minority populations might increase their risk for severe COVID-19–associated outcomes (*6*). As of May 10, 2023, only 17% of the U.S. population had received a bivalent COVID-19 vaccine dose, with lower coverage among some racial and ethnic minority populations, potentially driven by differences in vaccine access and acceptability (*5,7*).

After declining throughout the spring and early summer of 2023, COVID-19–associated hospitalization rates began increasing in mid-July 2023. Further increases are anticipated during the fall and winter respiratory virus season (*5*).

Methods

Since June 2020, ACIP has convened 37 public meetings to review data relevant to the potential use of COVID-19 vaccines.[§] The ACIP COVID-19 Vaccine Work Group, comprising experts in adult and pediatric medicine, obstetrics and gynecology, infectious diseases, vaccinology, vaccine safety, public health, and ethics, has met weekly to review COVID-19 surveillance data; evidence regarding immunogenicity, efficacy, effectiveness, and safety of COVID-19 vaccines; and implementation considerations. The Work Group conducted a systematic review of benefits and harms of vaccination, and used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology[¶] to assess the certainty of the evidence regarding benefits and harms associated with a bivalent vaccine administered in the United States during September 2022–April 2023. The Work Group selected this population, intervention, and pandemic period of high seroprevalence to identify evidence most applicable to what can be anticipated from this year's vaccine in the United States. The certainty of evidence was assessed separately for infants and children aged 6 months–11 years, and adolescents and adults aged ≥12 years based on the difference in recommended vaccine dosage for these two age groups. The Work Group also reviewed additional CDC data on VE and safety, as well as data on the updated vaccines provided by manufacturers (*8–10*). To assess the evidence for benefits and harms associated with COVID-19 vaccine use, and to guide deliberations, ACIP uses the Evidence to Recommendations (EtR) Framework.** Within this framework, ACIP considered the importance of COVID-19 as a public health problem, including during the Omicron XBB-lineage–predominant era (January 2023–September 2023), as well as issues of resource use, benefits and harms, patients' values, acceptability, feasibility, and equity related to vaccine use. ACIP evaluated data related to all vaccines for which updated 2023–2024 formulations were anticipated (i.e., Moderna, Novavax, and Pfizer-BioNTech).

Vaccine Effectiveness and Safety

Published assessments of previous vaccine formulations' VE and safety were evaluated using GRADE. GRADE is used to assess the confidence (high, moderate, low, or very low) that the true effect lies close to that of the estimated effect. Evidence that includes only randomized controlled trials begins at high certainty, whereas evidence that includes observational data begins at low certainty.

Among adolescents and adults, benefits of bivalent vaccination were assessed using pooled observational VE data for three outcomes: medically attended COVID-19,[††] hospitalization attributed to COVID-19, and death attributed to COVID-19. Pooled VE against medically attended COVID-19 was 53% (95% CI = 50%–56%), and hospitalization

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[†] https://wonder.cdc.gov/mcd-icd10-provisional.html (Accessed September 7, 2023).
[§] https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html (Accessed September 7, 2023).

[¶] https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html
** https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf
[††] Medically attended COVID-19 was defined as an emergency department or urgent care visit.

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attributed to COVID-19 was 48% (95% CI = 30%–61%). For both critical outcomes, the certainty assessment was low.[§§] Pooled VE against death attributed to COVID-19 was 61% (95% CI = 41%–74%), and the certainty assessment was very low because of serious concern for inconsistency. Among infants and children, insufficient observational data were identified for a systematic review of benefits, but benefits were indirectly inferred from adolescent and adult data. The certainty assessment was very low for all three outcomes because of serious concern for indirectness.

Studies from the Vaccine Safety Datalink (VSD), a post-authorization vaccine safety monitoring system, were used to assess rates of serious adverse events (i.e., myocarditis or pericarditis and anaphylaxis, which were the outcomes specified for GRADE) that have been associated with vaccination (myocarditis after receipt of COVID-19 vaccine has been reported primarily in adolescent and young adult males)[¶¶] (*11*), and the certainty assessment was low among adolescents and adults and very low among infants and children. Severe reactogenicity (grade ≥3*** local or systemic reactions) was assessed using pooled clinical trial data after any original monovalent primary series dose. Severe reactogenicity occurred more often in the vaccine than placebo study arms, and the certainty assessment for the clinical trial body of evidence was low because of very serious concern for indirectness[†††] in both age groups. The GRADE evidence profile is available at www.cdc.gov/vaccines/acip/recs/grade/covid-19-2023-2024-Monovalent.html.

Additional, updated CDC VE data were also reviewed, including data showing patterns of waning bivalent vaccine–induced immunity against infection and COVID-19–associated hospitalization during a period with increased Omicron XBB sublineage circulation (*12,13*). During

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[§§] Evidence that includes observational data starts at low certainty.

[¶¶] Among persons aged ≥12 years, based on events occurring in a 0–1 day risk interval after either dose of primary series vaccination, the estimated incidence of confirmed anaphylaxis among adolescents and adults was 4.8 (95% CI = 3.2–6.9) per million doses of Pfizer-BioNTech COVID-19 vaccine and 5.1 (95% CI = 3.3–7.4) per million doses of Moderna COVID-19 vaccine. Among persons aged 12–39 years, based on events occurring in 7-day risk interval after vaccination versus a comparison interval in vaccinated persons, rates of chart-reviewed myocarditis or pericarditis per one million doses, were as high as 188 (95% CI = 86.0–356.9) in males aged 16–17 years after a monovalent booster dose of Pfizer-BioNTech COVID-19 vaccine.

[***] Grade 3 or 4 reactogenicity is generally defined as reactions that prevent daily routine activity, require use of a pain reliever, or require an emergency department visit or hospitalization. Definitions used for each clinical trial are provided on CDC webpages. (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html; https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html)

[†††] Very serious concern for indirectness was noted because the body of evidence did not include anyone who received an updated dose, was from an earlier period of the pandemic, and excluded persons with previous COVID-19 infection, pregnant or breastfeeding women, and persons who were immunocompromised.

September 2022–August 2023, VE against hospitalization among adults aged ≥65 years without an immunocompromising condition waned from 67% (95% CI = 62%–71%) at 7–59 days postvaccination to 28% (95% CI = 18%–36%) at 120–179 days (*13*). VE of both the original monovalent and bivalent vaccines against critical outcomes (invasive mechanical ventilation, intensive care unit admission, or death) has remained more durable than VE against less severe outcomes among adults, including those with and without immunocompromising conditions (*12,14*). VE patterns were similar among children and adults, although available data were more limited in children (*13,15*). VE against emergency department and urgent care visits among persons aged 5–17, 18–64, and ≥65 years ranged from 59%–63% by age group 7–59 days after a bivalent dose, waning to 36%–47% by age group 60–119 days after a bivalent dose (*13*). VE has historically been lower and has waned more quickly among adults with immunocompromise than among immunocompetent adults, although bivalent VE trends are less clear (*12,13*).

Additional, updated data on COVID-19 vaccine safety from VSD were also reviewed. The risk for myocarditis or pericarditis after receipt of a bivalent vaccine dose is uncertain because myocarditis is a rare outcome, and bivalent vaccination coverage is relatively low, especially in adolescents and young adults. Myocarditis rates after booster doses in adolescent and young adult males are lower than rates after primary series vaccination, but estimates for monovalent booster and bivalent doses are limited by the lower numbers of doses administered in VSD in this group (*16*). A longer interval between doses has been associated with lower rates of myocarditis (*17*).

ACIP recommendations for the updated COVID-19 vaccines were also guided by data on immunogenicity provided by the vaccine manufacturers. Data from Moderna, Novavax, and Pfizer-BioNTech show that monovalent XBB component–containing COVID-19 vaccines increase the immune response against the currently circulating XBB-sublineage variants (*8–10*). The evidence used to guide EtR is available at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-2023-2024-Monovalent-etr.html.

Cost Effectiveness

COVID-19 vaccination is a cost-effective intervention, particularly in adults aged ≥65 years, among whom incidence is highest. For this age group, a dose of the vaccine is cost saving (at an assumed cost of $120 per dose). Among adults aged 50–64 years, the incremental cost-effectiveness ratio of updated COVID-19 vaccines was estimated to be $25,787 per quality-adjusted life year, with estimates in those aged ≥50 years

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robust to input changes across plausible ranges (*18*). For adults aged 18–49 years, the incremental cost-effectiveness ratio for updated COVID-19 vaccines was estimated to be $115,588 per quality-adjusted life year, although estimates in younger adults were more sensitive to changes in input, with higher VE or hospitalization rates increasing cost-effectiveness (*18*). Cost-effectiveness estimates are not yet available for pediatric populations (*18*).

Recommendations for Use of 2023–2024 COVID-19 Vaccines in Persons Aged ≥6 Months

On September 12, 2023, ACIP recommended vaccination with the updated (2023–2024 Formula) COVID-19 vaccine for all persons aged ≥6 months.§§§ The recommendation is inclusive of FDA-licensed or authorized updated mon-ovalent XBB component–containing COVID-19 vaccines (i.e., Moderna, Novavax and Pfizer-BioNTech updated COVID-19 vaccines), consistent with the FDA-licensed indication or EUA. The recommendation for children aged 6 months–11 years is an interim recommendation because the updated COVID-19 vaccines for this age group are currently authorized under EUA. In addition, the recommendation for the updated Novavax COVID-19 vaccine is an interim recommendation because the Novavax COVID-19 vaccine is currently authorized under EUA.

Infants and children aged 6 months–4 years are recom-mended to receive a multidose initial series (previously referred to as the primary series) and at least 1 updated mRNA COVID-19 vaccine dose depending on vaccination history as defined herein. Infants and children aged 6 months–4 years who are unvaccinated are recommended to receive either 2 updated Moderna COVID-19 vaccine doses or 3 updated Pfizer-BioNTech COVID-19 vaccine doses (Table 1). Infants and children aged 6 months–4 years who previously received original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 or 2 homologous (i.e., from the same manufacturer) updated COVID-19 mRNA vaccine doses, depending on vaccine manufacturer and the number of previous vaccine doses received. Infants and children aged 6 months–4 years who completed the initial series with original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 updated COVID-19 vaccine dose, at least 2 months after receipt of the last COVID-19 vaccine dose. Infants and

children aged 6 months–4 years may receive either the updated Moderna or Pfizer-BioNTech COVID-19 vaccine; however, all doses administered to an infant or child in this age group should be from the same manufacturer.

For those receiving updated mRNA COVID-19 vaccines, persons aged ≥5 years without immunocompromise are recom-mended to receive 1 updated COVID-19 vaccine dose, irre-spective of previous COVID-19 vaccination history (Table 2). For those receiving updated Novavax COVID-19 vaccines, persons ages ≥12 years without immunocompromise are rec-ommended to receive 2 updated COVID-19 vaccine doses if previously unvaccinated and 1 updated dose if previously vaccinated with any COVID-19 vaccine. For those who have received previous COVID-19 vaccines, the updated vaccine should be administered ≥2 months after receipt of the most recent dose.

Recommendations for 2023–2024 COVID-19 Vaccines in Persons Aged ≥6 Months Who Are Moderately or Severely Immunocompromised

Unvaccinated persons aged 6 months–11 years who are mod-erately or severely immunocompromised are recommended to receive an initial vaccination series of 3 homologous updated (2023–2024 Formula) mRNA COVID-19 vaccine doses. Unvaccinated persons aged ≥12 years who are moderately or severely immunocompromised can complete an initial vacci-nation series with 3 homologous doses of updated mRNA or 2 doses of updated Novavax COVID-19 vaccine.¶¶¶ Persons aged ≥6 months who are moderately or severely immunocom-promised and previously received 1 or 2 original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 or 2 homologous updated COVID-19 vaccine doses, depending on the number of previous vaccine doses. Persons aged ≥6 months who are moderately or severely immunocom-promised who previously received ≥3 original monovalent or bivalent mRNA vaccine doses are recommended to receive 1 updated COVID-19 vaccine dose. Persons aged ≥12 years who are moderately or severely immunocompromised and who previously received original Novavax COVID-19 vaccine or Janssen (Johnson & Johnson) COVID-19 vaccine, includ-ing those who also received original monovalent or bivalent mRNA COVID-19 vaccine doses, are recommended to receive 1 updated COVID-19 vaccine dose from any FDA-authorized or approved manufacturer.

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§§§ ACIP voted (13 to one) to recommend vaccination with 2023–2024 (monovalent, XBB-containing) COVID-19 vaccines as authorized under EUA or approved by Biologics License Application in persons aged ≥6 months.

¶¶¶ Apart from the administration of additional doses, the FDA EUA for Novavax COVID-19 vaccine does not provide for a specific vaccination schedule for persons who are moderately or severely immunocompromised.

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TABLE 1. Recommended COVID-19 vaccination schedule for persons aged 6 months–4 years who are not moderately or severely immunocompromised,* by COVID-19 vaccination history — United States, September 2023

Previous COVID-19 vaccination history (before updated mRNA vaccine)[†]	Updated mRNA vaccine	No. of updated mRNA vaccine doses indicated	Interval between doses
Unvaccinated	Moderna	2	Dose 1 and dose 2: 4–8 wks
	Pfizer-BioNTech	3	Dose 1 and dose 2: 3–8 wks
			Dose 2 and dose 3: ≥8 wks
Received Moderna vaccine			
1 dose any Moderna	Moderna	1	4–8 wks after last dose
≥2 doses any Moderna	Moderna	1	≥8 wks after last dose
Received Pfizer-BioNTech vaccine			
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	Dose 1: 3–8 wks after last dose
			Dose 1 and dose 2: ≥8 wks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	≥8 wks after last dose
≥3 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	≥8 wks after last dose

* Additional clinical considerations, including detailed schedules and tables by age and vaccination history for those who are and are not moderately or severely immunocompromised, are available. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
[†] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised

TABLE 2. Recommended COVID-19 vaccination schedule for persons aged ≥5 years who are not moderately or severely immunocompromised,* by COVID-19 vaccination history — United States, September 2023

COVID-19 vaccination history before updated vaccine[†]	Updated vaccine	No. of updated doses indicated	Interval between doses
Unvaccinated	Moderna	1	—
	Pfizer-BioNTech	1	—
	Novavax (aged ≥12 yrs only)	2	Dose 1 and dose 2: 3–8 wks
Receipt of ≥1 COVID-19 vaccine dose, including Moderna, Pfizer-BioNTech, Novavax (aged ≥12 yrs only), or Janssen (Johnson & Johnson) (aged ≥18 yrs only)	Moderna	1	≥8 wks after last dose
	Pfizer-BioNTech	1	≥8 wks after last dose
	Novavax (aged ≥12 yrs only)	1	≥8 wks after last dose

* Additional clinical considerations, including detailed schedules and tables by age and vaccination history for those who are and are not moderately or severely immunocompromised, are available. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
[†] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#not-immunocompromised

Persons who are moderately or severely immunocompromised, have completed an initial series, and have received ≥1 updated COVID-19 vaccine dose, may receive additional updated COVID-19 vaccine doses, guided by the clinical judgment of a health care provider and personal preference and circumstances. Any further additional doses should be administered ≥2 months after the last COVID-19 vaccine dose. Additional clinical considerations, including detailed schedules and tables by age and vaccination history for those who are and are not moderately or severely immunocompromised, are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Implementation Considerations

COVID-19 vaccines are transitioning from federal procurement and distribution into the commercial marketplace during fall 2023. Under the Affordable Care Act (ACA), ACIP recommendations for routine immunization that have been adopted by CDC and are listed on CDC Immunization Schedules are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without cost-sharing requirements. The Coronavirus Aid, Relief, and Economic Security (CARES) Act expedited coverage for COVID-19 vaccines; since January 5, 2021, ACA-covered insurers must cover, without cost sharing, any COVID-19 vaccine FDA authorized under an EUA or FDA approved under a Biologics License Application immediately upon authorization or approval of the vaccine (19). Thus, for U.S. residents with applicable ACA commercial medical insurance coverage, COVID-19 vaccines will be covered immediately. In addition, COVID-19 vaccines are covered under Medicare Part B, and nearly all Medicaid beneficiaries can receive COVID-19 vaccines without cost-sharing. COVID-19 vaccines are also included in the Vaccines for Children Program,**** which provides vaccines to approximately one half of U.S. persons aged <19 years at no cost. The Bridge Access Program for COVID-19 Vaccines is a public-private partnership serving as a temporary measure to maintain access to COVID-19 vaccines for adults who are uninsured or underinsured, working through both public health clinics and participating retail pharmacies.[††††] Before

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**** https://www.cdc.gov/vaccines/programs/vfc/index.html
[††††] https://www.cdc.gov/vaccines/programs/bridge/index.html (Accessed September 7, 2023).

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Summary

What is already known about this topic?

Since September 2022, bivalent mRNA COVID-19 vaccines have been recommended in the United States, but the variants these vaccines were designed to protect against are no longer circulating widely. In September and October 2023, the Food and Drug Administration approved and authorized updated 2023–2024 Formula monovalent XBB.1.5 component–containing COVID-19 vaccines, formulated to target current variants more closely, specifically Omicron variant XBB.1.5, for persons aged ≥6 months.

What is added by this report?

On September 12, 2023, the Advisory Committee on Immunization Practices recommended vaccination with updated COVID-19 vaccines for all persons aged ≥6 months.

What are the implications for public health practice?

The updated COVID-19 vaccines are meant to broaden vaccine-induced immunity and provide protection against the currently circulating SARS-CoV-2 XBB-sublineage variants including against severe COVID-19–associated illness and death.

vaccination, providers should provide the EUA Fact Sheet,§§§§ manufacturer's package insert, or other written materials regarding the vaccine being administered and counsel vaccine recipients about expected systemic and local adverse reactions (reactogenicity).

Reporting of Vaccine Adverse Events

Adverse events after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting is encouraged for any clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by telephone at 1-800-822-7967.

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§§§§ https://www.cdc.gov/vaccines/covid-19/eua/index.html

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Notes from the Field

Severe *Bartonella quintana* Infections Among Persons Experiencing Unsheltered Homelessness — New York City, January 2020–December 2022

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Bartonella quintana infection is a vectorborne disease transmitted by the human body louse (*1*). In the United States, homelessness is the principal risk factor for *B. quintana* infection (*2*), likely attributable to limited access to hygiene facilities (*1*). This infection is not nationally notifiable in the United States, and its incidence is unknown. Acute *B. quintana* infection can cause fever, headache, and bone pain; severe manifestations include chronic bacteremia, bacillary angiomatosis, and infective endocarditis (*3*). Because the bacterium requires special conditions to grow in culture, standard blood cultures are usually negative (*4*). Diagnosis by serology is most common; however, cross-reactivity with other *Bartonella* species (e.g., *B. henselae*) can hamper interpretation. Molecular assays specific for *B. quintana* have been developed (*5*), but availability is limited to a few laboratories. Once diagnosed, infection can be cured by several weeks to months of antibiotic therapy.

Investigation and Outcomes

In January and April 2023, the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) was alerted to two cases of *B. quintana* infection that occurred during 2022 among persons who had experienced unsheltered homelessness in NYC and later died (one died because of the infection, and the other because of an unrelated cause). DOHMH conducted retrospective active surveillance within clinical laboratories of five large NYC hospital networks to identify additional cases with culture, molecular, or serologic laboratory results for *B. quintana* or *Bartonella* spp. and reviewed electronic medical records of all identified patients. One patient's family provided clinical outcome details not found in the medical record. Housing status was determined from the medical record or the NYC Department of Homeless Services (DHS) system. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[†]

Four additional cases were identified that occurred in NYC during January 2020–December 2022 (Table). Four of the six total cases occurred during 2022. Five patients received a positive molecular diagnostic test result specific for *B. quintana*[§]; one received a positive *Bartonella* polymerase chain reaction (PCR) test result not specific to *B. quintana*. Five patients were hospitalized for complications of *B. quintana* infection; the median duration of hospitalization was 34 days (range = 8–78 days). Four patients received a diagnosis of culture-negative, left-sided endocarditis and underwent surgical valve replacement; three experienced renal failure, and two died from endocarditis-related complications. One patient died from complications of traumatic injury not related to *B. quintana* infection. All six patients had experienced recent unsheltered homelessness either at the time of hospitalization (four) or within the preceding year (two) and had incidental contact or no contact with the NYC DHS shelter or outreach system; five had a documented mental health or substance use disorder; no cases were epidemiologically linked.

Preliminary Conclusions and Actions

B. quintana infection can result in severe outcomes, including death, and incur substantial health care costs from prolonged hospitalizations and surgical interventions. The total number of *B. quintana* cases is likely higher than what is reported here for several reasons: 1) persons experiencing unsheltered homelessness often do not seek health care services, 2) health care providers are less likely to consider bartonellosis in patients without severe disease, and 3) laboratory diagnosis is challenging.

To help identify patients at risk for *B. quintana* infection, clinicians should consider housing status. Persons experiencing homelessness who have mental health conditions or substance use disorders might be less likely to access preventive hygiene services. Clinicians and health care systems could increase diagnostic and treatment support for behavioral health conditions

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* These senior authors contributed equally to this report.

† 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.

§ Three patients received a diagnosis of *B. quintana* based on reverse transcriptase–PCR testing and molecular sequencing at the New York State Department of Health Wadsworth Center; two patients received a diagnosis based on *B. quintana* PCR testing and molecular sequencing of retrospectively identified fixed tissue samples at CDC's Infectious Disease Pathology Branch.

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TABLE. Demographic information, clinical features, risk factors, and outcomes of six persons experiencing homelessness who received a diagnosis of *Bartonella quintana* infection — New York City, January 2020–December 2022.

Characteristic	No. (%)
Age, yrs, mean (range)	52 (38–69)
Sex	
Female	1 (17)
Male	5 (83)
Diagnosis*	
Aortic valve endocarditis	4 (67)
Mitral valve endocarditis	1 (17)
Bacillary angiomatosis	1 (17)
Bacteremia	1 (17)
History of unsheltered homelessness	6 (100)
History of alcohol use	5 (83)
History of mental health condition	3 (50)
HIV infection[†]	1 (17)
Hospital admission, yr	
2020	1 (17)
2021	1 (17)
2022	4 (67)
Outcome	
Traumatic injury–related death	1 (17)
Endocarditis-related death	2 (33)
Renal failure	3 (50)

* One patient received two diagnoses.
† CD4 T-cell count <50 cells/mm^3 at time of diagnosis.

in this population to prevent serious medical conditions, including bartonellosis resulting from body louse infestation. In addition, it is important that patients with a history of unsheltered homelessness and either prolonged subjective fevers without a known etiology, a vasoproliferative skin rash, or a diagnosis of culture-negative endocarditis be tested for *B. quintana* infection with a molecular diagnostic laboratory assay and considered for empiric treatment in consultation with an infectious disease physician.

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Notes from the Field

Firearm Homicide Rates, by Race and Ethnicity — United States, 2019–2022

Scott R. Kegler, PhD[1]; Thomas R. Simon, PhD[2]; Steven A. Sumner, MD[2]

The rate of firearm homicide in the United States rose sharply from 2019 through 2020, reaching a level not seen in more than 2 decades, with ongoing and widening racial and ethnic disparities (1). During 2020–2021, the rate increased again (2). This report provides provisional firearm homicide data for 2022, stratified by race and ethnicity, presented both annually and by month (or quarter) to document subannual changes.

Investigation and Outcomes

National Vital Statistics System final mortality data for 2019–2021 and provisional mortality data for 2022, stratified by race and ethnicity, were downloaded via CDC WONDER.* Data are monthly for all groups except non-Hispanic American Indian or Alaska Native (AI/AN) and non-Hispanic Asian or Pacific Islander (A/PI) groups, which are presented quarterly because of small monthly counts. Corresponding population estimates were downloaded from the U.S. Census Bureau.† Annual and monthly (or quarterly for AI/AN and A/PI) crude rates were calculated by race and ethnicity, with all rates expressed per 100,000 person-years. This activity was reviewed by CDC, deemed not research, and conducted consistent with applicable federal law and CDC policy.§

During 2022, the national firearm homicide rate decreased for the first time since the sharp increase from 2019 to 2020. Nonetheless, the rate in 2022 (5.9 per 100,000) remained substantially higher than the 2019 rate (4.4), corresponding to 5,223 more firearm homicides in 2022 than in 2019

(Table). Rate patterns show notable differences by race and ethnicity (Supplementary Figure; https://stacks.cdc.gov/view/cdc/133535). Rates among non-Hispanic Black or African American (Black), AI/AN, and Hispanic or Latino (Hispanic) persons were notably higher during the period from 2020 through 2022 compared with 2019. The annual rate among Black persons during 2022 (27.5) was lower than that in 2021 (30.4) or 2020 (28.3) but was still substantially higher than in 2019 (20.5). Among AI/AN persons, the rate during 2022 (9.3) exceeded the rates in both 2021 (7.7) and 2020 (7.9). During 2022, the rate among Hispanic persons leveled off (5.5) but remained higher than that in 2019 (3.8). Rates among non-Hispanic White and A/PI persons, although lower, also increased from 2019 to 2021, followed by a decrease in 2022.

Preliminary Conclusions and Analysis

Although the overall national rate of firearm homicide decreased from 2021 to 2022, the rate remained higher than in 2019. The onset of higher rates has been attributed to a range of factors, including economic and social stressors and disruptions in health and emergency services related to longstanding systemic inequities (such as employment or housing), which were worsened by the COVID-19 pandemic (1,3,4).

Although firearm homicide rates decreased for some groups in 2022, rates remained elevated overall compared with 2019, particularly among Black persons, and the rate increased among AI/AN persons. Continued prevention efforts, particularly those addressing social and structural conditions that contribute to violence, are needed to mitigate risks and inequities. These efforts include policies and programs promoting economic and housing security, hospital and community-based outreach and violence interruption programs, initiatives to enhance secure firearm storage to prevent unauthorized access or use, environmental changes such as remediating vacant lots, and therapeutic approaches to address trauma.¶ Such efforts can be furthered through partnerships involving community organizations that serve and represent those most affected by violence.

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* https://wonder.cdc.gov (Accessed August 10, 2023). Persons within some racial and ethnic groups, particularly AI/AN persons, might be undercounted because of misclassification. https://www.cdc.gov/nchs/data/series/sr_02/sr02_172.pdf; https://www.cdc.gov/nchs/data/nvsr/nvsr70/NVSR70-12.pdf

† Monthly population estimates, by age, sex, race, and Hispanic origin, April 1, 2010–July 1, 2020 (NC-EST2020-ALLDATA to cover January 2019–March 2020) and monthly population estimates by age, sex, race, and Hispanic origin, April 1, 2020–July 1, 2022, with short-term projections to December 2023 (NC-EST2022-ALLDATA to cover April 2020–December 2022). https://www.census.gov (Accessed June 29, 2023).

§ 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.

¶ https://www.cdc.gov/violenceprevention/firearms/fastfact.html

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TABLE. Firearm homicide annual rates and counts, by race and ethnicity — United States, 2019–2022

Race and ethnicity*	Rate† (no.)			
	2019	2020	2021	2022
A/PI, NH	1.0 (202)	1.0 (208)	1.2 (241)	1.1 (233)
AI/AN, NH	6.4 (154)	7.9 (191)	7.7 (185)	9.3 (224)
Black or African American, NH	20.5 (8,438)	28.3 (11,832)	30.4 (12,721)	27.5 (11,565)
White, NH	1.6 (3,129)	2.0 (3,969)	2.1 (4,064)	2.0 (3,828)
Hispanic or Latino, any race	3.8 (2,301)	4.8 (2,947)	5.5 (3,455)	5.5 (3,500)
Overall§	**4.4 (14,414)**	**5.8 (19,384)**	**6.3 (20,958)**	**5.9 (19,637)**

Sources: CDC WONDER; U.S. Census Bureau (NC-EST2020-ALLDATA; NC-EST2022-ALLDATA).
Abbreviations: A/PI = Asian or Pacific Islander; AI/AN = American Indian or Alaska Native; NH = non-Hispanic.
* Persons within some racial and ethnic groups, particularly AI/AN persons, might be undercounted because of misclassification. https://www.cdc.gov/nchs/data/series/sr_02/sr02_172.pdf; https://www.cdc.gov/nchs/data/nvsr/nvsr70/NVSR70-12.pdf
† Crude rates represent the number of firearm homicides per 100,000 persons.
§ Rates and numbers for the "Overall" category include the non-Hispanic multiple-race population grouping, not shown separately in the table.

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Notes from the Field

Mycobacterium abscessus Outbreak Related to Contaminated Water Among Ventilator-Dependent Residents of a Pediatric Facility — Pennsylvania, 2022

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Mycobacterium abscessus, a nontuberculous mycobacterium found in water and soil, is an opportunistic pathogen responsible for waterborne illness outbreaks in health care settings (*1*). On September 29, 2022, the Pennsylvania Department of Health (PADOH) received notification of *M. abscessus*–positive respiratory isolates from ventilator-dependent residents of a 34-bed pediatric facility. The facility is licensed for residential services, but not as a health care facility. A case was defined as the first *M. abscessus*–positive culture identified from a resident of this facility during March–August 2022. Three cases were identified: two colonizations and one clinical infection. PADOH investigated this outbreak to identify risk factors and recommend infection prevention and control (IPC) measures.

Investigation and Outcomes

On October 12, PADOH conducted a site visit to observe IPC practices. Three instances of respiratory care were observed, during which respiratory therapists failed to follow aseptic technique. Of 37 observed opportunities for hand hygiene, 30 (81%) were compliant. With regard to tracheostomy tube reprocessing (i.e., cleaning and disinfection for reuse), the manufacturer provided different instructions for home care and health care settings; the latter included stricter processes to reduce the risk for pathogen transmission. Staff members did not follow either of the manufacturer's processes, and instead, created their own procedure using nonmedical cleaning tools and an ultraviolet baby bottle sterilizer for which there is no documentation of effectiveness. PADOH recommended that the facility follow the more stringent manufacturer instructions for tracheostomy tube reprocessing for health care settings* and use aseptic practices during respiratory care. A second site visit on October 31 showed improvement in IPC practices; however, staff members were still not reprocessing tracheostomy tubes following manufacturer recommendations

for health care. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.†

Multiple areas of the building had not been in use for 2 years, raising concern about stagnant water and contamination. The facility did not have a water management plan or monitor water quality, as is recommended to prevent water-related infections (*2*). On October 31, PADOH collected 21 environmental samples from faucets, aerators, showerheads and drains, filtered water and ice machines, and water samples from clinical care areas where residents with *M. abscessus* colonization or infection resided. *Mycobacterium* species were identified in 16 (76%) of 21 environmental samples; *M. abscessus* was identified from a shower drain swab (Table). Heterotrophic plate counts of paired first-catch and post-flush§ water samples in a room sink of a resident and the reprocessing room sink where tracheostomy tubes were reprocessed exceeded Environmental Protection Agency (EPA) standards for safe drinking water¶ (*3*). PADOH recommended that the facility hire a water management consultant, develop a water management program, and install point-of-use filters in clinical areas until water quality consistently met EPA standards. The facility implemented recommendations in collaboration with a water management consultant; PADOH continued collaborative monitoring for an 8-month period.

Preliminary Conclusions and Actions

Epidemiologic and laboratory evidence suggest that this outbreak of *M. abscessus* was related to substandard water quality and inadequate IPC practices. Extended disuse of space in the building potentially resulted in stagnant water in plumbing, and the lack of a water management program meant that water quality was unmonitored. The facility licensing requirements did not emphasize IPC standards necessary for residents with high medical needs, including those who are dependent on ventilators. In ventilator-capable congregate settings IPC-recommended procedures should meet health care standards to prevent transmission of infectious organisms.

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* https://8949755.fs1.hubspotusercontent-na1.net/hubfs/8949755/User%20Manual/Bivona%20TTS%20Neonatal%20and%20Pediatric%20Trach%20Tube%20Instruction%20PKG-DFU-PNT-2%20Rev004%2009_13%20(007).pdf

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

§ First-catch samples were collected before aerator removal and occurred before the water outlet being sampled was used. Post-flush samples were collected after letting the water run for 5 minutes.

¶ EPA standards for safe drinking water are a heterotrophic plate count ≤500 colony-forming units/mL.

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TABLE. Organism growth and heterotrophic plate count* results for environmental specimens collected from water sources in a pediatric facility — Pennsylvania, 2022

Sampling site	Sample type	NTM identified	Heterotrophic plate counts (CFU/mL)[†]
Resident 1 room sink	First-catch water	*Mycobacterium franklinii; M. chelonae*	25,000
	Post-flush water	*M. franklinii; M. chelonae*	7,800
	Faucet swab	*M. gordonae*	NP
Tracheostomy tube reprocessing room sink	First-catch water	*M. chelonae; M. llatzerense; M. franklinii*	9,600
	Post-flush water	*M. llatzerense*	5,500
	Faucet swab	No NTM growth[§]	NP
Resident 2 room sink	Faucet swab	*M. gordonae*	NP
	Aerator swab	No suspected growth	NP
Filtered water machine	First-catch water	*M. chelonae; M. llatzerense*	NP
	Spout swab	*M. gordonae*	NP
Stand-alone shower in shower room	First-catch water	*M. llatzerense*	NP
	Faucet swab	No NTM growth	NP
	Drain swab	*M. chelonae; M. abscessus*	NP
Multipurpose room sink	First-catch water	*M. franklinii; M. llatzerense*	NP
	Faucet swab	*M. gordonae*	NP
Hallway handwashing sink	First-catch water	*M. llatzerense*	NP
	Faucet swab	*M. gordonae*	NP
Ice machine	Ice	*M. peregrinum; M. llatzerense*	NP
	Ice guard swab	No NTM growth	NP
	Chute swab	No NTM growth	NP
	Drain swab	No NTM growth	NP

Abbreviations: CFU = colony-forming unit; HPC = heterotrophic plate count; NP = not performed; NTM = nontuberculosis mycobacterium.
* HPCs measure carbon-consuming microorganisms in water and can be used to assess conditions affecting microbial growth in a water source or distribution system. HPCs were performed on paired first-catch and post-flush water samples only. HPCs were not performed on swab samples.
[†] HPCs are reported as CFUs per mL and provide an estimate of the total number of viable organisms in a sample. Environmental Protection Agency standards for safe drinking water are HPC ≤500 CFU/mL.
[§] Selective medium was used to culture and isolate the target organism or species, and no presumptive NTM growth was found in the environmental sample.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. Hollis Houston reports stock options in Fidelity Healthcare Technology. No other potential conflicts of interest were disclosed.

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QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Rate* of Emergency Department Visits,[†] by Homeless Status[§] — National Hospital Ambulatory Medical Care Survey, United States, 2010–2021
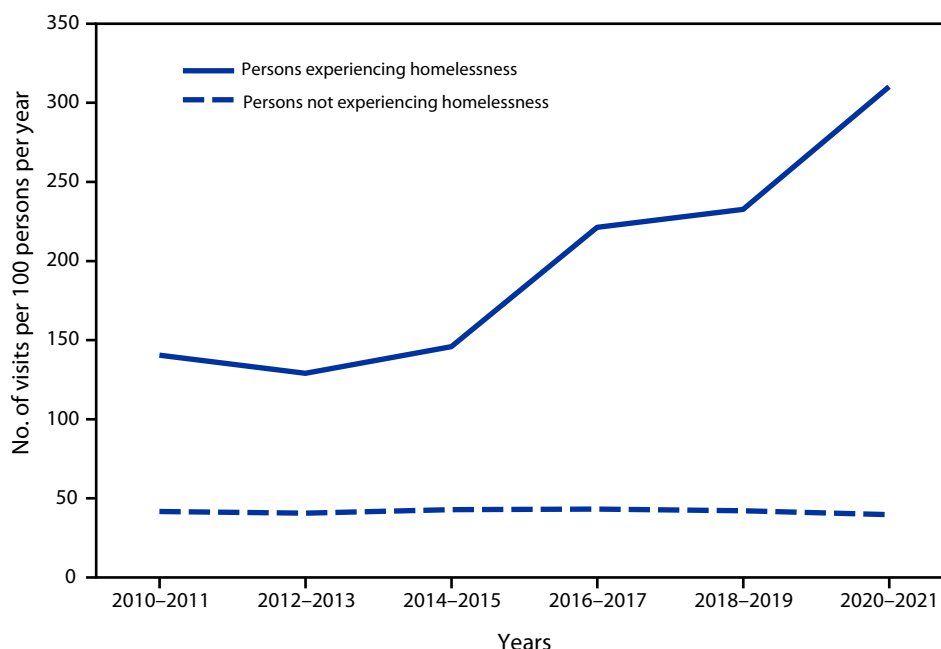
* Visit rates are based on estimates of the U.S. population experiencing homelessness, reported by the U.S. Department of Housing and Urban Development, from data collected on a single night in January of each year during 2010–2021. The estimate for 2021 was adjusted for incompleteness. Visit rates for the population not experiencing homelessness are based on estimates of the U.S. civilian, noninstitutionalized population developed by the U.S. Census Bureau and reflect the population as of July 1 of each year during 2010–2021.
[†] Based on a sample of visits to emergency departments in noninstitutional general and short-stay hospitals, exclusive of federal, military, and Veterans Administration hospitals, located in U.S. states and the District of Columbia.
[§] Persons experiencing homelessness are identified as having no home or living in a homeless shelter. Persons not experiencing homelessness are identified as having a private residence, living in a nursing home, or having some other living arrangement. Patient residence was missing for 3.0% of emergency department visits; these records were excluded from the analysis.

The rate of visits to hospital emergency departments by persons experiencing homelessness increased from an estimated 141 visits per 100 persons per year during 2010–2011 to 310 during 2020–2021. Rates increased during 2016–2017 compared with 2014–2015, and again during 2020–2021 compared with 2018–2019. Visit rates for persons not experiencing homelessness did not vary significantly across years, ranging from 42 visits per 100 persons per year during 2010–2011 to 40 during 2020–2021. Visit rates for persons experiencing homelessness were higher than rates for persons not experiencing homelessness in all years.

Source: National Center for Health Statistics, National Hospital Ambulatory Medical Care Survey, 2010–2021. https://www.cdc.gov/nchs/ahcd/ahcd_questionnaires.htm

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