Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 70 / No. 43
October 29, 2021

Routine Vaccination Coverage — Worldwide, 2020

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Endorsed by the World Health Assembly in 2020, the Immunization Agenda 2030 (IA2030) strives to reduce morbidity and mortality from vaccine-preventable diseases across the life course (*1*). This report, which updates a previous report (*2*), presents global, regional,* and national vaccination coverage estimates and trends as of 2020. Changes are described in vaccination coverage and the numbers of unvaccinated and undervaccinated children as measured by receipt of the first and third doses of diphtheria, tetanus, and pertussis-containing vaccine (DTP) in 2020, when the COVID-19 pandemic began, compared with 2019. Global estimates of coverage with the third dose of DTP (DTP3) and a polio vaccine (Pol3) decreased from 86% in 2019 to 83% in 2020. Similarly, coverage with the first dose of measles-containing vaccine (MCV1) dropped from 86% in 2019 to 84% in 2020. The last year that coverage estimates were at 2020 levels was 2009 for DTP3 and 2014 for both MCV1 and Pol3. Worldwide, 22.7 million children (17% of the target population) were not vaccinated with DTP3 in 2020 compared with 19.0 million (14%) in 2019. Children who did not receive the first DTP dose (DTP1) by age 12 months (zero-dose children) accounted for 95% of the increased number. Among those who did not receive DTP3 in 2020, approximately 17.1 million (75%) were zero-dose children. Global coverage decreased in 2020 compared with 2019 estimates for the completed series of *Haemophilus influenzae* type b (Hib), hepatitis B vaccine (HepB), human papillomavirus vaccine (HPV), and rubella-containing vaccine (RCV). Full recovery from COVID-19–associated disruptions will require targeted, context-specific strategies to identify and catch up zero-dose and undervaccinated children, introduce interventions to minimize missed vaccinations, monitor coverage, and respond to program setbacks (*3*).

In 1974, the World Health Organization (WHO) established the Expanded Programme on Immunization to ensure that all infants have access to four vaccines (Bacillus Calmette-Guérin vaccine [BCG], DTP, Pol, and MCV) to protect against six diseases (tuberculosis, diphtheria, tetanus, pertussis, poliomyelitis, and measles). Since then, additional vaccines and doses have been introduced during the first year of life (e.g., pneumococcal conjugate vaccine [PCV], rotavirus, RCV, HepB, and Hib) and later in childhood and adolescence (e.g., MCV2 and HPV) (*4*). WHO and UNICEF derive national vaccination coverage

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

* Based on World Health Organization regional classifications. https://www.who.int/about/who-we-are/regional-offices

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estimates through annual country-by-country review of available data, including administrative and survey-based coverage[†,§] (*5*). DTP3 coverage by age 12 months is an indicator of immunization program performance. Children who do not receive DTP1 (zero-dose children) reflect a lack of access to immunization services. Those who receive DTP1 but do not complete the series are considered to have dropped out; they represent underutilization of immunization services among children with access.

WHO and UNICEF estimates during 2010–2019 indicate that global coverage with the DTP series stagnated, with coverage estimates ranging from 89% to 90% for DTP1 and from 84% to 86% for DTP3. From 2019 to 2020, global coverage declined from 90% to 87% for DTP1 and from 86% to 83% for DTP3, levels last observed in 2006 and 2009 for DTP1 and DTP3, respectively. In 2020, DTP1 coverage ranged from 79% in the WHO African Region to 97% in the European Region (Table 1). DTP3 coverage estimates ranged from 72% in the African Region to 95% in the Western Pacific Region. The Western Pacific Region was the only region with unchanged DTP3 coverage estimates from 2019 to 2020, whereas all others experienced decreases. Worldwide, the number of children who did not complete the 3-dose DTP series increased by 20% to 22.7 million from 2019 to 2020. Among them, 17.1 million (75%) were zero-dose children, and 5.6 million (25%) had started, but not completed, the DTP series. Approximately 95% of the increased number of children who failed to complete the DTP series between 2019 and 2020 (3.7 million) were zero-dose children. During 2019–2020, global DTP1-to-DTP3 dropout was stable at 4%–5%, ranging from 0.8% in the Western Pacific Region to 8% in the African Region.

The number of zero-dose children varied by WHO region, economic classification,[¶] and country eligibility for support

[†] For a given vaccine, the administrative coverage is the number of vaccine doses administered to persons in a specified target group divided by the estimated target population. Doses administered during routine immunization visits are counted, but doses administered during supplemental immunization activities (mass campaigns) usually are not. During vaccination coverage surveys, a representative sample of households is visited, and caregivers of children in a specified target age group (e.g., 12–23 months) are interviewed. Dates of vaccination are transcribed from the child's home-based record, recorded based on caregiver recall, or transcribed from health facility records. Survey-based vaccination coverage is calculated as the proportion of persons in a target age group who received a vaccine dose.

[§] For 35 countries that did not report immunization coverage data for 2020 by July 6, 2021, estimated coverage in 2019 was used. These countries represent <5% of the global birth cohort in 2020. Among the 35 countries, 17 were from the European Region, seven were from the Western Pacific Region, and five were from the African Region. WHO/UNICEF estimates of national immunization coverage are available at https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/immunization-coverage/who-unicef-estimates-of-national-immunization-coverage.

[¶] Low-income economies are defined as those with a gross national income (GNI) in USD per capita in 2010 of ≤$1,005, in 2019 of ≤$1,035 and in 2020 of ≤$1,045; middle-income economies are those with a GNI per capita in 2010 of $1,006–12,275, in 2019 of $1,036–$12,535 and in 2020 of $1,046–$12,695; high-income economies are those with a GNI per capita in 2010 of ≥$12,275, in 2019 of ≥$12,536, and in 2020 of ≥$12,696; calculated using the World Bank Atlas method (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups). Cook Islands and Niue (Western Pacific Region) are missing GNI data and are excluded from this categorization.

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

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

TABLE 1. Vaccination coverage,* by vaccine and World Health Organization region — worldwide, 2020

Vaccine	No. (%) of countries with vaccine in schedule	WHO region % coverage†						
		Global	AFR	AMR	EMR	EUR	SEAR	WPR
BCG	156 (80)	85	79	68	89	94	87	95
DTP1	194 (100)	87	79	88	87	97	88	96
DTP3	194 (100)	83	72	82	81	94	85	95
HepB BD	114 (58)	42	6	60	35	41	51	84
HepB3	190 (98)	83	72	82	81	91	85	95
Hib3	192 (99)	70	72	81	81	79	83	25
HPV, last§	111 (57)	13	18	44	0	29	3	5
MCV1	194 (100)	84	68	85	83	94	88	95
MCV2	179 (92)	70	36	73	76	91	78	94
PCV3	148 (76)	49	68	76	52	79	27	16
Pol3	194 (100)	83	71	81	84	94	85	94
RCV1	173 (89)	70	36	85	45	94	87	95
Rota, last¶	114 (52)	46	53	71	53	30	58	2

Abbreviations: AFR = African Region; AMR = Region of the Americas; BCG = Bacille Calmette-Guérin vaccine; DTP3 = third dose of diphtheria and tetanus toxoids and pertussis-containing vaccine; EMR = Eastern Mediterranean Region; EUR = European Region; HepB BD = birth dose of hepatitis B vaccine; HepB3 = third dose of hepatitis B vaccine; Hib3 = third dose of *Haemophilus influenzae* type b vaccine; HPV, last = final dose of human papillomavirus vaccine; MCV1 = first dose of measles-containing vaccine; MCV2 = second dose of MCV; PCV3 = third dose of pneumococcal conjugate vaccine; Pol3 = third dose of polio vaccine; RCV1 = first dose of rubella-containing vaccine; Rota, last = final dose of rotavirus vaccine series; SEAR = South-East Asia Region; WHO = World Health Organization; WPR = Western Pacific Region.

* Summary tables of WHO recommendations for routine immunization. https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/who-recommendations-for-routine-immunization---summary-tables

† BCG coverage based on 156 countries with BCG in the national schedule; coverage for all other vaccines based on 194 countries (global) or all countries in the specified region. Administrative coverage is the number of vaccine doses administered to those in a specified target group divided by the estimated target population. During vaccination coverage surveys, a representative sample of households is visited and caregivers of children in a specified target group (e.g., those aged 12–23 months) are interviewed. Dates of vaccination are transcribed from the child's home-based record or from health facility records or are recorded based on caregiver recall. Survey-based vaccination coverage is calculated as the proportion of persons in a target age group who received a vaccine dose.

§ Number of doses to complete the HPV series depends on age of recipient.

¶ Number of doses to complete the rotavirus vaccine series varies among vaccine products.

from Gavi, the Vaccine Alliance** (Table 2). During 2019–2020, the number of zero-dose children was stable in the European Region at 0.3 million but increased in the African (from 7.1 million to 7.7 million), Americas (from 1.6 million to 1.7 million), Eastern Mediterranean (from 1.8 million to 2.3 million), European (from 2.8 million to 3.4 million), South-East Asia (from 2.0 to 4.1 million), and Western Pacific (from 0.9 million to 1.0 million) regions (Figure). In 2020, middle-income countries had the largest number of zero-dose children (12.1 million; 71%); countries in the African and South-East Asia regions each accounted for 4.1 million (24%) children. Low-income countries accounted for 4.5 million (26%) zero-dose children. In 2020, 13.7 million (80%) zero-dose children lived in Gavi-eligible countries. Approximately two thirds (11.1 million; 65%) of zero-dose children in 2020 lived in 10 countries: Angola, Brazil, Democratic Republic of the Congo, Ethiopia, India, Indonesia, Mexico, Nigeria, Pakistan, and Philippines.

During 2010–2019, global coverage with MCV1 stagnated between 84% and 86%, while MCV2 coverage increased from 42% to 71%, reflecting second dose introductions in many countries.†† From 2019 to 2020, global MCV1 coverage decreased to the 2014 level of 84%, whereas MCV2 coverage was relatively stable at 71% in 2019 and 70% in 2020. MCV1 coverage in 2020 ranged from 68% in the African Region to 95% in the Western Pacific Region (Table 1). Among all countries, MCV2 coverage varied from 36% in the African Region to 94% in the Western Pacific Region.

During 2019–2020, global coverage decreased for the completed series of Hib vaccine (from 72% to 70%), RCV vaccine (from 71% to 70%), HepB (3-dose series: from 85% to 83%; birth dose stable at 42%), and HPV (from 15% to 13%). Global coverage with the completed PCV series remained stable at 49%, whereas rotavirus vaccination coverage increased from 39% to 46%. One country introduced PCV, and seven countries introduced rotavirus vaccine (Table 1).

Discussion

Following high (although stagnant) routine vaccination coverage during 2010–2019, a notable decline in global coverage

** Gavi, the Vaccine Alliance, is a public-private global health partnership with the goal of increasing access to immunization in poor countries. Country eligibility is defined by an average 3-year GNI per capita of ≤$1,580. Based on Gavi 4.0 (2016–2020), eligibility includes 68 low- and middle-income countries eligible to receive financial assistance through grants contingent on a country's GNI per capita. As GNI increases, a country moves through Gavi's different eligibility phases until reaching the transition phase, when GNI exceeds the eligibility threshold. https://www.gavi.org

†† During 2010–2019, 42 countries introduced the second dose of MCV2 into their immunization schedule. In 2020, only Madagascar introduced MCV2 into its immunization schedule.

TABLE 2. Number and percentage of surviving infants not receiving the first dose of diphtheria and tetanus toxoids and pertussis-containing vaccine (zero-dose children), by World Health Organization region, Gavi eligibility, and World Bank economic classification — worldwide, 2010, 2019, and 2020

Characteristic/Year	WHO region*							Economic classification†			Among Gavi-eligible countries§
	Global¶	AFR	AMR	EMR	EUR	SEAR	WPR	Low	Middle	High	
2010											
Total no. of countries	**193**	**46**	**35**	**21**	**53**	**11**	**27**	**35**	**106**	**49**	**67**
No. of surviving infants (millions)	133.1	30.5	15	16.2	11.2	35.8	24.4	25.1	95.3	12.6	76.1
Global % of surviving infants	—	23	11	12	8	27	18	19	72	9	57
No. of zero-dose children (millions)	14.9	6.1	0.5	2.6	0.5	4.3	0.9	3.3	11.2	0.3	12.7
Global % of zero-dose children	—	41	3	17	3	29	6	22	75	2	85
2019											
Total no. of countries	**194**	47	35	21	53	11	27	29	103	60	**67**
No. of surviving infants (millions)	135.8	35.7	14.5	17.5	10.9	33.8	23.2	21.8	101.3	12.5	80.2
Global % of surviving infants	—	26	11	11	8	25	17	16	75	9	59
No. of zero-dose children (millions)	13.6	7.1	1.6	1.8	0.3	2.0	0.9	4.2	9.0	0.3	10.6
Global % of zero-dose children	—	52	12	13	2	15	6	31	66	2	78
2020											
Total no. of countries	**194**	47	35	21	53	11	27	27	108	57	**68**
No. of surviving infants (millions)	135.7	36.3	14.5	17.5	10.8	33.7	22.9	21.6	101.4	12.2	80.7
Global % of surviving infants	—	26	11	13	8	25	17	16	75	9	59
No. of zero-dose children (millions)	17.1	7.7	1.7	2.3	0.3	4.1	1.0	4.5	12.1	0.3	13.7
Global % of zero-dose children	—	45	10	13	2	24	6	26	71	2	80

Abbreviations: AFR = African Region; AMR = Region of the Americas; EMR = Eastern Mediterranean Region; EUR = European Region; GNI = gross national income; SEAR = South-East Asia Region; USD = U.S. dollars; WHO = World Health Organization; WPR = Western Pacific Region.

* Included countries are WHO member states (N = 193 for 2010; N = 194 for 2019 and 2020).

† Low-income economies are defined as those with a GNI in USD per capita in 2010 of ≤$1,005, in 2019 of ≤$1,035, and in 2020 of ≤$1,045; middle-income economies are those with a GNI per capita in 2010 of $1,006–12,275, in 2019 of $1,036–12,535, and in 2020 of $1,046–12,695; high-income economies are those with a GNI per capita in 2010 of ≥$12,275, in 2019 of ≥$12,536, and in 2020 of ≥$12,696; calculated using the World Bank Atlas method (https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups). Categorization is based on the World Bank's economic classification for 2021. Cook Islands and Niue (WPR) are missing GNI data and are excluded from this categorization. Similarly, 2020 data for Venezuela were excluded as temporarily unclassified pending release of revised national accounts statistics.

§ Based on Gavi 4.0 (2016–2020), eligibility includes 68 low- and middle-income countries eligible to receive financial assistance through grants contingent on a country's GNI per capita. Eligibility is defined as a country's average 3-year GNI per capita of ≤$1,580. As GNI increases, a country moves through Gavi's different eligibility phases until reaching the transition phase when GNI exceeds the eligibility threshold. https://www.gavi.org

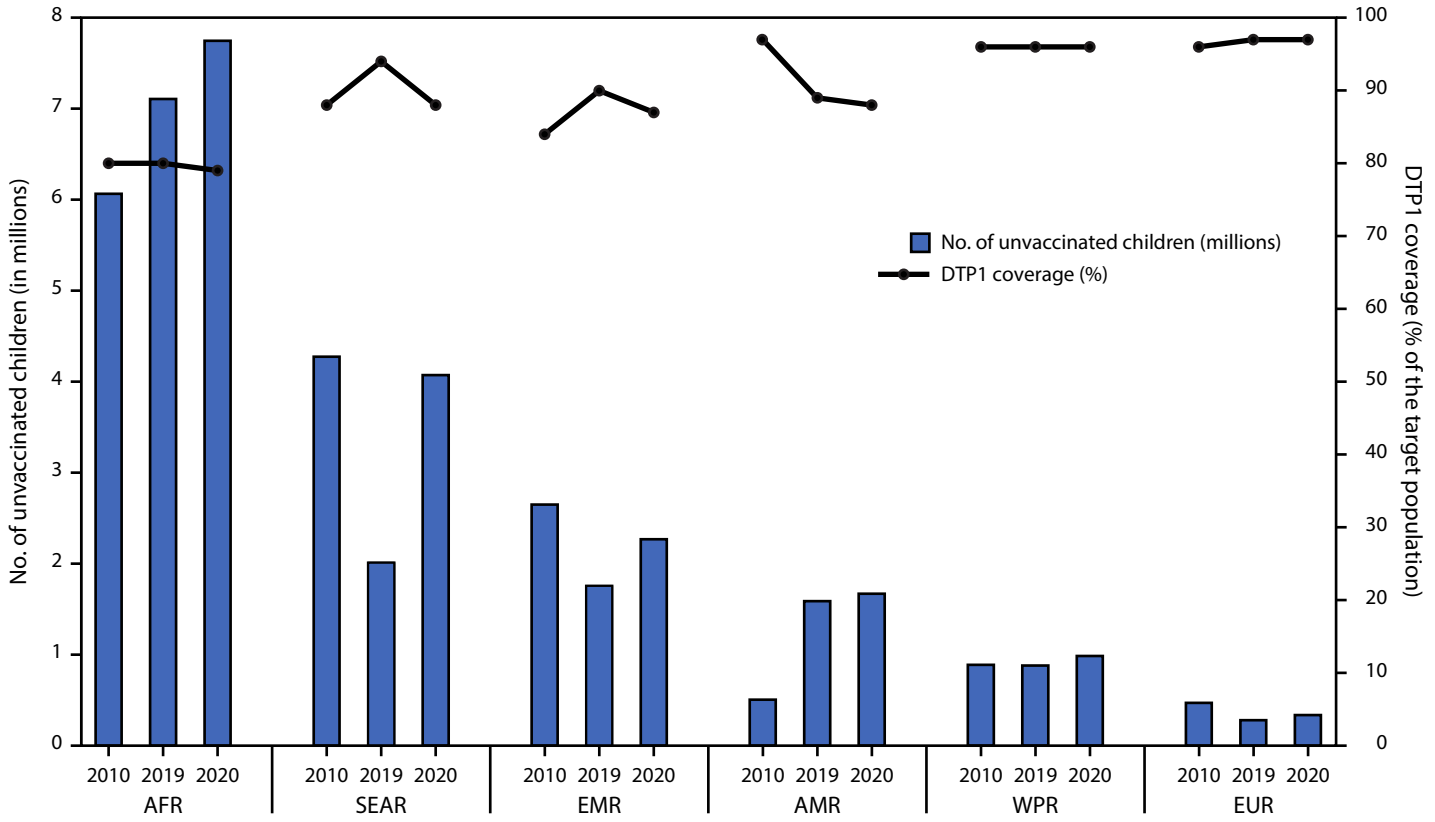
¶ Because of rounding, percentages across rows for regions do not necessarily sum to 100%.

for most vaccines occurred from 2019 to 2020. Although this decrease represented only a few percentage points, approximately 3 million more children did not complete the infant vaccination series in 2020. Even vaccines with apparent stable or increased coverage (i.e., MCV2, PCV, and rotavirus) were adversely affected. However, the drops in global coverage were offset by recent vaccine or dose introductions in some countries. The decrease in coverage in 2020 is likely related to effects of the COVID-19 pandemic. Surveys conducted in 2020 to gauge immunization program disruptions indicated decreased access because of physical distancing and transportation reductions, concerns by caregivers and health workers about COVID-19 exposure, and supply chain interruptions (*6*). The impacts to immunization coverage in 2020 were variable across regions and countries, with the South-East Asia and Eastern Mediterranean regions experiencing the largest declines in DTP3 coverage. DTP3 coverage in the Americas has continued a downward trend since 2016 (*2*).

Zero-dose children tend to live in vulnerable communities served by outreach services that are more prone to disruption and less resilient to recovery (*6*). Extending immunization services to reach zero-dose children and communities is one of the objectives of IA2030 and the Gavi 5.0 strategy (*1*,*7*). Achieving this objective requires an understanding of the socioeconomic, cultural, geographic, and systemic barriers to vaccination in these communities and the development of appropriate, context-specific strategies to increase access, availability, and demand for immunization services (*8*).

Although evidence suggests that routine immunization began to recover toward the end of 2020 (*6*), catch-up vaccination strategies and continued monitoring are essential to address the immunity gaps caused by immunization program disruptions (*9*,*10*). Catch-up strategies might include more immediate activities, such as mass vaccination activities and targeted communication to persons identified as having missed vaccine doses. Countries should also develop a catch-up vaccination framework within routine immunization, which could

FIGURE. Estimated number of zero-dose children* during the first year of life and estimated coverage with first dose of diphtheria and tetanus toxoids and pertussis-containing vaccine, by World Health Organization region — worldwide, 2010, 2019, and 2020



Abbreviations: AFR = African Region; AMR = Region of the Americas; DTP1 = first dose of diphtheria and tetanus toxoids and pertussis-containing vaccine; EMR = Eastern Mediterranean Region; EUR = European Region; SEAR = South-East Asia Region; WPR = Western Pacific Region.

* Zero-dose children are surviving infants who did not receive the first dose of DTP1 during the first year of life. Increase in the number of zero-dose children in the African Region reflects population growth.

include modifying immunization policies, improving defaulter tracking, training health workers to incorporate catch-up strategies into the immunization program, screening children for vaccination status at any health service encounter or at school entry, and expanding age-based eligibility for vaccinations to ensure that unvaccinated older children receive missed vaccines. A robust catch-up framework could also strengthen program resilience to withstand large-scale disruptions because the program could, at lower cost, rely on the routine immunization program to identify and administer missed vaccines to children rather than depending solely on costly mass vaccination events.

The findings in this report are subject to at least five limitations. First, 2019 data were used for 35 countries that did not report 2020 data; however, these countries included <5% of the 2020 global birth cohort.[§§] Second, data quality limitations could have resulted in inaccurate estimations of administrative coverage (*5*). Third, sampling and recall bias could have affected survey-based estimates of coverage (*5*). Fourth, estimates for 2020 are not directly informed by survey data in all countries because of survey implementation disruptions. Finally, estimates do not include statistical uncertainty.

Action is urgently needed to address immunity gaps caused by pandemic-related disruptions in immunization delivery to prevent vaccine-preventable disease outbreaks in countries with health systems already burdened by COVID-19. Reversing worrisome trends in some countries and extending previous gains in vaccination coverage beyond prepandemic levels will require targeted and context-specific approaches to eliminate barriers to vaccination, particularly in communities with large populations of zero-dose children. Defining country-specific strategies to identify missed children, minimize missed opportunities for vaccination, and implement catch-up vaccination is critical to lessen the impact of the COVID-19 pandemic on progress toward achieving global immunization goals.

[§§] Given that these countries represent <5% of the global birth cohort in 2020, the missing data likely had a limited impact on reported estimates.

Summary

What is already known about this topic?

Global coverage with the third dose of diphtheria and tetanus toxoids and pertussis-containing vaccine (DTP3) and of polio vaccine (Pol3) and the first dose of measles-containing vaccine (MCV1) remained between 84% and 86% during 2010–2019.

What is added by this report?

In 2020, estimated global coverage with DTP3 and Pol3 decreased to 83%; MCV1 coverage decreased to 84%. Globally, 17.1 million zero-dose children did not receive the first DTP dose, an increase of 3.5 million from 2019.

What are the implications for public health practice?

Full recovery from COVID-19–associated disruptions will require targeted, context-specific strategies to identify and catch up zero-dose and undervaccinated children, introduce interventions to minimize missed vaccinations, monitor coverage, and respond to program setbacks.

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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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Cake Decorating Luster Dust Associated with Toxic Metal Poisonings — Rhode Island and Missouri, 2018–2019

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During 2018–2019, the Rhode Island Department of Health (RIDOH) and the Missouri Department of Health and Senior Services (DHSS) investigated cases of metal poisonings associated with commercially and home-prepared cakes decorated with products referred to as luster dust. Several types of glitters and dusts, broadly known as luster dust,* for use on prepared foods can be purchased online and in craft and bakery supply stores (*1*). Decorating foods with luster dust and similar products is a current trend, popularized on television programs, instructional videos, blogs, and in magazine articles.† Some luster dusts are specifically produced with edible ingredients that can be safely consumed. Companies that make edible luster dust are required by law to include a list of ingredients on the label (*2*). Luster dusts that are safe for consumption are typically marked "edible" on the label. Some luster dusts used as cake decorations are not edible or food grade; labeled as "nontoxic" or "for decorative purposes only," these luster dusts are intended to be removed before consumption (*3*). RIDOH (2018) and Missouri DHSS (2019), investigated heavy metal poisonings associated with commercially and home-prepared cakes decorated with luster dust after receiving reports of children (aged 1–11 years) who became ill after consuming birthday cake. Cases in Rhode Island were associated with copper ingestion, and the case in Missouri was associated with a child's elevated blood lead level. In Rhode Island, luster dust products that had been used in cake frosting were found to contain high levels of multiple metals.§ These events indicate that increased vigilance by public health departments and further guidance to consumers and bakeries are needed to prevent unintentional poisonings. Labeling indicating that a product is nontoxic does not imply that the product is safe for consumption. Explicit labeling indicating that nonedible products are not safe for human consumption is needed to prevent illness from inappropriate use of inedible products on foods. Educating consumers, commercial bakers, and public health professionals about potential hazards of items used in food preparation is essential to preventing illness and unintentional poisoning from toxic metals and other nonedible ingredients.

In October 2018, the RIDOH Center for Acute Infectious Disease Epidemiology (CAIDE) investigated a report that six children aged 1–11 years became ill after attending a child's birthday party. Symptoms of vomiting and diarrhea began 30 minutes to 10 hours after consumption of the cake, and usually lasted less than 10 hours. One person was reported to have experienced longer symptom duration and visited an emergency department for treatment. Investigators identified the birthday cake as a common food item consumed by all the children who became ill, and noted the party as the only common event. The cake, ordered from a local bakery, had been decorated with a thick layer of frosting mixed with luster dust described on the label as "gold dust" (Figure 1). CAIDE interviewed four persons who did not become ill and who reported either not eating any cake frosting (three) or eating no cake at all (one). Symptoms and illness onsets were consistent with a heavy metal poisoning (*4*), and the cake frosting was identified

FIGURE 1. Birthday cake with rose gold dust frosting, a bottle of gold dust used for cake decorating, and industrial drums containing fine copper powder* — Rhode Island, 2018

Photos/Rhode Island Department of Health
* Copper powder was commercially sold as rose gold dust.

* Other terms include pearl dust, petal dust, disco dust, twinkle dust, sparkle dust, highlighter, and shimmer powder.
† https://web.archive.org/web/20150905165126/http://www.craftsy.com/article/cake-decorating-history-overview-techniques
§ RIDOH measured high levels of multiple metals in luster dusts. State health departments in Rhode Island and Missouri could only confirm health issues associated with copper poisonings or elevated blood lead levels, respectively; there might have been other toxicity-associated outcomes.

as the suspected food item. CAIDE obtained a picture of the cake and shared this information with the RIDOH Center for Food Protection (CFP) for further investigation.

CFP environmental health food specialists investigated the Rhode Island bakery on-site and implemented immediate control measures. In addition, a food flow analysis, conducted with CDC's National Environmental Assessment Reporting System (NEARS) manager, traced each step in the bakery's food preparation system to identify potential hazards and to collect evidence of contributing factors and environmental antecedents to understand and address the root causes of the foodborne illnesses. The cake ingredients and preparation process were recorded. The cake had been baked, frozen, and frosted; luster dust was added to a butter extract and painted on the cake with a brush in intervals to produce a thick layer. The luster dust applied as a decoration to the cake's frosting was labeled as rose gold dust, and marked as "nonedible," "nontoxic," and "for decoration only."

During the CFP investigation, all nonedible luster dust containers were placed under embargo. Some bottles were not clearly labeled as edible or nonedible; luster dust bottles without ingredients listed were considered nonedible. RIDOH identified and embargoed other products coated with luster dust (including chocolate pops and chocolate-covered pretzels) that were on display for retail. CFP collected several containers of luster dust, including the rose gold dust that had been used on the birthday cake, and a leftover slice of cake from the party host's residence for chemical testing by the state health laboratory.

CFP traced three possible sources of the rose gold dust to three local companies: a cake pop bakery that sold the rose gold dust as a cake decoration, a wholesale culinary company that sold the powder to decorate cake stands, and an importer who was able to identify that the rose gold dust was fine copper powder that had been imported from a manufacturer that initially sold the powder for use as a metallic pigment for consumer goods such as floor coverings.

Testing performed by the state health laboratory supported the suspected cause of illnesses as copper metal poisoning (*5*). Laboratory analysis identified 22.1 mg of copper per gram of rose gold frosting (nearly 900 mg of copper on the cake slice) and assigned a NEARS contamination factor of C3 (a poisonous substance accidently or inadvertently added) (*6*), which in this instance occurred as a result of misreading labels. Analysis by RIDOH of 28 other inedible luster dusts from the cake's bakery found elevated levels of aluminum, barium, chromium, copper, iron, lead, manganese, nickel, and zinc. RIDOH visited additional bakeries and found widespread use of nonedible luster dust on food items. RIDOH issued guidance to bakeries, clarifying that labeling indicating that a product is nontoxic does not always indicate that the product is edible, and that edible luster dusts list the ingredients on the product's label.

Summary

What is already known about this topic?

Food decorating products known as "luster dust" are widely used on cakes and candy.

What is added by this report?

During 2018–2019, two states investigated heavy metal poisonings associated with commercially and home-prepared cakes using luster dusts, which were found to contain high levels of copper, lead, and other metals.

What are the implications for public health practice?

Labeling indicating that a product is nontoxic does not imply that the product is safe for consumption. Educating consumers, commercial bakers, and public health professionals about potential hazards of items used in food preparation is essential to preventing illness and unintentional poisoning from toxic metals and other nonedible ingredients.

Subsequent to the investigation, the RIDOH Rapid Response Team presented results from the investigation at a 2018 national food safety conference. Among the attendees were the Missouri DHSS Rapid Response Team, which then disseminated information within their state to prepare response teams and alert food safety investigators about the possible risks for toxicity from luster dust products.

In May 2019, Missouri DHSS identified a cake decorating material referred to as primrose petal dust as a lead hazard during an environmental investigation of an elevated blood lead level (12 μg/dL) in a Missouri resident child aged 1 year. The child's home, including painted surfaces and various household items, was tested for lead levels with a handheld x-ray fluorescence analyzer, which detected the presence of lead in a jar of bright yellow primrose petal dust that had been recently used in creating decorative flowers for the child's home-baked birthday cake (Figure 2). The container for the primrose petal dust used for the cake was labeled as "nontoxic" and "made in USA" and the brand was sold by a Florida cake decorating company, which marketed it as a nontoxic color for decorating baked goods, candies, chocolate, and sugar art.

Laboratory tests conducted by the Missouri DHSS State Public Health Laboratory indicated that the primrose petal dust sample contained 250,000 ppm (25%) lead. Lead is a potent neurotoxicant, particularly in children, whose growing bodies readily absorb lead, which affects brain and other nervous system development (*7*). The Missouri DHSS issued a press release that warned consumers not to apply primrose petal dust to any food product and to immediately discard any food products that contain primrose petal dust as an ingredient. In addition, the Missouri DHSS suggested that pregnant

FIGURE 2. Birthday cake with icing flowers tinted with primrose petal dust used for cake decorating — Missouri, 2019

Photos/Missouri Department of Health and Senior Services

women and parents of children who might have consumed these products consult their physician and consider having blood lead levels tested. The Food and Drug Administration (FDA) was made aware of this investigation.¶

Discussion

The use of luster dust in homemade and commercially prepared goods is a popular trend; however, not all glitters are created equal. Although some glitters and dusts are edible and safe for use on food, many others are not. A recent FDA advisory (*2*) indicated that luster dust products should only be consumed if they are labeled as edible and contain a list of ingredients. By federal regulation under the Federal Food, Drug, and Cosmetic Act, the FDA requires that food additives meet certain safety and labeling guidelines (*8*). A premarket approval process is required before any listed color additive is deemed safe for its intended use or uses in or on food, drugs, or cosmetics. This premarket approval includes an assessment of toxicity based on availability of sufficient safety testing data; however, lack of such data does not deem a substance nontoxic. Even if labeled as nontoxic, these inedible products are intended for decoration only and should not be consumed. When an FDA investigation determines that a regulatory violation has occurred, the agency can take a number of enforcement actions to protect the public's health (*8*). Specific enforcement activities include actions to correct and prevent violations, remove products or goods from the market, and punish offenders; this can range from issuing warning letters about violations to recommending criminal fines and prosecutions.

¶The Florida Department of Agriculture and Consumer Services was also informed about the investigation results.

Labeling indicating that a product is nontoxic does not imply that the product is safe for consumption. Explicit labeling indicating that nonedible products are not safe for human consumption is needed to prevent illness and unintentional poisonings. Educating consumers, commercial bakers, and public health professionals about potential hazards of items used in food preparation is essential to preventing illness and unintentional poisoning from toxic metals and other nonedible ingredients.

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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. Brendalee Viveiros reports grant support from the Food and Drug Administration Rapid Response Team. No other potential conflicts of interest were disclosed.

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Current Marijuana Use and Alcohol Consumption Among Adults Following the Legalization of Nonmedical Retail Marijuana Sales — Colorado, 2015–2019

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In Colorado, excessive alcohol use* contributed to $5 billion in economic costs in 2010 (*1*) and >1,800 deaths annually during 2011–2015 (*2*). The most common pattern of excessive drinking is binge drinking (consumption of four or more drinks on an occasion for women or five or more drinks for men) (*3*), which is associated with increased likelihood of using other substances, including marijuana (*4*). Retail (i.e., nonmedical) marijuana sales began in Colorado on January 1, 2014. The Colorado Department of Public Health and Environment (CDPHE) and CDC used data from Colorado's 2015–2019 Behavioral Risk Factor Surveillance System (BRFSS) to examine current use of marijuana (including hashish) by drinking patterns among 45,991 persons aged ≥18 years who responded to questions about alcohol and marijuana use. The age-standardized, weighted prevalence of current marijuana use among persons who reported binge drinking (34.4%) was significantly higher than the prevalence among current non–binge drinkers (14.8%) and nondrinkers (9.9%). Evidence-based strategies recommended by the Community Preventive Services Task Force to reduce excessive alcohol use and tobacco use (e.g., increasing prices or reducing access) can reduce alcohol- and tobacco-related harms. Similar strategies might be effective in reducing marijuana use and its potential harms as well.

BRFSS is an annual state-based, random-digit–dialed landline and mobile telephone survey that collects information on health conditions and risk factors† among the noninstitutionalized U.S. adult population aged ≥18 years. The current study was conducted using the following question, which was added to the Colorado survey: "During the past 30 days, on how many days did you use marijuana or hashish?" Current marijuana use was defined as having used marijuana, including hashish, on ≥1 day in the past 30 days. Frequency of marijuana use during the past 30 days§ was categorized as use on 1–3, 4–19, and ≥20 days (daily or near daily use). Questions from the BRFSS core questionnaire were used to measure alcohol consumption in the past 30 days, including the number of drinking days and the number of binge drinking episodes. Respondents were categorized into three groups by drinking pattern: 1) binge drinking¶ (consumption of four or more drinks for women or five or more drinks for men, on an occasion, one or more times in the past 30 days); 2) current drinking without binge drinking** (consumption of one or more alcoholic drinks on ≥1 day in the past 30 days but did not report binge drinking) (current non–binge drinking); and 3) nondrinking†† (no consumption of an alcoholic beverage in the past 30 days).

Colorado BRFSS data from 2015 to 2019 were combined, with an average response rate of 54% and a total sample of 56,513 respondents; 10,522 (19%) respondents were excluded because alcohol or marijuana data were missing or could not be analyzed (e.g., responses of "don't know/not sure"), yielding a final sample of 45,991 respondents. CDPHE calculated age-standardized or age-specific, weighted percentages with 95% confidence intervals (CIs) to assess the prevalence of binge drinking by sociodemographic characteristics and of marijuana use by sociodemographic characteristics and drinking patterns. Age-standardized prevalence of marijuana use by drinking patterns was also assessed by cigarette smoking status.§§ Chi-square tests were used to assess significance of differences ($p<0.05$) in bivariate analyses. All analyses were performed using SAS (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶¶

* Excessive drinking is defined as binge drinking (four or more drinks for women or five or more drinks for men on an occasion), high weekly consumption (eight or more drinks for women or ≥15 drinks for men in a week), and any drinking by pregnant women or persons aged <21 years. https://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm

† https://www.cdc.gov/brfss/data_documentation/index.htm

§ Determined by responses to the question, "During the past 30 days, on how many days did you use marijuana or hashish?"

¶ Defined as having four or more drinks for women or five or more drinks for men, on an occasion, one or more times in the past 30 days, determined by responses to the core question, "Considering all types of alcoholic beverages, how many times during the past 30 days did you have X (X = 5 for men, X = 4 for women) or more drinks on an occasion?" One drink is equivalent to a 12-ounce beer, a 5-ounce glass of wine, or a drink with one shot of liquor.

** Defined as having one or more drinks of any alcoholic beverage ≥1 day in the past 30 days but not reporting binge drinking, determined by responses to the core questions, "During the past 30 days, how many days per week or per month did you have at least one drink of any alcoholic beverage such as beer, wine, a malt beverage or liquor?" and "Considering all types of alcoholic beverages, how many times during the past 30 days did you have X (X = 5 for men; X = 4 for women) or more drinks on an occasion?"

†† Defined as no reported alcohol use in the past 30 days, determined by response to the core question, "During the past 30 days, how many days per week or per month did you have at least one drink of any alcoholic beverage such as beer, wine, a malt beverage or liquor?"

§§ Current cigarette smoking is defined as adults who have smoked at least 100 cigarettes in their entire life and now smoke cigarettes on some days or every day and determined by responses to the core questions, "Have you smoked at least 100 cigarettes in your entire life?" and "Do you now smoke cigarettes every day, some days, or not at all?" Adults who did not meet these criteria were categorized as cigarette nonsmokers.

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

Overall, the age-standardized, weighted prevalence of binge drinking was 18.8% and of current marijuana use was 16.6% (Table). The prevalence of binge drinking was highest among adults aged 25–34 years (29.8%) and 18–24 years (25.8%), men (23.7%), non-Hispanic White adults (19.6%), and Hispanic adults (18.5%). The prevalence of current marijuana use was highest among young adults (aged 18–24 years) (28.0%) and men (20.2%), and lowest among Hispanic adults (13.3%). Approximately one third (34.4%) of adults who binge drank reported current marijuana use, which was significantly higher than that reported among current non–binge drinkers (14.8%) and nondrinkers (9.9%). Among adults who binge drank, current use of marijuana was most common among young adults aged 18–24 years (52.4%) and least common among adults aged ≥65 years (17.9%). By race/ethnicity, among persons who binge drank, current marijuana use was most common among non-Hispanic Black adults (44.4%) and least common among Hispanic adults (28.6%). Among adults who reported binge drinking and current marijuana use in the past 30 days, approximately one half (47.3%) reported daily or near daily (≥20 days) use of marijuana, 28.1% reported use on 4–19 days, and 24.6% reported use on 1–3 days.

Independent of drinking pattern, cigarette smokers were more likely than nonsmokers were to use marijuana (Figure). The prevalence of marijuana use among persons who binge drank and smoked cigarettes (48.1%) was twice that of nondrinkers who smoked cigarettes (24.4%); however, among persons who did not smoke cigarettes, the prevalence of marijuana use was approximately four times as high among persons who binge drank (29.7%) as among nondrinkers (7.5%).

TABLE. Weighted prevalence* of binge drinking and current marijuana use† by drinking pattern,§ overall and by sociodemographic characteristics¶ — Colorado Behavioral Risk Factor Surveillance System, 2015–2019

	Weighted %** (95% CI)				
	All respondents (N = 45,991)		Current marijuana use by drinking pattern		
	Binge drinking	Current marijuana use	Nondrinking	Current non–binge drinking	Binge drinking
Characteristic	(n = 6,023)	(n = 5,586)	(n = 1,376)	(n = 2,400)	(n = 1,810)
All					
Crude††	17.6 (17.1–18.1)	15.8 (15.4–16.3)	9.5 (8.9–10.1)	14.2 (13.5–14.9)	33.9 (32.3–35.4)
Age-standardized	18.8 (18.2–19.3)	16.6 (16.0–17.1)	9.9 (9.2–10.5)	14.8 (14.1–15.5)	34.4 (32.8–36.0)
Age group, yrs††					
18–24	25.8 (23.6–27.9)	28.0 (25.9–30.2)	12.2 (10.0–14.5)	31.1 (27.0–35.3)	52.4 (47.7–57.2)
25–34	29.8 (28.2–31.4)	24.4 (22.9–26.0)	16.0 (13.6–18.4)	20.9 (18.6–23.2)	37.8 (34.7–40.9)
35–44	22.1 (20.7–23.4)	16.8 (15.6–18.0)	9.8 (8.2–11.3)	15.8 (14.0–17.5)	30.2 (27.0–33.3)
45–54	17.2 (16.2–18.3)	12.1 (11.2–13.0)	10.1 (8.7–11.5)	9.7 (8.5–10.9)	23.0 (20.1–25.9)
55–64	11.2 (10.4–12.0)	12.9 (12.1–13.7)	9.3 (8.2–10.5)	12.7 (11.5–13.8)	26.8 (23.5–30.0)
≥65	4.3 (3.9–4.7)	6.4 (5.9–6.9)	4.2 (3.6–4.8)	7.6 (6.8–8.3)	17.9 (14.3–21.5)
Gender					
Men	23.7 (22.8–24.5)	20.2 (19.4–21.0)	13.4 (12.3–14.6)	17.1 (16.0–18.2)	35.4 (33.4–37.5)§§
Women	14.0 (13.3–14.7)	13.0 (12.3–13.7)	7.3 (6.5–8.0)	12.5 (11.5–13.5)	32.5 (29.9–35.2)
Race/Ethnicity					
White, non-Hispanic	19.6 (18.9–20.2)	17.4 (16.8–18.0)	11.4 (10.5–12.2)	14.3 (13.5–15.1)§§	35.1 (33.3–37.0)
Hispanic	18.5 (17.2–19.7)	13.3 (12.2–14.4)	6.0 (5.0–7.0)	16.1 (13.9–18.4)	28.6 (25.1–32.2)
Other, non-Hispanic	15.2 (12.8–17.6)	16.7 (14.4–19.1)	9.3 (6.7–11.8)	15.8 (12.3–19.4)	41.9 (33.3–50.5)
Black, non-Hispanic	12.7 (9.8–15.6)	17.9 (14.8–21.1)	10.5 (6.7–14.3)	18.3 (13.6–23.1)	44.4 (32.2–56.7)
Education level					
Less than high school	16.2 (14.2–18.2)	14.5 (12.6–16.4)	8.5 (6.7–10.2)	17.9 (13.6–22.2)	31.4 (24.8–37.9)
High school or GED	19.1 (17.9–20.2)	19.7 (18.5–20.1)	12.3 (11.0–13.7)	20.1 (18.0–22.1)	37.5 (34.1–40.9)
Some post-high school	19.3 (18.3–20.4)	18.4 (17.4–19.4)	10.8 (9.6–12.0)	17.0 (15.6–18.5)	36.8 (33.8–39.9)
College graduate	18.8 (18.0–19.6)	13.4 (12.7–14.1)	6.5 (5.5–7.4)	10.8 (10.0–11.6)	30.7 (28.4–33.0)

Abbreviations: CI = confidence interval; GED = general educational development certificate.

* Age-standardized to the 2000 U.S. population unless otherwise noted.

† Current marijuana use is defined as any marijuana use, including hashish, reported on at least 1 day during the past 30 days.

§ Drinking patterns were categorized into three groups: 1) binge drinking (consumed four or more drinks for women or five or more drinks for men, on an occasion, one or more times in the past 30 days); 2) current non–binge drinking (consumed one or more drinks of any alcoholic beverage ≥1 day in the past 30 days but did not report any binge drinking); and 3) nondrinking (did not consume any alcoholic beverages in the past 30 days).

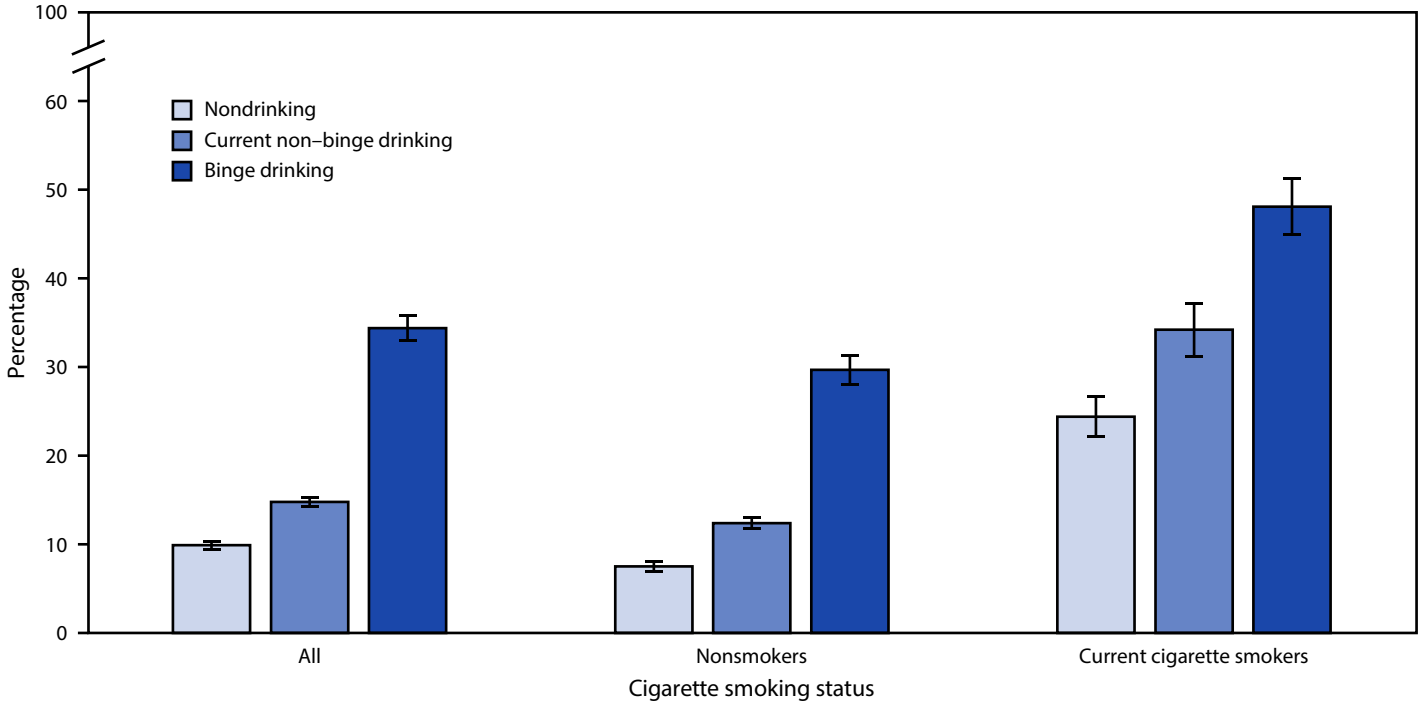
¶ All categorical differences are significant ($p<0.05$) unless otherwise noted.

** Weighted to the Colorado population of noninstitutionalized adults.

†† Crude and age-specific percentages are not age-standardized.

§§ Marijuana use among persons who binge drank did not vary significantly by gender. Marijuana use among non–binge drinkers did not vary significantly by race/ethnicity.

FIGURE. Age-standardized* prevalence† of current marijuana use§ in the past 30 days, by drinking pattern¶ and cigarette smoking status — Colorado Behavioral Risk Factor Surveillance System, 2015–2019**



* Age-standardized to the 2000 U.S. population.
† With 95% confidence intervals indicated by error bars.
§ Current marijuana use is defined as any marijuana use, including hashish, reported on ≥1 day during the past 30 days.
¶ Drinking patterns were categorized into three groups: 1) binge drinking (consumed four or more drinks for women, or five or more drinks for men, on an occasion, one or more times during the past 30 days); 2) current non–binge drinking (consumed one or more drinks of any alcoholic beverage ≥1 day during the past 30 days but did not report any binge drinking); and 3) nondrinking (did not consume any alcoholic beverages during the past 30 days).
** Current cigarette smoking is defined as having smoked at least 100 cigarettes in lifetime and currently smoking cigarettes on some days or every day.

Discussion

During 2015–2019, one third of adults in Colorado who reported binge drinking also reported using marijuana, consistent with other studies that have shown that persons who binge drank are more likely to use other substances, including marijuana, than are nondrinkers (*4*). The study findings indicate that persons who binge drank were more likely to report marijuana use than were nondrinkers, and the magnitude of this relationship varied by cigarette smoking status. Independent of drinking pattern, persons who smoked cigarettes were more likely to report marijuana use than were nonsmokers. The higher prevalence of marijuana use among persons who reported binge drinking, were younger, and who smoked cigarettes also aligns with other research findings (*5,6*).

In this study, approximately one half of adults who binge drank and currently used marijuana reported daily or near daily marijuana use, which is similar to the prevalence of daily or near daily marijuana use among all Colorado adults who use marijuana.*** Although this study did not specifically assess respondents' use of alcohol and marijuana on the same occasion, another study of U.S. adults found that the prevalence of using both substances on the same occasion was twice as high as the prevalence of using both substances, though not on the same occasion (*7*). A 2017 National Academies of Sciences report found mixed evidence regarding whether using alcohol and marijuana on the same occasion increased risk of harms such as motor vehicle crashes, suggesting a need for more research (*8*). A literature review by CDPHE also documented the mixed evidence; however, the majority of the 10 studies reviewed (including two of higher quality) found an association between using alcohol and marijuana on the same occasion and increased impairment and motor vehicle crash risk (*9*).

The findings in this report are subject to at least three limitations. First, self-reported data on substance use might be underreported because of recall and social desirability biases; therefore, the estimates presented might be conservative. Second, there might be nonresponse or selection biases in the characteristics of persons who choose to participate in the BRFSS survey. Finally, these findings cannot be generalized to the United States because they represent adults in one state

*** https://marijuanahealthinfo.colorado.gov/health-data/behavioral-risk-factor-surveillance-system-brfss-data

Summary

What is already known about this topic?

Retail (nonmedical) marijuana sales began in Colorado on January 1, 2014. Adults who binge drink are more likely to use other substances than are nondrinkers.

What is added by this report?

During 2015–2019, one third (34.4%) of Colorado adults who binge drank used marijuana compared with one tenth (9.9%) of nondrinkers.

What are the implications for public health practice?

Adding questions to state surveillance systems on alcohol, marijuana, and other substance use on the same occasion could strengthen the surveillance for risk factors or risks associated with using multiple substances. The Community Preventive Services Task Force recommends evidence-based strategies (e.g., increasing prices or reducing access) to reduce excessive drinking, tobacco use, and related harms. Similar strategies might also be effective for reducing marijuana use and its potential harms.

only in which nonmedical adult marijuana use is legal. The association between alcohol and marijuana use likely differs across jurisdictions because of local norms, laws, and policies.

This is the first study to assess the relationship between binge drinking and marijuana use among a representative sample of adults in Colorado. Excessive alcohol use and nonmedical marijuana use can be associated with negative health outcomes (*8*,*10*). Because of the evolution of nonmedical marijuana legalization across the United States and limited evidence on the short-term and long-term chronic effects of using alcohol and marijuana on the same occasion (*8*), continued surveillance across the lifespan of excessive alcohol use and marijuana use among persons who drink might be important to guide states in the prevention of alcohol-related harms. Adding questions to state surveillance systems on the use of alcohol, marijuana, and other substances (e.g., opioids) on the same occasion could strengthen the surveillance for risk factors or health risks associated with using multiple substances during a single occasion. To reduce excessive alcohol and tobacco use and reduce alcohol- and tobacco-related harms, the Community Preventive Services Task Force[†††] recommends the use of evidence-based strategies such as increasing prices and reducing access. Similar strategies of limiting availability and increasing prices of marijuana (in states where marijuana sale and use is legal) might also be effective in reducing marijuana use and its potential harms.

[†††] https://www.thecommunityguide.org/topic/excessive-alcohol-consumption; https://www.thecommunityguide.org/topic/tobacco

Acknowledgment

Barbara Gabella, Colorado Department of Public Health and Environment.

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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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Update of the Blood Lead Reference Value — United States, 2021

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The negative impact of lead exposure on young children and those who become pregnant is well documented but is not well known by those at highest risk from this hazard. Scientific evidence suggests that there is no known safe blood lead level (BLL), because even small amounts of lead can be harmful to a child's developing brain (*1*). In 2012, CDC introduced the population-based blood lead reference value (BLRV) to identify children exposed to more lead than most other children in the United States. The BLRV should be used as a guide to 1) help determine whether medical or environmental follow-up actions should be initiated for an individual child and 2) prioritize communities with the most need for primary prevention of exposure and evaluate the effectiveness of prevention efforts. The BLRV is based on the 97.5th percentile of the blood lead distribution in U.S. children aged 1–5 years from National Health and Nutrition Examination Survey (NHANES) data. NHANES is a complex, multistage survey designed to provide a nationally representative assessment of health and nutritional status of the noninstitutionalized civilian adult and child populations in the United States (*2*). The initial BLRV of 5 μg/dL, established in 2012, was based on data from the 2007–2008 and 2009–2010 NHANES cycles. Consistent with recommendations from a former advisory committee, this report updates CDC's BLRV in children to 3.5 μg/dL using NHANES data derived from the 2015–2016 and 2017–2018 cycles and provides helpful information to support adoption by state and local health departments, health care providers (HCPs), clinical laboratories, and others and serves as an opportunity to advance health equity and environmental justice related to preventable lead exposure. CDC recommends that public health and clinical professionals focus screening efforts on populations at high risk based on age of housing and sociodemographic risk factors. Public health and clinical professionals should collaborate to develop screening plans responsive to local conditions using local data. In the absence of such plans, universal BLL testing is recommended. In addition, jurisdictions should follow the Centers for Medicare & Medicaid Services requirement that all Medicaid-enrolled children be tested at ages 12 and 24 months or at age 24–72 months if they have not previously been screened (*3*).

Methods, Rationale, and Evidence

CDC has been involved in defining the criteria for interpreting BLLs in children since 1971 (*4*) (Table 1). The criteria for interpreting BLLs in children was revised over time based on new clinical and scientific evidence and improved laboratory technologies.

In 2012, CDC's former Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended the establishment of the BLRV and proposed it be set at 5 μg/dL (*5*). This recommendation was based on the weight of evidence indicating that the adverse health effects of BLLs <10 μg/dL in children included neurologic, cardiovascular, immunologic, and endocrine effects. ACCLPP further recommended that the BLRV be updated every 4 years based on the 97.5th percentile of BLLs for children aged 1–5 years across the two most recent combined NHANES cycles for which data are available.

The Lead Exposure and Prevention Advisory Committee (LEPAC) was established under the Water Infrastructure Improvements for the Nation Act of 2016.* The LEPAC is charged with providing advice and guidance to the Secretary of U.S. Department of Health and Human Services (HHS), Director of CDC, and Administrator of Agency for Toxic Substances and Disease Registry on matters related to lead poisoning prevention and surveillance. In 2020, LEPAC charged a BLRV workgroup with providing advice and guidance regarding new scientific knowledge and technological developments to guide the BLRV. During a May 2021 meeting of the LEPAC, the workgroup recommended that the BLRV be updated from 5 μg/dL to 3.5 μg/dL using data derived from the two most recent NHANES cycles (2015–2016 and 2017–2018), and the LEPAC voted unanimously to accept this recommendation (*6*). Subsequently, the committee submitted

* Water Infrastructure Improvements for the Nation Act of 2016. Pub. L. 114–322. https://www.congress.gov/bill/114th-congress/senate-bill/612/text

TABLE 1. Definitions for interpreting children's blood lead levels — United States, 1960–2021

Year	Blood lead level (μg/dL)	Interpretation*
1960	60	NA
1970	40	Undue or increased lead absorption
1975	30	Undue or increased lead absorption
1978	30	Elevated blood lead level
1985	25	Elevated blood lead level
1991	10	Level of concern
2012	5	Reference value
2021	3.5	Reference value

Abbreviation: NA = not available.
* https://stacks.cdc.gov/view/cdc/61820

a formal recommendation to the HHS Secretary to update the BLRV from 5 μg/dL to 3.5 μg/dL. LEPAC's BLRV workgroup also advised that CDC address barriers and capacity issues for federal agencies and other partners to facilitate adopting the revised BLRV (*6*). This will include providing training and outreach to public health professionals. The HHS Secretary and CDC concur with the recommendation and have developed communication and implementation plans to announce and promote the BLRV update, including to those at greatest risk.

Policy Update

The BLRV is a population-based measurement which indicates that 2.5% of U.S. children aged 1–5 years have BLLs ≥3.5 μg/dL. It is not a health-based standard or a toxicity threshold. The BLRV should be used as a guide to 1) help determine whether medical or environmental follow-up actions should be initiated for an individual child and 2) prioritize communities with the most need for primary prevention of exposure and evaluate the effectiveness of prevention efforts. Whether a BLL measurement at or above the BLRV triggers medical or environmental follow-up will depend on existing jurisdictional laws, regulations, and resource availability. Follow-up lead testing to confirm BLLs is recommended. CDC strongly advises that providers follow CDC's Recommended Actions Based on Blood Lead Level (*7*).

Discussion

The geometric mean BLL in U.S. children aged 1–5 years has declined over time from 15.2 μg/dL in 1976–1980 to 0.83 μg/dL in 2011–2016 (Table 2) (*8*). During the same period among U.S. children aged 6–11 years, the geometric mean BLL declined from 12.7 μg/dL to 0.6 μg/dL. Despite this overall declining trend in geometric mean BLLs in U.S. children aged 1–5 years, certain children remain at substantial risk for exposure to lead and disproportionately experience negative health consequences. Their ongoing lead exposure reflects persistent structural inequities in the built environment and access to health care. In addition, the pernicious and irreversible effects of lead exposures perpetuate ongoing structural inequities and injustices (*9*). Thus, lead exposure can be considered both a result and cause of health inequity and environmental injustice.

The most common sources of lead exposure in the United States are lead-based paint and dust, lead-contaminated soil, and lead in water from lead pipes and plumbing fixtures (*1*). Other sources of exposure include some toys and jewelry, candies imported from other countries, traditional home remedies, and certain jobs and hobbies that involve working with lead-based products and might cause parents to bring lead into the home. Children who live near airports might be exposed to lead in air and soil from aviation gas. The 2018 Federal Action Plan to Reduce Lead Exposures and Associated Health Impacts[†] outlines steps that can be taken to reduce lead hazards at the individual, community, and whole system level. In addition, CDC provides extensive guidance on exposure

[†] https://www.epa.gov/sites/default/files/2018-12/documents/fedactionplan_lead_final.pdf

TABLE 2. Weighted geometric mean blood lead levels* in U.S. children aged 1–5 years, by selected sociodemographic characteristics — four National Health and Nutrition Examination Survey cycles, United States, 1999–2016

Characteristic	1999–2002		2003–2006		2007–2010		2011–2016	
	No.	GM, μg/dL (95% CI)	No.	GM, μg/dL (95% CI)	No.	GM, μg/dL (95% CI)	No.	GM, μg/dL (95% CI)
Overall	**1,621**	**1.95 (1.79–2.12)**	**1,879**	**1.61 (1.52–1.71)**	**1,653**	**1.33 (1.26–1.41)**	**2,321**	**0.83 (0.78–0.88)**
Age group, yrs								
1–2	779	2.19 (2.01–2.39)	919	1.81 (1.71–1.92)	793	1.49 (1.39–1.59)	1,024	0.93 (0.86–1.00)
3–5	842	1.82 (1.64–2.01)	960	1.48 (1.38–1.60)	860	1.24 (1.15–1.33)	1,297	0.77 (0.72–0.82)
Sex								
Male	851	1.95 (1.77–2.14)	951	1.61 (1.51–1.72)	872	1.34 (1.25–1.43)	1,213	0.86 (0.80–0.92)
Female	770	1.95 (1.77–2.16)	928	1.61 (1.49–1.73)	781	1.32 (1.24–1.41)	1,108	0.79 (0.74–0.85)
Race/Ethnicity†								
Black, non-Hispanic	439	2.81 (2.56–3.09)	530	2.43 (2.12–2.80)	338	1.77 (1.62–1.93)	608	1.07 (0.97–1.18)
Mexican American	541	1.89 (1.75–2.03)	611	1.57 (1.46–1.69)	490	1.28 (1.17–1.39)	526	0.78 (0.72–0.84)
White, non-Hispanic	454	1.83 (1.60–2.09)	535	1.44 (1.35–1.54)	536	1.26 (1.14–1.39)	563	0.79 (0.71–0.88)
Income to poverty ratio§								
<1.3	808	2.44 (2.24–2.66)	936	2.01 (1.85–2.18)	864	1.57 (1.48–1.67)	1,149	0.97 (0.90–1.05)
≥1.3	686	1.60 (1.45–1.77)	857	1.39 (1.30–1.49)	676	1.17 (1.08–1.27)	997	0.72 (0.67–0.77)

Abbreviations: CI = confidence interval; GM = geometric mean; NHANES = National Health and Nutrition Examination Survey.

* Weighted estimates derived from the observed data for the study population using NHANES-specified sampling weights. The GM blood lead levels in children aged 1–5 years have decreased over time.

† Data by race and Hispanic origin were limited to the three racial and Hispanic origin groups available across all survey cycles (non-Hispanic White, non-Hispanic Black, and Mexican American).

§ Computed as the total family income divided by the poverty threshold.

reduction (https://www.cdc.gov/nceh/lead/faqs/lead-faqs.htm). Steps that parents and caregivers can take to reduce lead exposure include becoming more educated about lead hazards; working with a Lead-Safe certified firm[§] to repair peeling or chipping lead-based paint; replacing lead service lines[¶]; washing children's hands, bottles, and toys; and removing shoes before entering the home. Lead exposure is not equally distributed across the United States, and young children at highest risk for exposure are those living in housing built before 1978, non-Hispanic Black or African American children, children eligible for Medicaid, and children living in areas with higher poverty rates (*8*). This updated BLRV will drive and support further assessment of BLLs by sociodemographic characteristics which can assist in creating more focused population-based interventions to help address systemic health inequities and environmental injustice. CDC's Childhood Lead Poisoning Prevention Program (CLPPP) is committed to making new and expanding investments in communities where young children are disproportionately affected by BLLs above the BLRV.

As population BLLs decrease, along with overt clinical signs of lead exposure, laboratory testing has become paramount in detection and subsequent management of lead exposures. Thus, laboratories play an essential role in the overall public health response to lead exposure. A BLRV of 3.5 μg/dL creates challenges as well as opportunities for state, local, and private laboratories that perform BLL testing. Some laboratories might need to reduce their reporting limit policies, adopt new repeat testing practices, improve limits of detection of laboratory developed tests, acquire new instrumentation, and validate updated or new laboratory-developed tests. Measures are also needed to eliminate lead contamination in laboratory consumables and processes and might increase workloads because of additional repeat and confirmatory testing. For example, skin prick tests can often be contaminated with environmental sources of lead, so collecting blood from the vein is less likely to have this contamination. Reducing the BLRV might strengthen considerations to tighten the federal proficiency testing criteria for acceptable blood lead testing performance from ±4 μg/dL or ±10%, whichever is greater, to something tighter. Optimizing laboratory practices to meet the more stringent proficiency testing criteria might also be needed. Laboratory methods are sufficiently precise to measure BLLs at 3.5 μg/dL.

HCPs play a vital role in addressing pediatric lead exposure by initiating recommended follow-up actions based on the child's BLL. The updated BLRV empowers HCPs to take earlier action to mitigate exposures for children aged 1–5 years with BLLs between 3.5 and 5 μg/dL, who, before this update, would not have been recommended to receive these services for a BLL <5 μg/dL. Earlier recognition of lead exposure enables providers and families to intervene by stopping exposure that might otherwise result in higher BLLs, thus likely limiting or preventing potential adverse health effects.

Although there are practical challenges,[**] HCPs who identify children with BLLs between 3.5 and 5 μg/dL should strive to ascertain possible sources of exposure by taking an environmental history and providing nutritional counseling which can help decrease lead absorption (*1*). Before this update, these actions were not recommended to occur for BLLs <5 μg/dL. In addition, HCPs can provide guidance on exposure reduction, regardless of whether sources are identified, and link children to health departments for appropriate services. Follow-up testing using venous samples should be conducted after any remediation activities have taken place to ensure that exposure reduction was effective in addition to assessing developmental progress at regular intervals and providing referrals to supportive services as needed.

CDC's CLPPP remains committed to eliminating lead hazards in the environment before children are exposed. Unfortunately, because lead hazards are ubiquitous in the environment, secondary prevention is necessary to identify and follow children who are exposed to lead. CDC recommends that public health and clinical professionals focus screening efforts on neighborhoods and children at high risk based on age of housing and sociodemographic risk factors. Public health and clinical professionals should collaborate to develop screening plans responsive to local conditions using local data. In the absence of such plans, universal BLL testing is recommended. In addition, jurisdictions should follow the Centers for Medicare & Medicaid Services requirement that all Medicaid-enrolled children be tested at ages 12 and 24 months or at age 24–72 months if they have not previously been screened (*3*).

Non-Hispanic Black children, those living in low-income households, and those who are immigrants or refugees are more likely to live in communities where lead is pervasive. These communities often have homes built before 1978, many of which contain lead-based paint. Although it is encouraging that progress has been made toward lowering population average BLLs, geographic, socioeconomic, and racial/ethnic disparities in lead exposure, especially among young children, persist. Efforts should be put in place focusing on eliminating lead exposure among the most vulnerable in the population, young children aged 1–5 years, and should become an environmental public health priority.

[§] https://cfpub.epa.gov/flpp/pub/index.cfm?do=main.firmSearch

[¶] https://www.epa.gov/ground-water-and-drinking-water/lead-service-line-replacement

[**] According to an analysis from the Health Impact Project (https://www.pewtrusts.org/-/media/assets/2017/08/hip_childhood_lead_poisoning_report.pdf), eliminating lead hazards from the places where children live, learn, and play could generate approximately $84 billion in long-term benefits per birth cohort. In addition, permanently removing lead hazards from the environment would benefit future birth cohorts, and savings would continue to grow over time.

Summary

What is already known about this topic?

No safe blood lead level (BLL) in children exists. Even low levels cause harm.

What is added by this report?

CDC updated the blood lead reference value (BLRV) to 3.5 μg/dL, which provides an opportunity for additional progress in addressing longstanding disparities in lead exposure and BLLs in children.

What are the implications for public health practice?

The BLRV should be used as a guide to empower public health partners to determine whether medical or environmental follow-up actions should be initiated for an individual child with BLLs between 3.5 and 5 μg/dL who previously would not have been recommended to receive these services until their BLL reached 5 μg/dL. In addition, it should be used to prioritize communities with the most need for primary prevention of exposure and evaluate the effectiveness of prevention efforts. Screening for BLLs should be done according to federal Medicaid and state requirements.

Acknowledgments

Matthew Ammon, Tammy Barnhill-Proctor, Jeanne Briskin, Tiffany DeFoe, Michael Focazio, Monique Fountain Hanna, Karla Johnson, Erika Marquez, Howard Mielke, Anshu Mohllajee, CDC's Lead Exposure and Prevention Advisory Committee (LEPAC); Ginger Chew, Bruce Lanphear, Julianne Nassif, Amanda Reddy, Mark Werner, Nsedu Obot Witherspoon, Blood Lead Reference Value (BLRV) workgroup; Wallace Chambers, Nathan Graber, Jill Ryer-Powder, BLRV workgroup and CDC's LEPAC; Riley Hightower, Madeline Jones, Thabo Mubukwanu, Shannon Omisore, Youlanda Outin, Alexis Pullia, Rio Schondelmeyer, BLRV Communications and Implementation Planning Team; Joseph Afful; Sharunda Buchanan, Adrienne Ettinger, Jeff Jarrett, CDC.

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

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Severity of Disease Among Adults Hospitalized with Laboratory-Confirmed COVID-19 Before and During the Period of SARS-CoV-2 B.1.617.2 (Delta) Predominance — COVID-NET, 14 States, January–August 2021

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On October 22, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

In mid-June 2021, B.1.671.2 (Delta) became the predominant variant of SARS-CoV-2, the virus that causes COVID-19, circulating in the United States. As of July 2021, the Delta variant was responsible for nearly all new SARS-CoV-2 infections in the United States.* The Delta variant is more transmissible than previously circulating SARS-CoV-2 variants (*1*); however, whether it causes more severe disease in adults has been uncertain. Data from the CDC COVID-19–Associated Hospitalization Surveillance Network (COVID-NET), a population-based surveillance system for COVID-19–associated hospitalizations, were used to examine trends in severe outcomes in adults aged ≥18 years hospitalized with laboratory-confirmed COVID-19 during periods before (January–June 2021) and during (July–August 2021) Delta variant predominance. COVID-19–associated hospitalization rates among all adults declined during January–June 2021 (pre-Delta period), before increasing during July–August 2021 (Delta period). Among sampled nonpregnant hospitalized COVID-19 patients with completed medical record abstraction and a discharge disposition during the pre-Delta period, the proportion of patients who were admitted to an intensive care unit (ICU), received invasive mechanical ventilation (IMV), or died while hospitalized did not significantly change from the pre-Delta period to the Delta period. The proportion of hospitalized COVID-19 patients who were aged 18–49 years significantly increased, from 24.7% (95% confidence interval [CI] = 23.2%–26.3%) of all hospitalizations in the pre-Delta period, to 35.8% (95% CI = 32.1%–39.5%, p<0.01) during the Delta period. When examined by vaccination status, 71.8% of COVID-19–associated hospitalizations in the Delta period were in unvaccinated adults. Adults aged 18–49 years accounted for 43.6% (95% CI = 39.1%–48.2%) of all hospitalizations among unvaccinated adults during the Delta period. No difference was observed in ICU admission, receipt of IMV, or in-hospital death among nonpregnant hospitalized adults between the pre-Delta and Delta periods. However, the proportion of unvaccinated adults aged 18–49 years hospitalized with COVID-19 has increased as the Delta variant has become more predominant. Lower vaccination coverage in this age group likely contributed to the increase in hospitalized patients during the Delta period. COVID-19 vaccination is critical for all eligible adults, including those aged <50 years who have relatively low vaccination rates compared with older adults.

COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19–associated hospitalizations in 99 counties across 14 states.† Among residents of a predefined surveillance catchment area, COVID-19–associated hospitalizations are defined as a positive real-time reverse transcription–polymerase chain reaction or rapid antigen detection test result for SARS-CoV-2 during hospitalization or within the 14 days preceding admission.§ Unadjusted age-specific monthly population-based hospitalization rates (hospitalizations per 100,000 persons) among all adults aged ≥18 years irrespective of pregnancy status during January–August 2021 were calculated by dividing the total number of hospitalized COVID-19 patients by population estimates within each age group in the surveillance catchment area.¶ Using previously described methods (*2*), clinical outcomes data were collected on a representative sample of hospitalized adults stratified by age and site of admission during

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

† Selected counties in California, Colorado, Connecticut, Georgia, Iowa, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah can be found at https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm.

§ https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html

¶ Rates cannot be stratified by pregnancy status because the underlying population of pregnant women in the catchment area is unknown. Rates are calculated using the National Center for Health Statistics' vintage 2019 bridged-race postcensal population estimates for the counties included in surveillance. https://www.cdc.gov/nchs/nvss/bridged_race.htm

January–August 2021. Using a standardized case report form, trained surveillance staff members abstracted data on sampled cases (updated monthly) from medical charts that included a discharge disposition. Pregnant women (496) were excluded from the analysis because reasons for hospital admission (*3*) and standards for ICU admission might differ from those for nonpregnant persons. Severe outcomes assessed included ICU admission, receipt of IMV, and all cause in-hospital death. Severe outcomes were compared during periods before (pre-Delta period) and during Delta variant predominance (Delta period). Because COVID-19 vaccination might affect clinical outcomes (*4*), and vaccination coverage changed during the study period, results were analyzed overall and stratified by COVID-19 vaccination status.** Vaccination status was determined using state immunization information systems data (*5*,*6*). Variances were estimated using Taylor series linearization method. Chi-square testing was used to compare differences between the pre-Delta and Delta periods; p-values <0.05 were considered statistically significant, adjusted for multiple comparisons using the Bonferroni correction method. Unless otherwise noted, percentages presented are weighted to account for the probability of selection for sampled cases (*2*). All analyses were conducted using SAS statistical software survey procedures (version 9.4; SAS Institute). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.††

Based on 87,879 COVID-19 hospitalizations among all adults during January 1–August 31, 2021, irrespective of pregnancy status, monthly population-based rates of COVID-19–associated hospitalizations declined among all adult age groups during the pre-Delta period (Figure 1). Rates subsequently increased during July–August, with the highest rates among adults aged ≥65 years and the lowest among those aged 18–49 years. Monthly ICU admission, IMV, and in-hospital death rates followed the same patterns as COVID-19–associated hospitalization rates by age group, with the highest rates in adults aged ≥65 years and the lowest in persons aged 18–49 years.

During January–August 2021, in a representative sample of 7,615 COVID-19 hospitalizations among nonpregnant adults with detailed clinical data available, 71.8% (weighted) of patients hospitalized during the Delta period were unvaccinated. Among unvaccinated hospitalized COVID-19 patients, the average monthly proportion who were aged 18–49 years significantly increased from 26.9% in the pre-Delta period to 43.6% during the Delta period (p<0.01) (Table). Among hospitalized COVID-19 patients who were fully vaccinated, the proportion of younger adults did not significantly change between the pre-Delta (10.6%) and Delta (10.8%) periods. Among sampled nonpregnant adults hospitalized with COVID-19, no statistically significant differences were observed between the pre-Delta and Delta periods by sex, race/ethnicity, or the proportion of patients who were admitted to an ICU, who received IMV, or who died while hospitalized, overall and stratified by age and vaccination status.

During January–August 2021, the proportion of patients aged ≥50 years hospitalized with COVID-19 who were admitted to an ICU or who died while hospitalized generally trended upward in the Delta period (Figure 2), with the largest increase in persons who died while hospitalized among adults aged ≥65 years, (from 10.2% in June to 18.1% in August), although the difference was not statistically significant (p = 0.70). Monthly proportions of adults hospitalized with COVID-19 who received IMV also did not change significantly during January–August 2021.

Discussion

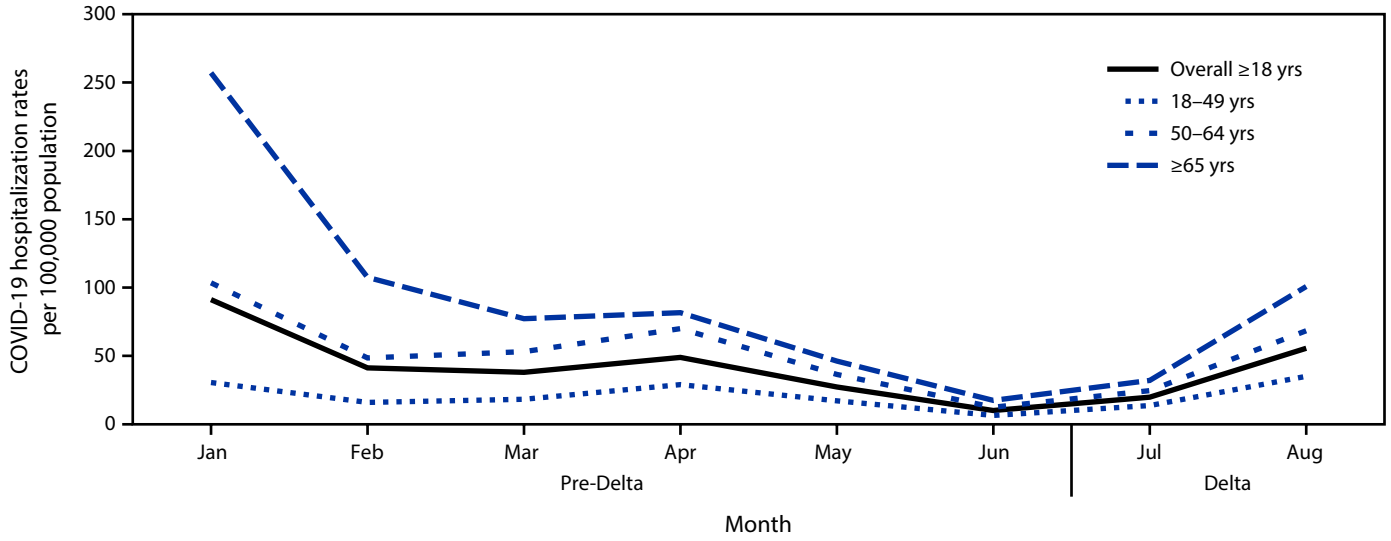
COVID-19–associated hospitalization rates increased after the SARS-CoV-2 Delta variant became predominant. However, the proportion of nonpregnant adults aged ≥18 years hospitalized with COVID-19 who were admitted to an ICU, received IMV, or died during their hospitalization did not significantly change during this period. No significant differences in severity were observed between the pre-Delta and Delta periods among fully vaccinated or unvaccinated hospitalized patients, overall or when stratified by age and vaccination status. However, during the Delta period, adults aged 18–49 years accounted for a larger proportion of hospitalized patients compared with the pre-Delta period. This was driven by the larger number of unvaccinated hospitalized patients in this age group, likely reflecting lower vaccination coverage in younger adults than in older adults.

Similar to this analysis, a previous study examining similar outcomes during March–December 2020 (before Delta variant predominance), found that rates of ICU admission, IMV, and in-hospital death mirrored adult hospitalization rates for that

** Fully vaccinated adults with a COVID-19–associated hospitalization were persons who had received the second dose of a 2-dose COVID-19 vaccine series or a single dose of a 1-dose product ≥14 days before receiving a positive SARS-CoV-2 test result associated with their hospitalization. Adults whose positive SARS-CoV-2 test date was ≥14 days after the first dose of a 2-dose series but <14 days after receipt of the second dose were considered partially vaccinated. Partially vaccinated adults, and those who received a single dose of a vaccine <14 days before the positive SARS-CoV-2 test result were not included in analyses by vaccination status but were included in rates and overall proportions that were not stratified by vaccination status. Adults with no documented receipt of any COVID-19 vaccine dose before the test date were considered unvaccinated. If the SARS-CoV-2 test date was not available, hospital admission date was used. Adults whose vaccination status had not yet been verified using the immunization information system data were considered to have missing vaccination status and were included in total proportions not stratified by vaccination status.

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

FIGURE 1. COVID-19–associated monthly hospitalization rates per 100,000 population among adults aged ≥18 years,* by age group, month, and period relative to SARS-CoV-2 B.1.617.2 (Delta) variant predominance† — COVID-NET, 14 states,§ January–August 2021



* Proportions are from a weighted sample of hospitalized adults with completed medical chart abstraction and a discharge disposition. Results are subject to change as additional data are reported.

† January–June 2021 is the pre-Delta period; the Delta period (July–August 2021) is when the Delta variant was the predominant circulating variant.

§ Selected counties in California, Colorado, Connecticut, Georgia, Iowa, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah can be found at https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm.

TABLE. Demographic characteristics and clinical interventions and outcomes among 7,615 nonpregnant adults aged ≥18 years hospitalized with COVID-19,* by vaccination status† and period relative to SARS-CoV-2 B.1.617.2 (Delta) variant predominance§ — COVID-NET, 14 states,¶ January–August 2021

	Weighted % of COVID-19 hospitalizations (95% CI)								
	Total hospitalizations**			Unvaccinated			Fully vaccinated		
Characteristic	Pre-Delta period	Delta period	p-value††	Pre-Delta period	Delta period	p-value††	Pre-Delta period	Delta period	p-value††
Total	**5,951**	**1,664**	—	**4,896**	**1,145**	—	**389**	**393**	—
Demographic characteristics§§									
Age group, yrs									
18–49	24.7 (23.2–26.3)	35.8 (32.1–39.5)	<0.01	26.9 (25.2–28.7)	43.6 (39.1–48.2)	<0.01	10.6 (6.8–15.4)	10.8 (7.1–15.4)	>0.99
50–64	31.2 (29.5–33.0)	30.4 (27.3–33.7)		32.4 (30.5–34.4)	33.6 (29.8–37.6)		17.2 (12.9–22.3)	18.8 (13.6–25.0)	
≥65	44.1 (42.0–46.2)	33.8 (30.4–37.4)		40.6 (38.3–43.0)	22.8 (19.1–26.8)		72.2 (65.8–78.0)	70.4 (63.6–76.7)	
Sex									
Male	52.2 (50.2–54.3)	52.3 (48.6–55.9)	>0.99	52.4 (50.2–54.6)	50.5 (46.1–55.0)	>0.99	51.7 (43.8–59.5)	56.7 (49.3–64.0)	>0.99
Female	47.8 (45.7–49.8)	47.7 (44.1–51.4)		47.6 (45.4–49.8)	49.5 (45.0–53.9)		48.3 (40.5–56.2)	43.3 (36.0–50.7)	
Race/Ethnicity¶¶									
White	50.0 (47.9–52.0)	47.8 (44.1–51.6)	>0.99	48.5 (46.2–50.8)	45.4 (40.9–49.9)	>0.99	65.7 (57.7–73.1)	57.2 (49.2–65.0)	>0.99
Black	28.5 (26.6–30.5)	32.1 (28.5–35.9)		29.6 (27.5–31.8)	34.0 (29.6–38.7)		16.6 (10.4–24.6)	23.5 (16.8–31.3)	
AI/AN	1.1 (0.8–1.4)	1.3 (0.8–2.0)		1.0 (0.7–1.3)	1.2 (0.6–2.1)		1.2 (0.4–2.9)	1.7 (0.6–3.7)	
A/PI	6.8 (5.6–8.2)	5.4 (3.4–8.1)		7.1 (5.7–8.6)	5.0 (2.7–8.3)		5.5 (2.5–10.2)	6.8 (2.8–13.5)	
Hispanic	13.6 (12.3–15.0)	13.4 (10.9–16.2)		13.8 (12.4–15.4)	14.4 (11.3–18.0)		11.0 (7.3–15.7)	10.8 (6.4–16.8)	
Long-term care facility resident* **									
Yes	7.8 (6.5–9.1)	3.2 (2.1–4.5)	<0.01	5.9 (4.7–7.3)	1.6 (0.7–3.0)†††	<0.01	16.7 (11.4–23.2)	8.3 (4.9–12.9)	0.59
No	92.2 (90.9–93.5)	96.8 (95.5–97.9)		94.1 (92.7–95.3)	98.4 (97.0–99.3)		83.3 (76.8–88.6)	91.7 (87.1–95.1)	
Hospitalization interventions and outcomes, by age group, yrs§§§									
ICU admission¶¶¶									
≥18	20.1 (18.5–21.9)	23.4 (20.4–26.6)	>0.99	20.1 (18.3–21.9)	22.6 (19.1–26.3)	>0.99	19.9 (14.2–26.6)	24.6 (18.2–32.0)	>0.99
18–49	17.1 (14.6–19.9)	17.1 (12.7–22.3)	>0.99	16.8 (14.2–19.6)	16.5 (11.7–22.2)	>0.99	—****	32.0 (16.5–51.1)††††	>0.99
50–64	21.4 (18.9–24.1)	27.8 (22.6–33.5)	>0.99	21.4 (18.7–24.4)	27.8 (22.2–34.0)	>0.99	18.4 (10.2–29.4)	—****	>0.99
≥65	21.0 (18.1–24.1)	26.2 (20.7–32.3)	>0.99	21.1 (17.8–24.8)	26.7 (18.8–35.9)	>0.99	19.6 (12.7–28.2)	24.2 (16.5–33.4)	>0.99

See table footnotes on the next page.

TABLE. (*Continued*) Demographic characteristics and clinical interventions and outcomes among 7,615 nonpregnant adults aged ≥18 years hospitalized with COVID-19,* by vaccination status† and period relative to SARS-CoV-2 B.1.617.2 (Delta) variant predominance§ — COVID-NET, 14 states,¶ January–August 2021

	Weighted % of COVID-19 hospitalizations (95% CI)								
	Total hospitalizations**			Unvaccinated			Fully vaccinated		
Characteristic	Pre-Delta period	Delta period	p-value††	Pre-Delta period	Delta period	p-value††	Pre-Delta period	Delta period	p-value††
Invasive mechanical ventilation§§§§									
≥18	11.5 (10.1–12.9)	11.2 (9.1–13.7)	>0.99	11.6 (10.1–13.1)	11.3 (8.8–14.2)	>0.99	9.4 (5.2–15.3)	12.7 (7.6–19.5)	>0.99
18–49	10.1 (8.1–12.4)	7.1 (4.2–10.9)	>0.99	9.7 (7.7–12.1)	7.2 (4.2–11.6)	>0.99	—****	7.4 (1.4–21.0)†††	>0.99
50–64	11.7 (9.8–13.9)	14.5 (10.7–19.1)	>0.99	11.7 (9.6–14.0)	16.7 (12.0–22.2)	>0.99	—****	7.0 (2.0–16.8)†††	>0.99
≥65	12.1 (9.7–14.8)	12.6 (8.7–17.6)	>0.99	12.7 (10.0–15.9)	11.2 (6.6–17.5)	>0.99	7.7 (3.3–15.0)	15.0 (8.3–24.3)	>0.99
In-hospital death¶¶¶¶									
≥18	8.6 (7.5–9.9)	9.9 (7.9–12.2)	>0.99	8.2 (7.0–9.5)	8.7 (6.6–11.1)	>0.99	7.2 (4.3–11.1)	13.9 (8.7–20.7)	>0.99
18–49	3.4 (2.2–5.0)	2.0 (0.7–4.3)†††	>0.99	3.2 (2.0–4.9)	2.1 (0.7–4.7)†††	>0.99	5.0 (0.6–16.7)	2.0 (0.0–12.8)†††	>0.99
50–64	7.5 (5.9–9.3)	9.5 (6.4–13.5)	>0.99	7.6 (5.8–9.6)	10.5 (6.8–15.2)	>0.99	4.2 (1.0–11.3)	7.3 (1.4–20.7)†††	>0.99
≥65	12.3 (10.2–14.8)	18.5 (13.8–23.9)	0.70	12.0 (9.6–14.7)	18.6 (12.6–25.9)	>0.99	8.2 (4.5–13.5)	17.4 (10.5–26.3)	>0.99

Abbreviations: A/PI = Asian or Pacific Islander; AI/AN = American Indian or Alaska Native; CI = confidence interval; ICU = intensive care unit.

* Data are from a weighted sample of hospitalized nonpregnant adults with completed medical record abstractions and a discharge disposition. Sample sizes presented are unweighted with weighted percentages.

† Vaccination status is not available for Iowa. Vaccination status is based on state immunization information system data. Fully vaccinated adults with a COVID-19–associated hospitalization were persons who had received the second dose of a 2-dose COVID-19 vaccine series or a single dose of a 1-dose product ≥14 days before receiving a positive SARS-CoV-2 test result associated with their hospitalization. Adults whose positive SARS-CoV-2 test date was ≥14 days after the first dose of a 2-dose series but <14 days after receipt of the second dose were considered partially vaccinated. Partially vaccinated adults, and those who received a single dose of a vaccine <14 days before the positive SARS-CoV-2 test result were not included in analyses by vaccination status but were included in rates and overall proportions that were not stratified by vaccination status. Adults with no documented receipt of any COVID-19 vaccine dose before the test date were considered unvaccinated. If the SARS-CoV-2 test date was not available, hospital admission date was used. Adults whose vaccination status had not yet been verified using the immunization information system data were considered to have missing vaccination status and were included in total proportions not stratified by vaccination status. Additional COVID-NET methods for determining vaccination status have been described previously. https://www.medrxiv.org/content/10.1101/2021.08.27.21262356v1

§ January–June 2021 is the pre-Delta period; the Delta period (July–August 2021) is when the Delta variant was the predominant circulating variant.

¶ Selected counties in California, Colorado, Connecticut, Georgia, Iowa, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah can be found at https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm.

** Total hospitalizations include data from selected counties in all 14 COVID-NET states with vaccination status, including fully vaccinated, partially vaccinated, and unvaccinated adults. As a result, the number of total hospitalizations exceeds the sum of fully vaccinated and unvaccinated adults.

†† Proportions between the pre-Delta and Delta period were compared with chi-square tests; p-values <0.05 were considered statistically significant, adjusted for multiple comparisons using the Bonferroni correction method.

§§ Percentages presented for demographic characteristics are weighted column percentages.

¶¶ Black, White, AI/AN, and A/PI persons were non-Hispanic; Hispanic persons could be of any race. If Hispanic ethnicity was unknown, non-Hispanic ethnicity was assumed. Persons with multiple, unknown, or missing race accounted for 3.4% (weighted) of all cases. These persons are excluded from the proportions of race/ethnicity but are otherwise included elsewhere in the analysis.

*** Long-term care facility residents include hospitalized adults who were identified as residents of a nursing home/skilled nursing facility, rehabilitation facility, assisted living/residential care, long-term acute care hospital, group/retirement home, or other long-term care facility upon hospital admission. A free-text field for other types of residences was examined; patients with a long-term care facility-type residence were also categorized as long-term care facility residents.

††† Relative standard errors >30%.

§§§ Percentages presented for hospitalization outcomes and interventions are weighted percentages of each age group with that outcome or intervention in the pre-Delta or Delta period.

¶¶¶ ICU admission status was missing in 0.9% (weighted) of hospitalizations; these hospitalizations are otherwise included elsewhere in the analysis.

**** Results with relative standard errors >30% and CI widths >20 were suppressed.

†††† CI widths >20.

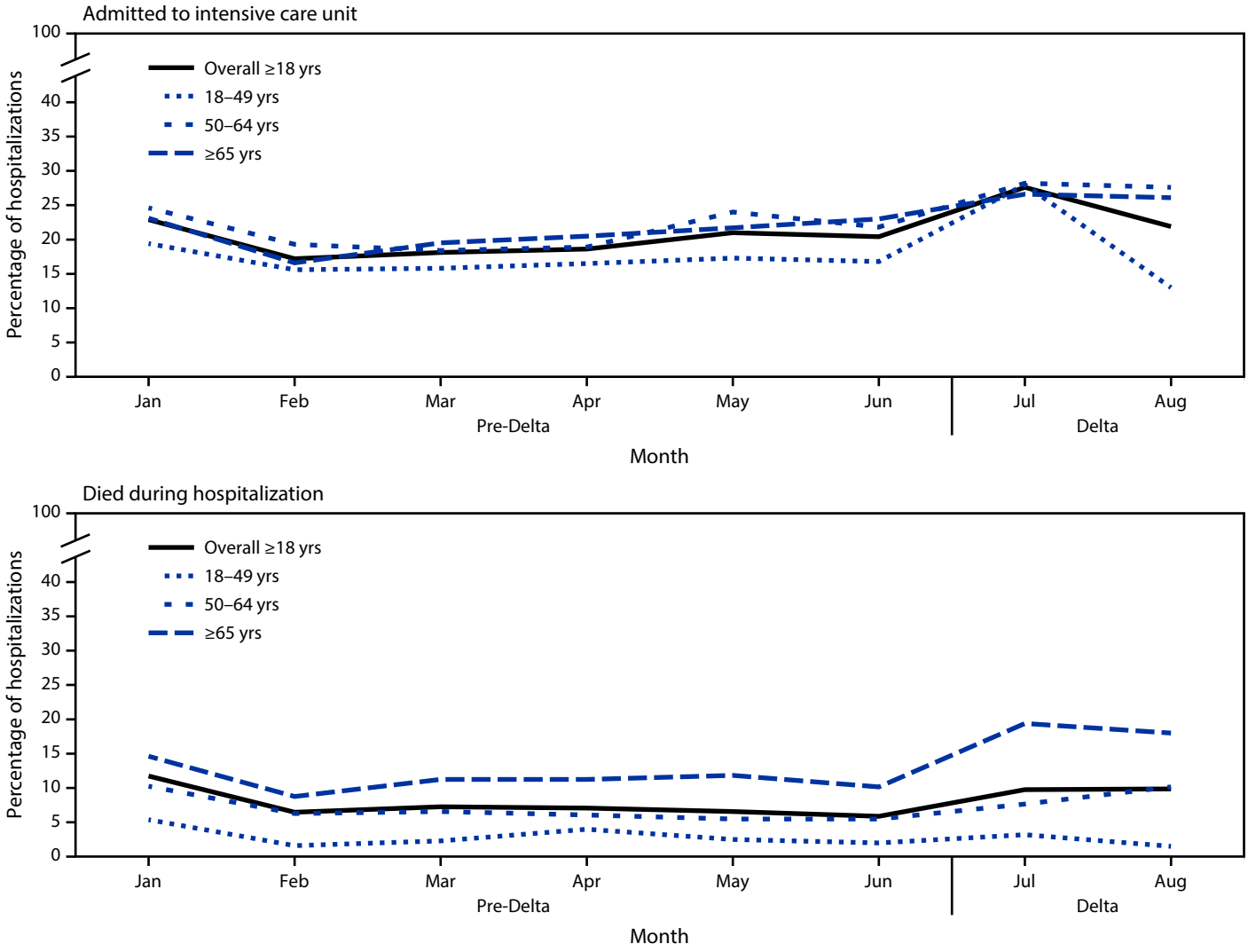
§§§§ Invasive of mechanical ventilation status was missing in 0.9% (weighted) of hospitalizations; these hospitalizations are otherwise included elsewhere in the analysis.

¶¶¶¶ In-hospital death status was missing in 1.2% (weighted) of hospitalizations; these hospitalizations are otherwise included elsewhere in the analysis.

period (*6*). These findings are similar to previous analyses of children and adolescents, which showed no significant differences in severe in-hospital outcomes between the pre-Delta and Delta periods (*7*,*8*). As rates of infection increased with the Delta variant, other studies have also shown increased risks for associated hospitalization (*9*,*10*), and a large Canadian study found an increased risk for ICU admission and death among a cohort of persons infected with the Delta variant (*10*). However, unlike this analysis, these studies were not limited to persons already hospitalized. Although the increasing trend in hospitalizations resulting in ICU admission or in-hospital death among adults aged ≥50 years was not statistically significant, trends in these outcomes will continue to be examined as outcomes from additional cases in later months of Delta predominance are identified.

Among unvaccinated hospitalized patients, the proportion of adults aged 18–49 years increased during the Delta period while the proportion aged ≥65 years decreased, whereas the

FIGURE 2. Percentage* of nonpregnant adult patients hospitalized with COVID-19 who were admitted to an intensive care unit and who died while hospitalized, by age group, month, and period relative to SARS-CoV-2 B.1.617.2 (Delta) variant predominance† — COVID-NET, 14 states,§ January–August 2021



* Proportions are from a weighted sample of hospitalized adults with completed medical chart abstraction and a discharge disposition. Results are subject to change as additional data are reported.

† January–June 2021 is the pre-Delta period; the Delta period (July–August 2021) is when the Delta variant was the predominant circulating variant.

§ Selected counties in California, Colorado, Connecticut, Georgia, Iowa, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah can be found at https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm.

age distribution among fully vaccinated hospitalized patients remained stable throughout the study period. All age groups included in this study were eligible to receive COVID-19 vaccines; however, as of August 31, 2021, the proportion of adults aged ≥65 years who are fully vaccinated (81.7%) is far higher than that of adults aged 18–64 years (58.6%).§§ Differences in vaccination coverage between age groups possibly contributed to the shift in proportional age distribution of hospitalized patients during the period of Delta predominance.

The findings in this report are subject to at least six limitations. First, COVID-19–associated hospitalizations might be undercounted because testing practices might have resulted in some persons who were admitted but did not receive testing for SARS-CoV-2. Second, the number of hospitalizations among adults aged 18–49 years is relatively small, and ICU admission, receipt of IMV, and in-hospital death are relatively rare outcomes among younger age groups, limiting the ability to examine statistical significance for some outcomes among this age group. Third, the COVID-NET surveillance catchment

§§ https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic

area represents about 10% of the U.S. population; thus, these findings should not be generalized nationally. Fourth, during periods of increased hospitalization and limited hospital capacity, clinical thresholds for hospitalization and ICU admission might shift and could potentially obscure trends in increased severity. Fifth, the analysis did not account for the propensity of persons to be vaccinated, and therefore could not determine the effectiveness of vaccination in reducing severe outcomes. Finally, data presented are preliminary and might change as additional cases are identified and reported, including cases from July and August that do not yet have a discharge disposition.[¶¶]

Rates of COVID-19–associated hospitalizations in adults increased during July–August 2021 as the Delta variant became predominant in the United States. Although this variant is more transmissible, this study did not find significantly higher proportions of hospitalizations with ICU admission, receipt of IMV, or in-hospital death in nonpregnant hospitalized adults. The proportion of unvaccinated adults aged 18–49 years hospitalized with COVID-19 has increased as the Delta variant has become more predominant. COVID-19 vaccination is critical for all eligible adults, including those aged <50 years who have relatively low vaccination rates compared with older adults.

[¶¶] For hospitalizations with admission dates during July–August 2021, 1.3% of cases are missing a discharge diagnosis.

Summary

What is already known about this topic?

The SARS-CoV-2 B.1.617.2 (Delta) variant is highly transmissible; however, whether it causes more severe disease in adults has been uncertain.

What is added by this report?

Analysis of COVID-NET data from 14 states found no significant increases in the proportion of hospitalized COVID-19 patients with severe outcomes during the Delta period. The proportion of hospitalized unvaccinated COVID-19 patients aged 18–49 years significantly increased during the Delta period.

What are the implications for public health practice?

Lower vaccination coverage in adults aged 18–49 years likely contributed to the increase in hospitalized patients during the Delta period. COVID-19 vaccination is critical for all eligible adults, including adults aged <50 years who have relatively low vaccination rates compared with older adults.

Acknowledgments

Roxanne Archer, Kareena Hundal, Sherry Quach, Maria Rosales, Lena Tayo, Tiffany Tsukuda, California Emerging Infections Program; Ann Basting, Tessa Carter, Maria Correa, Daewi Kim, Carol Lyons, Amber Maslar, Julie Plano, Connecticut Emerging Infections Program, Yale School of Public Health; Katelyn Ward, Jana Manning, Asmith Joseph, Allison Roebling, Chandler Surell, Stephanie Lehman, Taylor Eisenstein, Gracie Chambers, Suzanne Segler, Grayson Kallas, Marina Bruck, Rayna Ceaser, Georgia Emerging Infections Program, Georgia Department of Health, Veterans Affairs Medical Center, Foundation for Atlanta Veterans Education and Research; Jim Collins, Shannon Johnson, Sue Kim, Libby Reeg, Alexander Kohrman, Lauren Leegwater, Sierra Peguies-Khan, Chloe Brown, Michigan Department of Health and Human Services; Austin Bell, Kayla Bilski, Emma Contestabile, Claire Henrichsen, Amanda Gordon, Cynthia Kenyon, Melissa McMahon, Katherine Schleiss, Samantha Siebman, Emily Holodnick, Lisa Nguyen, Kristen Ehresmann, Jennifer Gilbertson, Jill Reaney, Alison Babb, Grace Hernandez, Kieu My Phi, Minnesota Department of Health; Daniel Sosin, Sunshine Martinez, Jasmyn Sanchez, Susan L. Ropp, Cory Cline, New Mexico Department of Health; Sarah Lathrop, Kathy M. Angeles, Emily B. Hancock, Yadira Salazar-Sanchez, Sarah A. Khanlian, Nancy Eisenberg, Melissa Christian, Dominic Rudin, Sarah Shrum Davis, Chelsea McMullen, New Mexico Emerging Infections Program; Yassir Talha, Murtada Khalifa, CDC Foundation, New Mexico Department of Health; Alison Muse, Suzanne McGuire, New York State Department of Health; Sophrena Bushey, Christina Felsen, Christine Long, University of Rochester School of Medicine and Dentistry; Ama Owusu-Dommey, Breanna McArdle, Public Health Division, Oregon Health Authority; Kylie Seeley, Oregon Health & Science University School of Medicine; Karen Lei, Katie Dyer, Terri McMinn, Danielle Ndi, Anise Elie, Kathy Billings, Manideepthi Pemmaraju, John Ujwok, Vanderbilt University Medical Center; Amanda Carter, Andrea George, Andrew Haraghey, Ashley Swain, Caitlin Shaw, Ian Buchta, Laine McCullough, Mary Hill, Ryan Chatelain, Tyler Riedesel, Salt Lake County Health Department.

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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. Evan J. Anderson reports grants from Pfizer, Merck, PaxVax, Micron, Sanofi-Pasteur, Janssen, MedImmune, and GlaxoSmithKline; personal fees from Pfizer, Medscape, Kentucky Bioprocessing, Inc., Sanofi-Pasteur, and Janssen, outside the submitted work; and institutional funding from the National Institutes of Health to conduct clinical trials of Moderna and Janssen COVID-19 vaccines. Laurie M. Billing and Eli Shiltz report grants from the Council of State and Territorial Epidemiologists during the conduct of the study. Ruth Lynfield reports editorial fees from the American Academy of Pediatrics Red Book (Committee on Infectious Diseases), which were donated to the Minnesota Department of Health. William Schaffner reports personal fees from VBI Vaccines, outside the submitted work. No other potential conflicts of interest were disclosed.

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COVID-19 Vaccination and Non–COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021

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On October 22, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

By September 21, 2021, an estimated 182 million persons in the United States were fully vaccinated against COVID-19.* Clinical trials indicate that Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273), and Janssen (Johnson & Johnson; Ad.26.COV2.S) vaccines are effective and generally well tolerated (*1*–*3*). However, daily vaccination rates have declined approximately 78% since April 13, 2021†; vaccine safety concerns have contributed to vaccine hesitancy (*4*). A cohort study of 19,625 nursing home residents found that those who received an mRNA vaccine (Pfizer-BioNTech or Moderna) had lower all-cause mortality than did unvaccinated residents (*5*), but no studies comparing mortality rates within the general population of vaccinated and unvaccinated persons have been conducted. To assess mortality not associated with COVID-19 (non–COVID-19 mortality) after COVID-19 vaccination in a general population setting, a cohort study was conducted during December 2020–July 2021 among approximately 11 million persons enrolled in seven Vaccine Safety Datalink (VSD) sites.§ After standardizing mortality rates by age and sex, this study found that COVID-19 vaccine recipients had lower non–COVID-19 mortality than did unvaccinated persons. After adjusting for demographic characteristics and VSD site, this study found that adjusted relative risk (aRR) of non–COVID-19 mortality for the Pfizer-BioNTech vaccine was 0.41 (95% confidence interval [CI] = 0.38–0.44) after dose 1 and 0.34 (95% CI = 0.33–0.36) after dose 2. The aRRs of non–COVID-19 mortality for the Moderna vaccine were 0.34 (95% CI = 0.32–0.37) after dose 1 and 0.31 (95% CI = 0.30–0.33) after dose 2. The aRR after receipt of the Janssen vaccine was 0.54 (95% CI = 0.49–0.59). There is no increased risk for mortality among COVID-19 vaccine recipients. This finding reinforces the safety profile of currently approved COVID-19 vaccines in the United States.

VSD, a collaborative project between CDC's Immunization Safety Office and nine health care organizations, collects electronic health data, including information on vaccines, for specific studies. In this cohort study of VSD members aged ≥12 years, vaccination status through May 31, 2021 was determined. Index dates were assigned to all persons on the basis of the distribution of vaccination dates among vaccinated persons.¶ Person-time for unvaccinated persons included unvaccinated person-time before COVID-19 vaccination among COVID-19 vaccinees, and unvaccinated person-time of persons who did not receive a COVID-19 vaccine by May 31, 2021. To ensure comparable health care–seeking behavior among persons who received a COVID-19 vaccine and those who did not (unvaccinated persons), eligible unvaccinated persons were selected from among those who received ≥1 dose of influenza vaccine in the last 2 years. Separate unvaccinated groups were selected for mRNA and Janssen vaccines.** Deaths were identified through VSD, which captures hospital deaths and deaths reported to health plans. In this study, non–COVID-19 deaths were assessed because a protective effect of COVID-19 vaccination for

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

† https://ourworldindata.org/coronavirus (Accessed September 21, 2021).

§ Among nine VSD sites, (all health care organizations), data is included from seven sites: Kaiser Permanente (KP) Southern California, Pasadena, California; KP Northern California, Oakland, California; KP Colorado, Denver, Colorado; KP Northwest, Portland, Oregon; KP Washington, Seattle, Washington; HealthPartners, Minneapolis, Minnesota; and Marshfield Clinic, Marshfield, Wisconsin. Harvard Pilgrim Health Care Institute, Boston, Massachusetts, did not participate in this study because it is not a data-contributing site; Denver Health, Denver, Colorado, did not participate in this study because of limited resources.

¶ Persons who were vaccinated during December 14, 2020–May 31, 2021 were included in the vaccinated group. In each VSD site, age group, and sex stratum, the distribution of vaccination dates of dose 1 were obtained and used to assign index dates to all persons. Among vaccinated persons, if the index date was before the vaccination date of dose 1, follow-up started on the index date, and persons in this group contributed both unvaccinated person-time (from index date to the day before vaccination date) and vaccinated person-time (from vaccination date); if the index date was on or after the vaccination date of dose 1, follow-up started on the vaccination date, and persons in this group only contributed person-time after vaccination. Follow-up ended upon death, disenrollment from health plans, receipt of a COVID-19 vaccine for unvaccinated persons during June 1, 2021–July 31, 2021, or end of follow-up (July 31, 2021), whichever occurred first.

** All available eligible comparators were used for analysis of mRNA COVID-19 vaccines. Because the Janssen COVID-19 vaccine was authorized months after the mRNA COVID-19 vaccines and demographic characteristics of Janssen versus mRNA COVID-19 vaccine recipients might differ, a separate group of comparators was selected for Janssen vaccine recipients on the basis of calendar time and demographic characteristics of Janssen vaccine recipients. Because the number of Janssen vaccine recipients was smaller, four eligible comparators were randomly selected for each vaccinated individual to achieve optimal statistical power.

COVID-19–related deaths was expected. Non–COVID-19 deaths were those that did not occur within 30 days of an incident COVID-19 diagnosis or receipt of a positive test result for SARS-CoV-2 (the virus that causes COVID-19) via reverse transcription–polymerase chain reaction or rapid test.

Standardized mortality rates (SMRs) (deaths per 100 person-years) were calculated and compared with a rate ratio test between vaccinated and unvaccinated groups (*6*); a population of VSD members who were enrolled in December 2020 was used as the standard population. Overall SMRs were reported separately for Pfizer-BioNTech, Moderna, and Janssen vaccines. Poisson models were used to calculate overall aRRs and 95% CIs adjusted for age, sex, race and ethnicity, and VSD site. SMRs and aRRs by age, sex, and race and ethnicity were also calculated, adjusting for other demographic characteristics. Analytical units were aggregated counts of deaths and person-years by vaccination status, age, sex, race and ethnicity, and VSD site. All analyses were conducted using SAS statistical software (version 9.4; SAS Institute).[††] This work was reviewed by CDC and VSD sites[§§] and was conducted consistent with applicable federal law and CDC policy.[¶¶]

The cohort consisted of 6.4 million COVID-19 vaccinees and 4.6 million unvaccinated persons with similar characteristics as the comparison groups. Among 3.5 million Pfizer-BioNTech vaccine recipients, 9.2% were aged 12–17 years, 69.4% were aged 18–64 years, 54.0% were female, 42.7% were White persons, 21.4% were Hispanic persons, 16.6% were Asian persons, and 5.1% were Black persons (Table 1). Among 2.6 million Moderna vaccine recipients, 71.7% were aged 18–64 years, 54.5% were female, 44.2% were White persons, 23.1% were Hispanic persons, 14.2% were Asian persons, and 5.6% were Black persons. Among 342,169 Janssen vaccine recipients, 87.5% were aged 18–64 years, 4.1% were aged ≥75 years, 48.0% were female, 45.1% were White persons, 20.3% were Hispanic persons, 13.4% were Asian persons, and 6.1% were Black persons.

After excluding COVID-19–associated deaths, overall SMRs after dose 1 were 0.42 and 0.37 per 100 person-years for Pfizer-BioNTech and Moderna, respectively, and were 0.35 and 0.34, respectively, after dose 2 (Table 2). These rates were lower than the rate of 1.11 per 100 person-years among the unvaccinated mRNA vaccine comparison group (p <0.001). Among Janssen vaccine recipients, the overall SMR was 0.84 per 100 person-years, lower than the rate of 1.47 per 100 person-years among the unvaccinated comparison group (p <0.001). Among persons aged 12–17 years, SMRs were similar among the Pfizer-BioNTech vaccine recipients and unvaccinated comparison groups (p = 0.68 after dose 1 and 0.89 after dose 2). SMRs were also similar between Janssen vaccine recipients and unvaccinated comparison groups among Asian persons (p = 0.11). Among other subgroups defined by vaccine received, age, sex, and race and ethnicity, COVID-19 vaccine recipients had lower SMRs than did their unvaccinated counterparts (p <0.05).

The overall aRR among Pfizer-BioNTech vaccine recipients compared with the unvaccinated comparison group was 0.41 (95% CI = 0.38–0.44) after dose 1 and 0.34 (95% CI = 0.33–0.36) after dose 2 (Table 3). Among Pfizer-BioNTech vaccine recipients aged 12–17 years, mortality risk among vaccinated and unvaccinated persons was similar after dose 1 (aRR = 0.85; 95% CI = 0.38–1.90) and after dose 2 (aRR = 0.73; 95% CI = 0.33–1.64). Among other age groups, aRRs ranged from 0.35 (95% CI = 0.29–0.42) among persons aged 45–64 years to 0.46 (95% CI = 0.39–0.54) among persons aged ≥85 years after dose 1, and from 0.28 (95% CI = 0.25–0.31) among persons aged 45–64 years to 0.39 (95% CI = 0.36–0.43) among those aged ≥85 years after dose 2. Similar aRRs among vaccinated persons compared with the unvaccinated comparison group were observed for recipients of the Moderna vaccine, ranging from 0.31 (95% CI = 0.26–0.37) among persons aged 45–64 years to 0.46 (95% CI = 0.31–0.69) among persons aged 18–44 years after dose 1, and 0.28 (95% CI = 0.26–0.32) among persons aged 65–74 years to 0.38 (95% CI = 0.29–0.50) among those aged 18–44 years after dose 2. The overall aRR for Janssen was 0.54 (95% CI = 0.49–0.59), and age-stratified aRRs ranged from 0.40 (95% CI = 0.34–0.49) among persons aged 45–64 years to 0.68 (95% CI = 0.56–0.82) among persons aged ≥85 years. Across vaccine type and dose, males and females had comparable aRRs. All vaccinated racial and ethnic groups had lower mortality risks than did unvaccinated comparison groups.

Discussion

In a cohort of 6.4 million COVID-19 vaccinees and 4.6 million demographically similar unvaccinated persons, recipients of the Pfizer-BioNTech, Moderna, or Janssen vaccines had lower non–COVID-19 mortality risk than did the unvaccinated comparison groups. There is no increased risk for mortality among COVID-19 vaccine recipients. This finding reinforces the safety profile of currently approved COVID-19 vaccines in the United States. The lower mortality risk after COVID-19 vaccination suggests substantial healthy vaccinee effects (i.e., vaccinated persons tend to be healthier than

[††] The procedure STDRATE was used to conduct rate ratio tests, and the procedure GENMOD was used to fit Poisson models.

[§§] All activities were approved by the institutional review boards at some participating institutions or as public health surveillance activities at other participating institutions.

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

TABLE 1. Demographic characteristics of COVID-19 vaccine recipients and unvaccinated comparison group — seven integrated health care organizations, United States, December 14, 2020–July 31, 2021

Characteristic	No. (%)				
	mRNA vaccine*			Janssen vaccine	
	Pfizer-BioNTech vaccine recipients	Moderna vaccine recipients	Unvaccinated comparison group†,§	Janssen vaccine recipients	Unvaccinated comparison group†
Total	**3,452,126 (100.0)**	**2,604,066 (100.0)**	**3,243,112 (100.0)**	**342,169 (100.0)**	**1,346,445 (100.0)**
Age group, yrs					
12–17	316,587 (9.2)	NA	311,445 (9.6)	NA	NA
18–44	1,322,147 (38.3)	951,899 (36.6)	1,153,735 (35.6)	141,317 (41.3)	558,996 (41.5)
45–64	1,072,819 (31.1)	913,075 (35.1)	987,703 (30.5)	158,157 (46.2)	624,106 (46.4)
65–74	440,879 (12.8)	454,391 (17.4)	468,679 (14.5)	28,721 (8.4)	109,143 (8.1)
75–84	219,888 (6.4)	216,968 (8.3)	233,870 (7.2)	9,835 (2.9)	37,745 (2.8)
≥85	79,806 (2.3)	67,733 (2.6)	87,680 (2.7)	4,139 (1.2)	16,455 (1.2)
Sex					
Male	1,586,867 (46.0)	1,185,265 (45.5)	1,395,196 (43.0)	177,867 (52.0)	696,190 (51.7)
Female	1,865,259 (54.0)	1,418,801 (54.5)	1,847,916 (57.0)	164,302 (48.0)	650,255 (48.3)
Race/Ethnicity					
Hispanic	738,931 (21.4)	600,654 (23.1)	871,863 (26.9)	69,602 (20.3)	329,921 (24.5)
White, non-Hispanic	1,472,716 (42.7)	1,151,826 (44.2)	1,397,345 (43.1)	154,188 (45.1)	585,489 (43.5)
Asian, non-Hispanic	573,754 (16.6)	369,069 (14.2)	432,782 (13.3)	45,909 (13.4)	200,430 (14.9)
Black, non-Hispanic	175,066 (5.1)	145,127 (5.6)	189,592 (5.8)	20,996 (6.1)	73,174 (5.4)
Multiple races/Other/Unknown	491,659 (14.2)	337,390 (13.0)	351,530 (10.8)	51,474 (15.0)	157,431 (11.7)

Abbreviations: Janssen = Johnson & Johnson; NA = not applicable.

* Among Pfizer-BioNTech COVID-19 vaccine recipients, 2,980,152 received the second dose by May 31, 2021; among Moderna COVID-19 vaccine recipients, 2,362,157 received the second dose by May 31, 2021.

† Unvaccinated comparison group included unvaccinated persons and COVID-19 vaccine recipients before COVID-19 vaccination. The assignment of index dates allowed COVID-19 vaccinees to contribute unvaccinated person-time before vaccination, thus avoiding immortal time bias.

§ mRNA vaccines included Pfizer-BioNTech and Moderna COVID-19 vaccines.

unvaccinated persons) (*7*,*8*), which will be explored in future analyses. Mortality rates among Janssen vaccine recipients were not as low as those among mRNA vaccine recipients. This finding might be because of differences in risk factors, such as underlying health status and risk behaviors among recipients of mRNA and Janssen vaccines that might also be associated with mortality risk.

Among persons aged 12–17 years, mortality risk did not differ between Pfizer-BioNTech vaccinees and unvaccinated persons; only 12 deaths occurred in this age group during the study period. The unvaccinated group might be more similar to the vaccinated group in risk factors than are vaccinated and unvaccinated adults. Stratified analyses by age, sex, and race and ethnicity showed that vaccinated adults had lower mortality than did unvaccinated adults across subgroups.

The findings in this report are subject to at least four limitations. First, the study was observational, and individual-level confounders that were not adjusted for might affect mortality risk, including baseline health status, underlying conditions, health care utilization, and socioeconomic status. Second, healthy vaccinee effects were found in all but the youngest age group. Such effects were also found in a cohort study conducted in a nursing home population, which reported substantially lower aRRs for 7-day mortality among vaccinated residents after dose 1 (0.34) and dose 2 (0.49) as compared with unvaccinated residents (*5*). Lower rates of non–COVID-19 mortality in vaccinated groups suggest that COVID-19 vaccinees are inherently healthier or engage in fewer risk behaviors (*7*,*8*); future analyses will address these issues. Third, although deaths associated with COVID-19 were excluded, causes of death were not assessed. It is possible that the algorithm used might have misclassified some deaths associated with COVID-19 because of lack of testing or because individual mortality reviews were not conducted. Finally, the findings might not be applicable to the general population. The VSD includes approximately 3% of the U.S. population, and is representative of the general population with regard to several demographic and socioeconomic characteristics (*9*). Other studies have already demonstrated the safety of COVID-19 vaccines authorized in the United States.

Despite these limitations, this study had several strengths. First, this was a cohort study with a large, sociodemographically diverse population, and it encompassed a study period of >7 months. Second, VSD sites were able to capture COVID-19 vaccines administered not just within but also outside their health care systems, including COVID-19 vaccine doses recorded in state immunization registries, allowing for more complete ascertainment of vaccination status. Third, the assignment of index dates allowed COVID-19 vaccinees to contribute unvaccinated person-time before vaccination, thus

TABLE 2. Number of deaths and standardized mortality rate (deaths per 100 person-years) not associated with COVID-19 among COVID-19 vaccine recipients and unvaccinated comparison groups, by age, sex, and race/ethnicity — seven integrated health care organizations, United States, December 14, 2020–July 31, 2021

	No. of deaths* (standardized mortality rate per 100 person-years)						
	mRNA vaccine					Janssen vaccine	
	Pfizer-BioNTech vaccine recipients†		Moderna vaccine recipients†				
Characteristic	After dose 1	After dose 2	After dose 1	After dose 2	Unvaccinated comparison group§	Vaccine recipients¶	Unvaccinated comparison group§
Overall**	**1,157 (0.42)**	**5,143 (0.35)**	**1,202 (0.37)**	**4,434 (0.34)**	**6,660 (1.11)**	**671 (0.84)**	**2,219 (1.47)**
Age group,†† yrs							
12–17	2 (0.01)	3 (0.01)	NA	NA	7 (0.01)	NA	NA
18–44	20 (0.02)	73 (0.02)	24 (0.03)	57 (0.02)	161 (0.07)	19 (0.04)	63 (0.08)
45–64	117 (0.16)	409 (0.13)	123 (0.16)	421 (0.17)	910 (0.51)	130 (0.25)	497 (0.66)
65–74	235 (0.79)	994 (0.62)	249 (0.63)	920 (0.58)	1,407 (2.13)	144 (1.49)	466 (2.77)
75–84	338 (2.32)	1,591 (1.89)	376 (2.00)	1,425 (1.77)	1,861 (6.34)	176 (5.59)	549 (9.13)
≥85	445 (7.90)	2,073 (6.85)	430 (7.16)	1,611 (6.57)	2,314 (18.76)	202 (15.35)	644 (23.76)
Sex§§							
Male	587 (0.49)	2,584 (0.41)	640 (0.45)	2,352 (0.42)	3,265 (1.30)	326 (0.96)	1,102 (1.68)
Female	570 (0.35)	2,559 (0.29)	562 (0.30)	2,082 (0.28)	3,395 (0.96)	345 (0.75)	1,117 (1.31)
Race/Ethnicity**							
Hispanic	144 (0.36)	584 (0.29)	197 (0.35)	701 (0.33)	1,230 (1.07)	92 (0.91)	365 (1.24)
White, non-Hispanic	781 (0.47)	3,560 (0.39)	732 (0.39)	2,804 (0.37)	3,993 (1.17)	416 (0.85)	1,364 (1.58)
Asian, non-Hispanic	72 (0.23)	408 (0.23)	67 (0.18)	317 (0.21)	460 (0.78)	56 (0.83)	157 (1.09)
Black, non-Hispanic	84 (0.54)	300 (0.37)	130 (0.65)	340 (0.44)	623 (1.53)	65 (0.99)	187 (1.97)
Multiple races/Other/ Unknown	76 (0.38)	291 (0.28)	76 (0.32)	272 (0.29)	354 (0.82)	42 (0.68)	146 (1.22)

Abbreviations: Janssen = Johnson & Johnson; NA = not applicable.

* Number of deaths as of July 31, 2021; deaths that occurred ≤30 days after an incident COVID-19 diagnosis or receipt of a positive SARS-CoV-2 test result were excluded.

† Vaccinated with mRNA COVID-19 vaccines during December 14, 2020–May 31, 2021.

§ Unvaccinated comparison group included unvaccinated persons and COVID-19 vaccine recipients before COVID-19 vaccination. The assignment of index dates allowed COVID-19 vaccinees to contribute unvaccinated person-time before vaccination, thus avoiding immortal time bias.

¶ Vaccinated with Janssen COVID-19 vaccine during February 27, 2021–May 31, 2021.

** Overall mortality rates and race- and ethnicity-specific mortality rates were age- and sex-standardized.

†† Age-specific mortality rates were sex-standardized.

§§ Sex-specific mortality rates were age-standardized.

Summary

What is already known about this topic?

Although deaths after COVID-19 vaccination have been reported to the Vaccine Adverse Events Reporting System, few studies have been conducted to evaluate mortality not associated with COVID-19 among vaccinated and unvaccinated groups.

What is added by this report?

During December 2020–July 2021, COVID-19 vaccine recipients had lower rates of non–COVID-19 mortality than did unvaccinated persons after adjusting for age, sex, race and ethnicity, and study site.

What are the implications for public health practice?

There is no increased risk for mortality among COVID-19 vaccine recipients. This finding reinforces the safety profile of currently approved COVID-19 vaccines in the United States. All persons aged ≥12 years should receive a COVID-19 vaccine.

avoiding immortal time bias (*10*), which can confer a spurious survival advantage to the treatment group in cohort studies. Index date assignments made the follow-up period comparable between COVID-19 vaccinees and their comparators and helped control for seasonality and general trends in mortality.

CDC recommends that everyone aged ≥12 years should receive a COVID-19 vaccine to help protect against COVID-19.*** This cohort study found lower rates of non–COVID-19 mortality among vaccinated persons compared with unvaccinated persons in a large, sociodemographically diverse population during December 2020–July 2021. There is no increased risk for mortality among COVID-19 vaccine recipients. This finding reinforces the safety profile of currently approved COVID-19 vaccines in the United States.

*** https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html (Accessed October 13, 2021).

TABLE 3. Adjusted relative risks for mortality of COVID-19 vaccine recipients and unvaccinated comparison groups*— seven integrated health care organizations, United States, December 14, 2020–July 31, 2021

	Vaccine type, aRR, (95% CI)				
	Pfizer-BioNTech		Moderna		Janssen
Characteristic	After dose 1	After dose 2	After dose 1	After dose 2	After dose 1
Overall†	**0.41 (0.38–0.44)**	**0.34 (0.33–0.36)**	**0.34 (0.32–0.37)**	**0.31(0.30–0.33)**	**0.54 (0.49–0.59)**
Age group,§ yrs					
12–17	0.85 (0.38–1.90)	0.73 (0.33–1.64)	NA	NA	NA
18–44	0.37 (0.24–0.57)	0.36 (0.28–0.46)	0.46 (0.31–0.69)	0.38 (0.29–0.50)	0.55 (0.36–0.82)
45–64	0.35 (0.29–0.42)	0.28 (0.25–0.31)	0.31 (0.26–0.37)	0.33 (0.29–0.37)	0.40 (0.34–0.49)
65–74	0.39 (0.33–0.47)	0.32 (0.29–0.35)	0.32 (0.27–0.37)	0.28 (0.26–0.32)	0.50 (0.39–0.63)
75–84	0.38 (0.33–0.46)	0.32 (0.29–0.35)	0.32 (0.27–0.38)	0.29 (0.26–0.32)	0.58 (0.48–0.71)
≥85	0.46 (0.39–0.54)	0.39 (0.36–0.43)	0.38 (0.32–0.45)	0.35 (0.31–0.39)	0.68 (0.56–0.82)
Sex¶					
Male	0.41 (0.37–0.46)	0.35 (0.33–0.38)	0.36 (0.32–0.40)	0.33 (0.31–0.35)	0.52 (0.46–0.60)
Female	0.41 (0.36–0.45)	0.33 (0.31–0.36)	0.33 (0.29–0.37)	0.30 (0.28–0.32)	0.56 (0.49–0.64)
Race/Ethnicity**					
Hispanic	0.36 (0.30–0.42)	0.29 (0.26–0.32)	0.33 (0.29–0.39)	0.31 (0.28–0.34)	0.58 (0.46–0.73)
White, non-Hispanic	0.44 (0.38–0.50)	0.37 (0.34–0.40)	0.35 (0.30–0.40)	0.32 (0.30–0.35)	0.53 (0.46–0.61)
Asian, non-Hispanic	0.31 (0.25–0.39)	0.32 (0.28–0.36)	0.23 (0.18–0.30)	0.27 (0.23–0.30)	0.68 (0.52–0.88)
Black, non-Hispanic	0.38 (0.31–0.47)	0.27 (0.24–0.31)	0.42 (0.35–0.49)	0.29 (0.25–0.32)	0.47 (0.36–0.63)
Multiple races/Other/Unknown	0.46 (0.36–0.60)	0.35 (0.30–0.41)	0.40 (0.30–0.51)	0.36 (0.30–0.42)	0.52 (0.38–0.71)

Abbreviations: aRR = adjusted relative risk; CI = confidence interval; Janssen = Johnson & Johnson; NA = not applicable; VSD = Vaccine Safety Datalink.

* Unvaccinated comparison groups included unvaccinated persons and COVID-19 vaccine recipients before COVID-19 vaccination. The assignment of index dates allowed COVID-19 vaccinees to contribute unvaccinated person-time before vaccination, thus avoiding immortal time bias.

† Overall relative risks were adjusted for age, sex, race and ethnicity, and VSD site.

§ Relative risks by age were adjusted for sex, race and ethnicity, and VSD site.

¶ Relative risks by sex were adjusted for age, race and ethnicity, and VSD site.

** Relative risks by race and ethnicity were adjusted for age, sex, and VSD site.

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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. Runxin Huang reports support for attending meetings or travel from Dynavax Technologies. Nicola P. Klein reports institutional support from Pfizer, Sanofi Pasteur, Merck, GlaxoSmithKline, and Protein Science (now Sanofi Pasteur to support vaccine studies). Elizabeth G. Liles reports research contracts from the National Human Genome Research Institute and Pfizer. Kerresa Morrissette reports research contracts from the National Institutes of Health, GlaxoSmithKline, and Merck Sharp & Dohme Corporation, outside the submitted work. No other potential conflicts of interest were disclosed.

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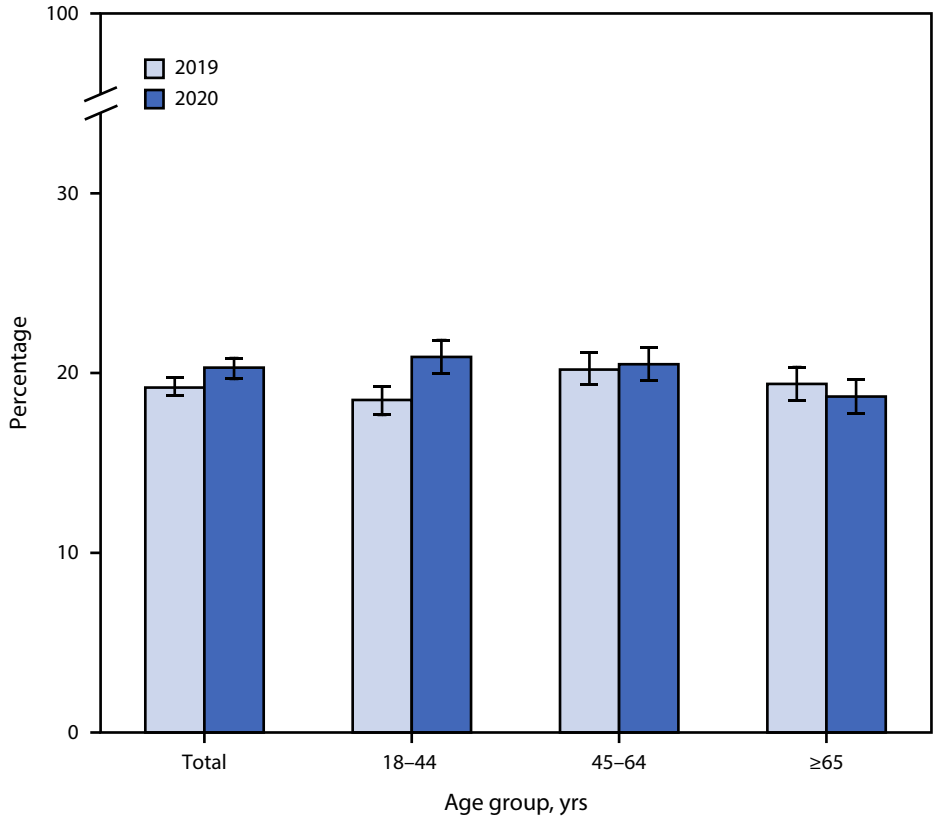
QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Percentage* of Adults Who Received Any Mental Health Treatment in the Past 12 Months,† by Age Group and Year — National Health Interview Survey, United States, 2019–2020§



* 95% confidence intervals indicated with error bars.
† Adults were considered to have received any mental health treatment if they reported having taken prescription medication for their mental health or having received counseling or therapy from a mental health professional in the past 12 months.
§ Estimates are based on household interviews of a sample of the civilian, noninstitutionalized U.S. population.

The percentage of adults who had received any mental health treatment in the past 12 months increased from 2019 to 2020 overall (19.2% to 20.3%) and among adults aged 18–44 years (18.5% to 20.9%). In 2019, the percentage of adults who had received any mental health treatment in the past 12 months was lower among those aged 18–44 years (18.5%) compared with those aged 45–64 years (20.2%) and ≥65 years (19.4%). In 2020, the percentage decreased with age, from 20.9% among adults aged 18–44 years to 18.7% among those aged ≥65 years.

Sources: National Center for Health Statistics. NCHS data brief, no. 380. https://www.cdc.gov/nchs/data/databriefs/db380-H.pdf; NCHS data brief, no. 419. https://www.cdc.gov/nchs/data/databriefs/db419.pdf

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ISSN: 0149-2195 (Print)