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Prevalence of Diagnosed Arthritis — United States, 2019–2021

Elizabeth A. Fallon, PhD[1]; Michael A. Boring, MS[2]; Anika L. Foster, DrPH[1]; Ellen W. Stowe, PhD[1]; Tyler D. Lites, MPH[1,3]; Erica L. Odom, DrPH[1]; Puja Seth, PhD[1]

Abstract

Arthritis includes approximately 100 conditions that affect the joints and surrounding tissues. It is a leading cause of activity limitations, disability, and chronic pain, and is associated with dispensed opioid prescriptions, substantially contributing to health care costs. Combined 2019–2021 National Health Interview Survey data were analyzed to update national prevalence estimates of self-reported diagnosed arthritis. An estimated 21.2% (18.7% age-standardized) of U.S. adults aged ≥18 years (53.2 million) had diagnosed arthritis during this time frame. Age-standardized arthritis prevalences were higher among women (20.9%) than men (16.3%), among veterans (24.2%) than nonveterans (18.5%), and among non-Hispanic White (20.1%) than among Hispanic or Latino (14.7%) or non-Hispanic Asian adults (10.3%). Adults aged ≥45 years represent 88.3% of all U.S. adults with arthritis. Unadjusted arthritis prevalence was high among adults with chronic obstructive pulmonary disease (COPD) (57.6%), dementia (55.9%), a disability (54.8%), stroke (52.6%), heart disease (51.5%), diabetes (43.1%), or cancer (43.1%). Approximately one half of adults aged ≥65 years with COPD, dementia, stroke, heart disease, diabetes, or cancer also had a diagnosis of arthritis. These prevalence estimates can be used to guide public health policies and activities to increase equitable access to physical activity opportunities within the built environment and other arthritis-appropriate, evidence-based interventions.

Introduction

Arthritis includes approximately 100 conditions that affect the joints and surrounding tissues. If not managed properly, arthritis can result in severe pain, activity limitations, and disability (*1*–*3*). Adults with arthritis have disproportionate rates of anxiety and depression and received 55.3% of all-cause prescription opioids dispensed in the United States in 2015 (*4*,*5*). Thus, arthritis is a significant driver of lost wages, disability, and medical costs (*3*,*6*). Updated arthritis prevalence estimates can help identify disproportionately affected groups, monitor arthritis prevalence over time, and guide resource allocation.

Methods

The National Health Interview Survey (NHIS) is an annual, nationally representative household survey of the noninstitutionalized U.S. civilian population.* One adult in a household is randomly selected to complete the in-home interview. When necessary, telephone follow-up is permitted to complete the interview.† If the selected person is physically or mentally unable to answer the survey, a knowledgeable proxy can answer

* https://www.cdc.gov/nchs/nhis/index.htm
† https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm

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on behalf of the selected person. During April–June 2020, the COVID-19 pandemic necessitated a change to telephone-only data collection. During July 2020–April 2021, interviews were attempted by telephone first, with in-home follow-up to complete data collection. In May 2021, data collection returned to prepandemic procedures.[§]

NHIS sample sizes and response rates for 2019, 2020, and 2021 were 31,997 (59.1%), 21,153 (48.9%), and 29,482 (50.9%), respectively.[¶] A person was identified as having arthritis if he or she responded "yes" to the question, "Have you ever been told by a doctor or other health care professional that you have arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?" Survey respondents answering "yes" or "no" to this item were included in the analytic sample (82,503; 99.8% of survey respondents). Data were weighted to account for complex survey design, selection probability, and nonresponse. Unadjusted and age-standardized[**] arthritis prevalence estimates for adults aged ≥18 years were calculated overall and by selected self-reported demographic and health characteristics. Subgroup prevalences were compared with a reference group using t-tests; all differences are significant at $\alpha = 0.05$. Analyses were conducted in SAS (version 9.4; SAS Institute) and SUDAAN (version 11.0; RTI International). This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[††]

Results

Approximately 53.2 million (95% CI = 52.1–54.4) or 21.2% (18.7% age-standardized) of U.S. adults aged ≥18 years had diagnosed arthritis (Table 1). Age-standardized prevalence was higher among women (20.9%) than men (16.3%) and among veterans (24.2%) than nonveterans (18.5%). Age-standardized prevalence was higher among non-Hispanic White (20.1%) than among Hispanic or Latino (14.7%) or non-Hispanic Asian adults (10.3%). There was no difference between non-Hispanic White and non-Hispanic Black or African American adults (19.7%), or non-Hispanic American Indian or Alaska Native adults (21.0%). The unadjusted prevalence of arthritis among U.S. adults with a disability was 54.8% (12.3 million); after adjusting for age, prevalence was higher among adults with a disability (40.5%) than among those without a disability (16.6%).

[§] https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2019/srvydesc-508.pdf; https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2020/srvydesc-508.pdf; https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2021/srvydesc-508.pdf

[¶] Per NHIS instructions, the "sample adult partial" data file from 2020 was combined with the 2019 and 2021 data for this analysis. https://www.cdc.gov/nchs/nhis/2020nhis.htm

[**] Age-standardized to the 2000 projected U.S. adult population with three age groups (18–44, 45–64, and ≥65 years). https://www.cdc.gov/nchs/data/statnt/statnt20.pdf

[††] 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.

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TABLE 1. Unadjusted and age-standardized* prevalence of diagnosed arthritis† among adults aged ≥18 years, by selected characteristics — National Health Interview Survey, United States, 2019–2021

Characteristic	Unweighted no. with arthritis§	Weighted no. with arthritis (millions)§	Distribution among adults with arthritis (%)¶	Prevalence of arthritis†	
				Unadjusted % (95% CI)	Age-standardized % (95% CI)
Overall (2019–2021)	**21,204**	**53.2**	**100**	**21.2 (20.7–21.6)**	**18.7 (18.3–19.1)**
Survey year					
2019 (Ref)	8,214	53.6	NA	21.4 (20.8–22.0)	19.2 (18.7–19.7)
2020**	5,382	52.3	NA	20.8 (20.0–21.5)	18.3 (17.7–19.0)††
2021	7,608	53.8	NA	21.3 (20.7–21.9)	18.6 (18.1–19.1)
Age group, yrs					
18–44 (Ref)	1,905	6.2	11.7	5.4 (5.1–5.7)	NA
45–64	7,390	21.3	40.0	26.0 (25.3–26.8)§§	NA
≥65	11,880	25.7	48.3	47.3 (46.4–48.2)§§	NA
Sex¶¶					
Female	13,032	31.5	59.2	24.2 (23.6–24.9)§§	20.9 (20.5–21.4)§§
Male (Ref)	8,171	21.7	40.8	17.9 (17.3–18.4)	16.3 (15.8–16.7)
Race and ethnicity* **					
American Indian or Alaska Native, NH	153	0.4	0.7	22.2 (17.3–28.1)	21.0 (16.8–26.0)
Asian, NH	496	1.6	2.9	10.5 (9.3–11.8)§§	10.3 (9.3–11.4)§§
Black or African American, NH	2,349	6.0	11.3	20.4 (19.3–21.6)§§	19.7 (18.8–20.7)
White, NH (Ref)	16,236	39.1	73.3	24.6 (24.1–25.2)	20.1 (19.7–20.6)
Hispanic or Latino, any race	1,586	5.2	9.8	12.4 (11.6–13.2)§§	14.7 (13.9–15.4)§§
Other, multiple races, NH	384	1.0	1.9	20.8 (18.3–23.6)§§	23.6 (21.1–26.2)§§
Sexual orientation†††					
Bisexual	201	0.6	1.1	12.6 (10.4–15.2)§§	24.7 (21.1–28.6)§§
Lesbian, gay, or homosexual	285	0.7	1.3	16.1 (14.0–18.4)§§	18.4 (16.4–20.5)
Straight or heterosexual (Ref)	19,755	49.4	96.2	21.5 (21.0–22.0)	18.6 (18.3–19.0)
Something else	90	0.2	0.5	20.0 (15.6–25.3)	25.6 (21.0–30.8)§§
Don't know	184	0.5	0.9	18.6 (15.3–22.3)	18.1 (15.3–21.3)
Highest educational attainment§§§					
Less than high school graduate (Ref)	2,380	7.4	14.0	26.3 (25.0–27.6)	20.3 (19.3–21.4)
High school graduate or equivalent	6,021	16.0	30.3	23.1 (22.3–23.9)§§	20.2 (19.5–20.8)
At least some college	6,585	16.2	30.6	22.0 (21.2–22.8)§§	20.3 (19.7–20.9)
College degree or greater	6,099	13.2	25.1	16.8 (16.3–17.4)§§	15.3 (14.8–15.7)§§
Employment status¶¶¶					
Employed or self-employed (Ref)	6,893	19.3	37.4	12.6 (12.2–13.1)	14.8 (14.4–15.2)
Retired	10,041	21.7	42.2	47.4 (46.4–48.3)§§	30.1 (23.5–37.5)§§
Unable to work or disabled	2,732	7.4	14.4	49.1 (47.4–51.0)§§	40.9 (39.0–42.9)§§
Unemployed	228	0.8	1.5	11.2 (9.6–13.1)	16.5 (14.1–19.3)
Other	730	2.4	4.6	10.2 (9.3–11.2)§§	16.1 (14.8–17.5)
Income to poverty ratio** **					
Poor/Near poor (<125%; Ref)	3,811	8.5	17.3	25.6 (24.5–26.7)	25.1 (24.1–26.0)
Low income (125% to <200%)	3,384	7.7	15.7	23.5 (22.4–24.6)§§	20.6 (19.7–21.6)§§
Middle income (200% to <400%))	6,465	15.3	31.3	22.0 (21.3–22.7)§§	19.5 (18.9–20.1)§§
High income (≥400%)	7,544	17.4	35.7	18.2 (17.7–18.8)§§	15.7 (15.3–16.1)§§
Veteran status††††					
Yes (Ref)	2,916	6.8	13.2	35.2 (33.9–36.6)	24.2 (22.9–25.7)
No	17,716	44.7	86.8	20.0 (19.5–20.4)§§	18.5 (18.1–18.9)§§
BMI (kg/m^2)§§§§					
Underweight/Healthy weight (<25; Ref)	5,396	12.7	24.6	15.5 (15.0–16.1)	14.7 (14.2–15.2)
Overweight (25 to <30)	6,852	17.1	33.0	20.5 (19.9–21.1)§§	16.8 (16.3–17.3)§§
Obesity (≥30)	8,373	22.0	42.4	27.5 (26.7–28.3)§§	24.5 (23.9–25.2)§§
Any disability¶¶¶¶					
Yes (Ref)	5,112	12.3	23.0	54.8 (53.4–56.2)	40.5 (38.9–42.2)
No	16,092	41.0	77.0	17.9 (17.4–18.3)§§	16.6 (16.3–17.0)§§
Heart disease*** **					
Yes (Ref)	3,516	8.2	15.5	51.5 (49.9–53.1)	36.3 (32.9–39.8)
No	17,603	44.8	84.5	19.0 (18.6–19.5)§§	17.8 (17.4–18.2)§§

See table footnotes on the next page.

TABLE 1. (*Continued*) Unadjusted and age-standardized* prevalence of diagnosed arthritis† among adults aged ≥18 years, by selected characteristics — National Health Interview Survey, United States, 2019–2021

Characteristic	Unweighted no. with arthritis§	Weighted no. with arthritis (millions)§	Distribution among adults with arthritis (%)¶	Prevalence of arthritis†	
				Unadjusted % (95% CI)	Age-standardized % (95% CI)
Diabetes***					
Yes (Ref)	4,072	10.2	19.1	43.1 (41.8–44.5)	28.8 (27.1–30.5)
No	17,117	43.0	80.9	18.9 (18.4–19.3)§§	17.8 (17.4–18.1)§§
Cancer***					
Yes (Ref)	3,641	8.3	16.3	43.1 (41.5–44.6)	27.7 (25.8–29.8)
No	16,511	42.6	83.7	18.8 (18.3–19.2)§§	18.0 (17.6–18.3)§§
Dementia***					
Yes (Ref)	542	1.4	2.6	55.9 (52.0–59.7)	47.8 (36.7–59.1)
No	20,645	51.8	97.4	20.8 (20.3–21.3)§§	18.6 (18.2–19.0)§§
Stroke***					
Yes (Ref)	1,563	3.7	7.0	52.6 (50.3–55.0)	39.0 (34.6–43.7)
No	19,619	49.5	93.0	20.2 (19.8–20.7)§§	18.3 (17.9–18.7)§§
COPD***					
Yes (Ref)	2,818	6.8	12.9	57.6 (55.8–59.5)	43.5 (40.8–46.2)
No	18,356	46.3	87.1	19.3 (18.9–19.8)§§	17.6 (17.2–17.9)§§

Abbreviations: BMI = body mass index; COPD = chronic obstructive pulmonary disease; NA = not applicable; NH = non-Hispanic; Ref = referent group.

* Unadjusted and age-standardized estimates are calculated using sampling weights to produce nationally representative prevalences. Age-standardized estimates were calculated using 82,290 (99.6%) respondents, with complete data for both arthritis and age questions. Estimates are age-standardized to the 2000 U.S. projected adult population, using three age groups: 18–44, 45–64, and ≥65 years. https://www.cdc.gov/nchs/data/statnt/statnt20.pdf

† Responded "yes" to the question, "Have you ever been told by a doctor or other health professional that you had some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?"

§ Might not sum to column total for some categories because of item-specific missing data.

¶ Might not sum to 100% because of rounding.

** During the COVID-19 pandemic (April 2020–May 2021), data collection procedures changed from in-home to telephone-based and back to in-home. This analysis combined the 2020 partial adult sample data file with 2019 and 2021 data to obtain arthritis prevalence for 2019–2021. Therefore, the 2020 estimate displayed is only used to explore the potential effects of COVID-19 and should not be used as a single year estimate of diagnosed arthritis for 2020. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2020/srvydesc-508.pdf

†† T-tests were used to determine statistically significant differences in arthritis prevalence by survey year; differences with p≤0.05 were considered statistically significant. Despite statistically significant differences by year for age-adjusted arthritis prevalence, crude prevalence and weighted population estimates were not substantively different across years.

§§ T-tests were used to determine statistically significant differences in arthritis prevalence for subgroups defined by selected characteristics; differences with p≤0.05 were considered statistically significant.

¶¶ Identified as "male" or "female" in response to the question, "are you male or female?"

*** Racial and ethnic categories from the sample adult file codebook were used. Persons identifying as "other single and multiple race," or "NH American Indian or Alaska Native and any other group" were combined into "Other, multiple races, NH."

††† The sample adult file codebook sexual orientation categories were used. Survey responses coded as "refused," "don't know," "not ascertained," or missing responses were excluded.

§§§ Responses to the question, "What is the highest level of school you completed…?" were combined into the following groups: 1) less than high school graduate: never attended/attended only kindergarten, grades 1–11, or attended 12th grade but did not get a diploma, 2) high school graduate or equivalent: graduated high school, or earned a general education development certificate, 3) at least some college: some college or associate degree, and 4) college degree or greater: bachelor's, master's, professional school, or doctoral degree.

¶¶¶ Persons responding "yes" to the question, "Do you usually work 35 hours or more per week in total at all jobs or businesses?" were considered "employed/self-employed." Persons responding "no" were asked "What is the MAIN reason you were not working for pay…?" with responses categorized as 1) unemployed: "unemployed, laid off, seasonal/contract work, looking for work," 2) retired: "retired," 3) unable to work/disabled: "unable to work for health reasons/disabled," and 4) other: all remaining valid options.

**** Income-to-poverty ratio values for the income-to-poverty ratio variable were calculated using National Health Interview Survey imputed income files. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2021/NHIS2021-imputation-techdoc-508.pdf; https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2020/NHIS2020-imputation-techdoc-508.pdf; https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2019/NHIS2019-imputation-techdoc-508.pdf

†††† Veterans were defined as respondents who answered "yes" to "Did you ever serve on active duty in the U.S. Armed Forces, military Reserves, or National Guard?"

§§§§ Self-reported height and weight were used to calculate BMI [weight (kg)/(height [m])^2].

¶¶¶¶ A respondent who reported a lot of difficulty or being unable to do an activity in any of the six Washington Group Short Set on Functioning items (vision, hearing, mobility, self-care, cognitive, or communication) was considered to have a disability.

***** Respondents were considered as having the following chronic diseases if they answered "yes" to "Have you ever been told by a doctor or other health professional that you have/had…" 1) heart disease: coronary heart disease, angina (angina pectoris), or heart attack (myocardial infarction); 2) cancer: cancer or a malignancy of any kind (excluding skin cancer); 3) dementia: dementia, including Alzheimer disease; 4) COPD, emphysema, or chronic bronchitis, 5) stroke, or 6) diabetes.

Adults aged ≥45 years represent 88.3% of all U.S. adults with arthritis. Nearly one half of adults with arthritis (48.3%; 25.7 million) were aged ≥65 years, and 40.0% (21.3 million) were aged 45–64 years. Age-standardized prevalence of arthritis was higher among adults with dementia (47.8%),[§§] chronic obstructive pulmonary disease (COPD) (43.5%), stroke (39.0%), heart disease (36.3%), diabetes (28.8%), or cancer (27.7%), than among adults without these chronic conditions (Table 1). The U.S. arthritis prevalence was substantial among adults with COPD (57.6%; 6.8 million), dementia (55.9%; 1.4 million), stroke (52.6%; 3.7 million), heart disease (51.5%; 8.2 million), diabetes (43.1%; 10.2 million), or cancer (43.1%; 8.3 million). Among adults aged ≥65 years, approximately one half of those with COPD (62.4%), stroke (57.9%), heart disease (57.4%), obesity (body mass index ≥30 kg/m^2; 56.8%), dementia (56.1%), diabetes (54.0%), or cancer (52.2%) also had diagnosed arthritis (Table 2) (Figure).

Discussion

During 2019–2021, 53.2 million (21.2%) U.S. adults aged ≥18 years had diagnosed arthritis. Approximately one half of adults aged ≥65 years with a chronic disease also reported diagnosed arthritis. Consistent with previous NHIS (*1*) and Behavioral Risk Factor Surveillance System data (*7*), arthritis prevalence was higher among women than men, among adults aged 45–64 and ≥65 years than among those aged 18–44 years, among veterans than among nonveterans, among persons with a disability than among those without a disability, and among persons reporting a comorbid chronic condition than among those without such a condition.

The 2019–2021 NHIS prevalence estimate is lower than the 2016–2018 NHIS prevalence estimate (58.5 million; 23.7%) (*1*). The NHIS survey was redesigned in 2019 (*8*), resulting in reordering and eliminating some arthritis-relevant questions, which might have led to differences in respondents' ability to recall an arthritis diagnosis. Therefore, estimates produced by NHIS before 2019 should not be statistically compared with NHIS estimates after 2019, but instead interpreted as independent estimates obtained from different survey methodologies. This study establishes a new baseline for monitoring NHIS arthritis prevalence estimates, beginning with the combined 2019–2021 data. These estimates can be used to guide public health activities, policies, and resource allocation for improving arthritis-attributable health outcomes and associated health care costs.

Limitations

The findings in this report are subject to at least five limitations. First, because of the cross-sectional nature of NHIS, causality among selected characteristics and arthritis diagnosis cannot be inferred. Second, arthritis diagnosis was self-reported and was not validated by medical record review. Third, social desirability, recall, and proxy response biases might lead to over- or underestimation of arthritis prevalence. Fourth, the single survey item assessing diagnosed arthritis does not capture undiagnosed arthritis or allow prevalence estimates to be

[§§] A total of 45.9% of respondents with dementia used a survey proxy, compared with 2.0% of survey respondents without dementia, indicating greater potential for proxy response bias among adults with dementia.

TABLE 2. Prevalence* of diagnosed arthritis† among adults aged ≥18 years with selected chronic conditions, by age group — National Health Interview Survey, United States, 2019–2021

Health condition	Age group, yrs		
	18–44 % (95% CI)	45–64 % (95% CI)	≥65 % (95% CI)
Obesity (BMI ≥30)[§]	8.6 (7.9–9.3)	34.4 (33.2–35.7)	56.8 (55.2–58.3)
Heart disease[¶]	23.7 (18.0–30.5)	46.6 (43.6–49.6)	57.4 (55.5–59.2)
Diabetes[¶]	15.0 (12.2–18.3)	38.8 (36.7–40.9)	54.0 (52.2–55.8)
Cancer[¶]	15.2 (12.1–18.8)	36.1 (33.6–38.8)	52.2 (50.4–54.0)
Dementia[¶]	—**	59.4 (48.3–69.5)	56.1 (51.9–60.2)
Stroke[¶]	26.8 (19.5–35.6)	50.0 (45.6–54.4)	57.9 (55.1–60.7)
COPD[¶]	26.8 (22.2–31.9)	62.4 (59.4–65.4)	62.4 (60.0–64.8)
No chronic condition[††]	3.6 (3.3–3.9)	17.1 (16.3–7.9)	36.7 (35.4–38.1)

Abbreviations: BMI = body mass index; COPD = chronic obstructive pulmonary disease.

* Calculated using sampling weights to produce nationally representative prevalence estimates.

† Responded "yes" to the question, "Have you ever been told by a doctor or other health professional that you had some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?"

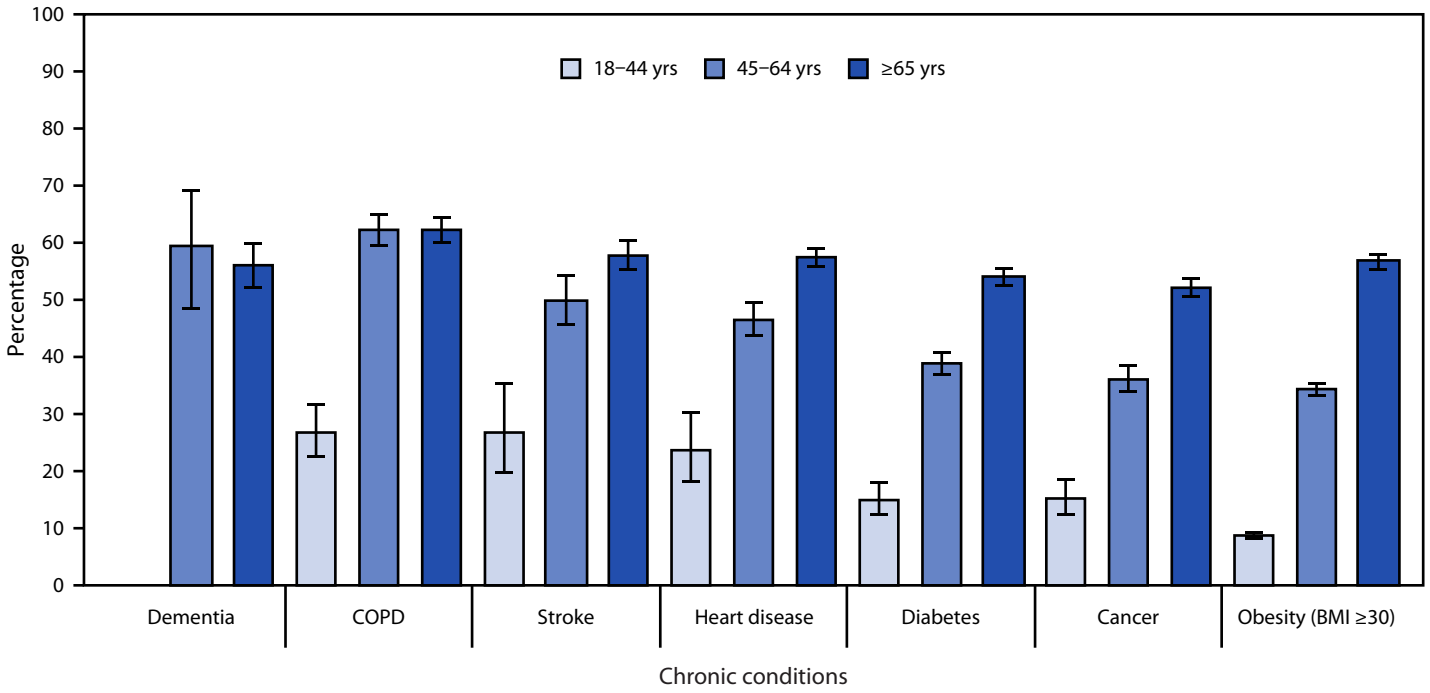
§ Self-reported height and weight were used to calculate BMI [weight (kg)/(height [m])^2].

¶ Respondents were considered as having the following chronic diseases if they answered "yes" to "Have you ever been told by a doctor or other health professional that you have/had…" 1) heart disease: coronary heart disease, angina (angina pectoris), or heart attack (myocardial infarction); 2) cancer: cancer or a malignancy of any kind (excluding skin cancer); 3) dementia: dementia, including Alzheimer disease; 4) COPD, emphysema, or chronic bronchitis, 5) stroke, or 6) diabetes.

** The estimate is suppressed on the basis of the data presentation standards for proportions. https://www.cdc.gov/nchs/data/series/sr_02/sr02_175.pdf

†† Respondents answered "no" to "Have you ever been told by a doctor or other health professional that you have/had…" for all of the following: 1) heart disease: coronary heart disease, angina (angina pectoris), or heart attack (myocardial infarction); 2) cancer: cancer or a malignancy of any kind (excluding skin cancer); 3) dementia: dementia, including Alzheimer disease; 4) COPD, emphysema, or chronic bronchitis, 5) stroke, or 6) diabetes.

FIGURE. Prevalence*,† of diagnosed arthritis§ among adults aged ≥18 years with selected chronic conditions,¶, by age group — National Health Interview Survey, United States, 2019–2021**



Abbreviations: BMI = body mass index; COPD = chronic obstructive pulmonary disease.

* Calculated using sampling weights to produce nationally representative prevalence estimates. 95% CIs indicated by error bars.

† The estimate for dementia (18–44 years) is suppressed based on the data presentation standards for proportions. https://www.cdc.gov/nchs/data/series/sr_02/sr02_175.pdf

§ Responded "yes" to the question, "Have you ever been told by a doctor or other health professional that you had some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia?"

¶ Respondents were considered as having the following chronic diseases if they answered "yes" to "Have you ever been told by a doctor or other health professional that you have or had…" 1) heart disease: coronary heart disease, angina (angina pectoris), or heart attack (myocardial infarction); 2) cancer: cancer or a malignancy of any kind (excluding skin cancer); 3) dementia: dementia, including Alzheimer disease; 4) COPD, emphysema, or chronic bronchitis, 5) stroke, or 6) diabetes.

** Self-reported height and weight were used to calculate BMI [weight (kg)/(height [m])^2].

calculated for arthritis subtypes. Finally, although annual prevalence estimates of arthritis were similar during 2019–2021, the COVID-19 pandemic necessitated changes in data collection methods and might have altered U.S. adult health care use and potentially affected estimates of diagnosed arthritis.

Implications for Public Health Practice

Physical activity is important for managing arthritis-attributable pain and improving physical function (*9*). Many adults, including those with arthritis, do not meet the 2018 Physical Guidelines for Americans recommendations for physical activity despite its known benefits¶¶; these recommendations include engaging in 150–300 minutes of moderate-intensity or 75–150 minutes of vigorous-intensity activity per week or an equivalent combination, as well as ≥2 days of strength training per week. The guidelines also recommend that adults aged ≥65 years do multicomponent physical activity that includes balance training and aerobic and muscle strengthening activities. When an older adult or adult with arthritis cannot meet these recommendations because of health conditions, they need to be as physically active as their health and abilities allow.***

Maintaining a healthy weight, engaging in sufficient physical activity, and avoiding joint injury are important for prevention. The CDC Arthritis Management and Wellbeing Program recognizes community-based, arthritis-appropriate, evidence-based interventions (AAEBIs)††† to increase physical activity and chronic disease self-management among adults with arthritis. A recommendation from a health care provider can increase the likelihood that adults with arthritis attend

¶¶ Part C. https://health.gov/sites/default/files/2019-09/PAG_Advisory_Committee_Report.pdf

*** https://health.gov/sites/default/files/2019-09/Physical_Activity_Guidelines_2nd_edition.pdf

††† https://www.cdc.gov/arthritis/interventions/index.htm

Summary

What is already known about this topic?

Arthritis is a leading cause of activity limitations, disability, and chronic pain, and is associated with dispensed opioid prescriptions, substantially contributing to health care costs.

What is added by this report?

During 2019–2021, 21.2% of U.S. adults (53.2 million) reported diagnosed arthritis. Approximately one half (52.2%–62.4%) of adults aged ≥65 years with self-reported diagnosed dementia, chronic obstructive pulmonary disease, stroke, heart disease, diabetes, or cancer also had a reported diagnosis of arthritis.

What are the implications for public health practice?

These prevalence estimates can be used to guide public health policies and activities to increase equitable access to physical activity opportunities within the built environment and other community-based, arthritis-appropriate, evidence-based interventions.

education programs and engage in physical activity (*10*). CDC funds national and state organizations[§§§] to increase the availability of AAEBIs in the community, as well as to increase awareness among health care providers and health systems about the need to screen adults with arthritis for physical activity and facilitate the use of appropriate tools for physical activity screening, counseling, and referral to AAEBIs, with emphasis on reaching populations and communities with high prevalences of arthritis. Increasing equitable access to physical activity opportunities within the built environment and across settings (e.g., worksites, community organizations, and home), implementing AAEBIs as independent interventions or in combination with other chronic disease management programs (e.g., Diabetes Prevention Program), and adopting health care systems policies and actions facilitating health care provider screening, counseling, and referrals or linkages, are public health priorities to address arthritis and arthritis-attributable health outcomes.

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

Corresponding author: Elizabeth A. Fallon, EFallon@cdc.gov.

[1]Division of Population Health, National Center for Chronic Disease Prevention and Health Promotion, CDC; [2]American Society of Radiologic Technologists, Smyrna, Georgia; [3]Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee.

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High Influenza Incidence and Disease Severity Among Children and Adolescents Aged <18 Years — United States, 2022–23 Season

Elizabeth B. White, PhD[1,2]; Alissa O'Halloran, MSPH[1]; Devi Sundaresan, MPH[1]; Matthew Gilmer, MS[1,3]; Ryan Threlkel, MPH[1]; Arielle Colón, MPH[1]; Katie Tastad, PhD[1]; Shua J. Chai, MD[4,5]; Nisha B. Alden, MPH[6]; Kimberly Yousey-Hindes, MPH[7]; Kyle P. Openo, DrPH[8,9,10]; Patricia A. Ryan, MS[11]; Sue Kim, MPH[12]; Ruth Lynfield, MD[13]; Nancy Spina, MPH[14]; Brenda L. Tesini, MD[15]; Marc Martinez, BA[16]; Zachary Schmidt, MPH[17]; Melissa Sutton, MD[18]; H. Keipp Talbot, MD[19]; Mary Hill, MPH[20]; Matthew Biggerstaff, ScD[1]; Alicia Budd, MPH[1]; Shikha Garg, MD[1]; Carrie Reed, DSc[1]; A. Danielle Iuliano, PhD[1]; Catherine H. Bozio, PhD[1]

Abstract

During the 2022–23 influenza season, early increases in influenza activity, co-circulation of influenza with other respiratory viruses, and high influenza-associated hospitalization rates, particularly among children and adolescents, were observed. This report describes the 2022–23 influenza season among children and adolescents aged <18 years, including the seasonal severity assessment; estimates of U.S. influenza-associated medical visits, hospitalizations, and deaths; and characteristics of influenza-associated hospitalizations. The 2022–23 influenza season had high severity among children and adolescents compared with thresholds based on previous seasons' influenza-associated outpatient visits, hospitalization rates, and deaths. Nationally, the incidences of influenza-associated outpatient visits and hospitalization for the 2022–23 season were similar for children aged <5 years and higher for children and adolescents aged 5–17 years compared with previous seasons. Peak influenza-associated outpatient and hospitalization activity occurred in late November and early December. Among children and adolescents hospitalized with influenza during the 2022–23 season in hospitals participating in the Influenza Hospitalization Surveillance Network, a lower proportion were vaccinated (18.3%) compared with previous seasons (35.8%–41.8%). Early influenza circulation, before many children and adolescents had been vaccinated, might have contributed to the high hospitalization rates during the 2022–23 season. Among symptomatic hospitalized patients, receipt of influenza antiviral treatment (64.9%) was lower than during pre–COVID-19 pandemic seasons (80.8%–87.1%). CDC recommends that all persons aged ≥6 months without contraindications should receive the annual influenza vaccine, ideally by the end of October.

Introduction

During the 2022–23 season, influenza activity in the United States began in early October, earlier than in most previous seasons, and returned to pre–COVID-19 levels (*1*). In addition, high pediatric influenza hospitalization rates in the southeast (*2*), co-circulation of influenza virus with SARS-CoV-2 and respiratory syncytial virus (RSV), and a limited reduction in the availability of the influenza antiviral medication oseltamivir* were observed. Each year, CDC assesses seasonal severity by comparing current season's influenza activity with thresholds based on peak influenza activity in previous seasons (*3*) and estimates the numbers and rates of influenza-associated medical visits, hospitalizations, and deaths in the United States (*4*). This report describes the 2022–23 influenza season among children and adolescents, including seasonal severity, estimated incidence, and characteristics of hospitalized patients. This analysis focuses on the 2022–23 influenza season compared with 2016–17 through 2021–22, excluding 2020–21 (during the peak of the COVID-19 pandemic) when influenza activity was minimal.

Methods

CDC classifies each influenza season's severity using three indicators. First, the percentage of all outpatient visits for influenza-like illness (ILI), defined as fever plus cough or sore throat, is obtained from the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) (*5*). Second, rates of laboratory-confirmed influenza hospitalization† are estimated through the Influenza Hospitalization Surveillance Network (FluSurv-NET)§,¶ (*6*). Finally, the percentage of all deaths due

* https://emergency.cdc.gov/han/2022/han00482.asp

† A FluSurv-NET patient was defined as a person who 1) was a resident of the surveillance catchment area, 2) had a hospital admission during October 1–April 30 of a given season, and 3) received a positive influenza test result ≤14 days before or anytime during hospitalization.

§ FluSurv-NET is a population-based surveillance network for influenza-associated hospitalizations. The 2022–23 season included data from selected counties in 13 U.S. states, covering approximately 9% of the U.S. population: California, Colorado, Connecticut, Georgia, Maryland, Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

¶ Within hospitals participating in FluSurv-NET, influenza testing is performed at the clinician's discretion or based on facility-level practices. For the severity assessment and incidence estimates, influenza-associated hospitalization rates were adjusted for influenza testing practices and diagnostic test sensitivity to account for possible underdetection of influenza test–positive hospitalizations.

to influenza is calculated from National Vital Statistics System death registry data** (*5*). For each severity indicator, 50th, 90th, and 98th percentile intensity thresholds (ITs) are calculated from a distribution based on the geometric mean of peak weekly values in previous seasons†† (*3*,*7*). Seasonal severity is classified as low if at least two of the three indicators peak below IT_{50}, and as moderate, high, or very high if at least two of the three indicators peak above IT_{50}, IT_{90}, or IT_{98}, respectively.

The incidence of influenza-associated outpatient visits, hospitalizations, and deaths is estimated each season and is presented in this report as events per 100,000 population. Influenza-associated hospitalizations are estimated by applying the FluSurv-NET hospitalization rates, after adjustment for possible underdetection based on the probability of being tested and diagnostic test sensitivity,¶ to the U.S. population. To estimate influenza-associated outpatient visits, the ratio of outpatient illnesses to hospitalizations and the proportion of those with ILI who seek care are applied to the hospitalization estimates. To estimate influenza-associated deaths, the ratio of hospitalizations to deaths is applied to the hospitalization estimates (*4*,*8*). Pediatric rates are estimated for children aged <5 years and for children and adolescents aged 5–17 years.

Characteristics of influenza-associated hospitalizations, including influenza vaccination status,§§ were abstracted from medical charts by trained FluSurv-NET surveillance staff members using a standard case report form. Data were collected for all hospitalized children and adolescents across the 2016–17 through 2021–22 seasons and for an age-stratified sample during the 2022–23 season. Weighted proportions are reported overall and by age group (<5 and 5–17 years).

This analysis presents preliminary 2022–23 season data,¶¶ reported as of September 21, 2023, among children and adolescents, compared with data from 2016–17 through 2021–22 (excluding 2020–21). Analyses were conducted using R (version 4.1.2; R Foundation) and SAS (version 9.4; SAS Institute). This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.*** FluSurv-NET sites obtained human subjects and ethics approval from their respective state health department, academic partner, and participating hospital institutional review boards.

Results

For children and adolescents, the 2022–23 influenza season was classified as high severity, with the weekly percentage of outpatient visits for ILI, influenza-associated hospitalization rate, and percentage of deaths due to influenza all peaking between IT_{90} and IT_{98} (Figure 1). The percentage of outpatient visits that were for ILI and the rate of influenza-associated hospitalizations peaked in late November 2022, 3 weeks before the percentage of influenza deaths peaked; deaths remained high for 4 weeks in December 2022.

Nationally, point estimates of the rates of influenza-associated medical visits, hospitalization, and death estimated during the 2022–23 season were higher among children aged <5 years than among children and adolescents aged 5–17 years (Figure 2). However, among children and adolescents aged 5–17 years, rates of influenza-associated medical visits and hospitalizations were higher during 2022–23 than any season since 2016–17. Children aged <5 years had the second highest rates of influenza-associated medical visits (11,443 per 100,000) and hospitalization (119 per 100,000) in 2022–23 since the 2016–17 season. Rates of influenza-associated deaths in 2022–23 were low and consistent with previous seasons: 1.2 per 100,000 among children <5 and 0.5 per 100,000 among children and adolescents aged 5–17 years (Supplementary Figure, https://stacks.cdc.gov/view/cdc/133678).

During October 1, 2022–April 30, 2023, FluSurv-NET identified 2,762 influenza-associated hospitalizations in children and adolescents aged <18 years, 2,108 of which were sampled and had clinical data available. The median age was 5 years (IQR = 2–9 years), 57.4% were male, and 50.5% had an underlying condition, similar to recent seasons (Table). The most common underlying medical conditions were asthma, neurologic disorders, and obesity. Most (95.4%) infections were with influenza A virus; 80.2% of those subtyped were A(H3N2) and 19.6% were A(H1N1)pdm09. More than one half (57.1%) of the 2022–23 season's total pediatric hospitalizations occurred during October and November 2022, higher than the percentages occurring in October and November in

** The National Center for Health Statistics (NCHS) collects death certificate data from state vital statistics offices for all deaths occurring in the United States. Deaths included in the U.S. Influenza Surveillance System are those classified based on *International Classification of Diseases, Tenth Revision* (ICD-10) cause of death codes as associated with influenza, COVID-19, or pneumonia. Data are aggregated by the week of death occurrence. To avoid bias arising from COVID-19, counts of NCHS ICD-10–coded influenza deaths were used instead of pneumonia and influenza deaths to calculate mortality thresholds and assess severity.

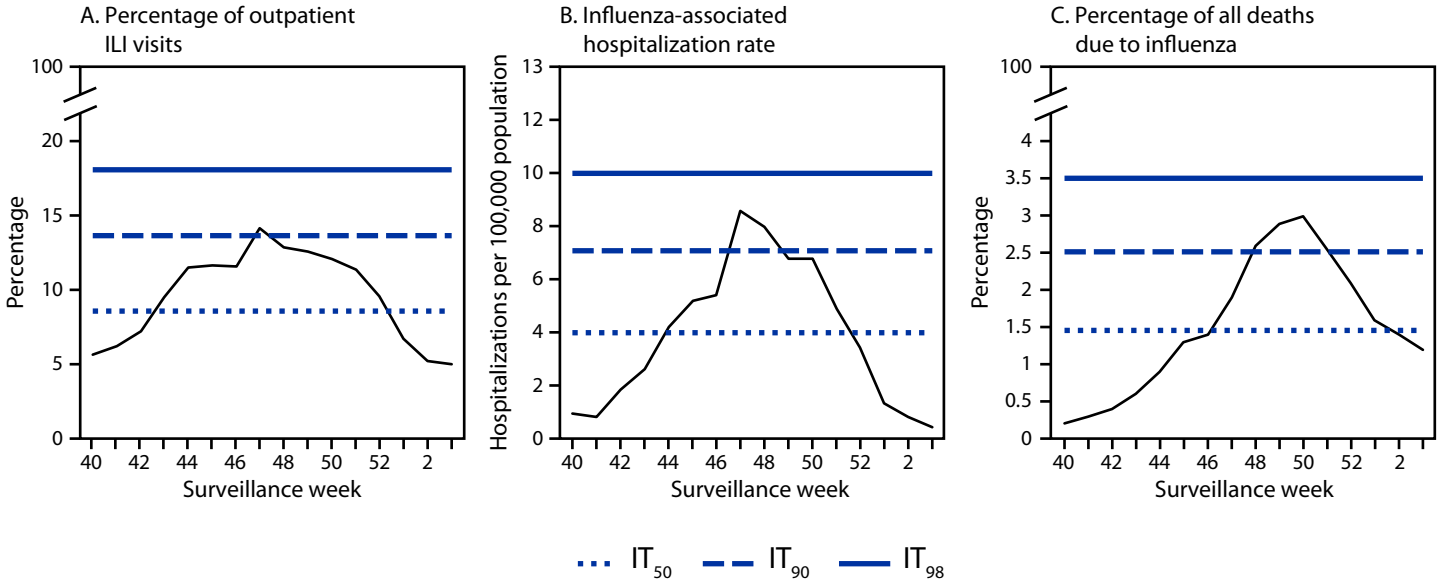
†† ITs for the percentage of outpatient visits for ILI were calculated using ILINet data from 2016–17 through 2021–22, excluding 2020–21. ITs for influenza-associated hospitalizations were calculated using FluSurv-NET data from 2006–07 through 2021–22, excluding 2011–12 and 2020–21. ITs for the percentage of deaths due to influenza were calculated using NCHS data from 2010–11 through 2021–22, excluding 2011–12 and 2020–21.

§§ A patient was considered to have received the current seasonal influenza vaccine if ≥1 dose was administered ≥14 days before receipt of a positive influenza test result. Ascertainment of vaccination status was performed using hospital records, state immunization registries, primary care provider surveys, and patient or proxy interview.

¶¶ FluSurv-NET data, as well as incidence and severity estimates, are current as of September 21, 2023. Incidence and severity analyses are finalized once data on testing practices are available, usually 2 years after the end of the season. Incidence estimates and severity assessment interpretations might change.

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

FIGURE 1. Percentage of outpatient visits for influenza-like illness (A), influenza-associated hospitalization rates (B), and percentage of all-cause deaths due to influenza (C) among children and adolescents aged <18 years — United States, 2022–23 influenza season*



Abbreviations: FluSurv-NET = Influenza Hospitalization Surveillance Network; ILI = influenza-like illness; ILINet = Outpatient Influenza-like Illness Surveillance Network; IT = intensity threshold; NCHS = National Center for Health Statistics.

* In 2022–23, ITs for the percentage of outpatient visits for ILI were calculated using ILINet data from 2016–17 through 2021–22, excluding 2020–21. ITs for influenza-associated hospitalizations were calculated using FluSurv-NET data from 2006–07 through 2021–22, excluding 2011–12 and 2020–21. ITs for the percentage of deaths due to influenza were calculated using NCHS data from 2010–11 through 2021–22, excluding 2011–12 and 2020–21.

the 2016–17 through 2021–22 seasons (1.6%–6.8%). Among hospitalized children and adolescents in 2022–23, 18.3% had received an influenza vaccine, compared with 35.8%–41.8% in 2016–17 through 2021–22. The proportion of pediatric patients with respiratory symptoms who received influenza antiviral treatment during their hospitalization in 2022–23 (64.9%) was similar to the proportion in 2021–22 (61.5%), but lower than that during pre–COVID-19 pandemic seasons (80.8%–87.1%). Among all pediatric hospitalizations, the proportions who were admitted to an intensive care unit (18.4%), who required invasive mechanical ventilation (4.7%), or who died in hospital (0.4%) were similar to the proportions during previous influenza seasons.

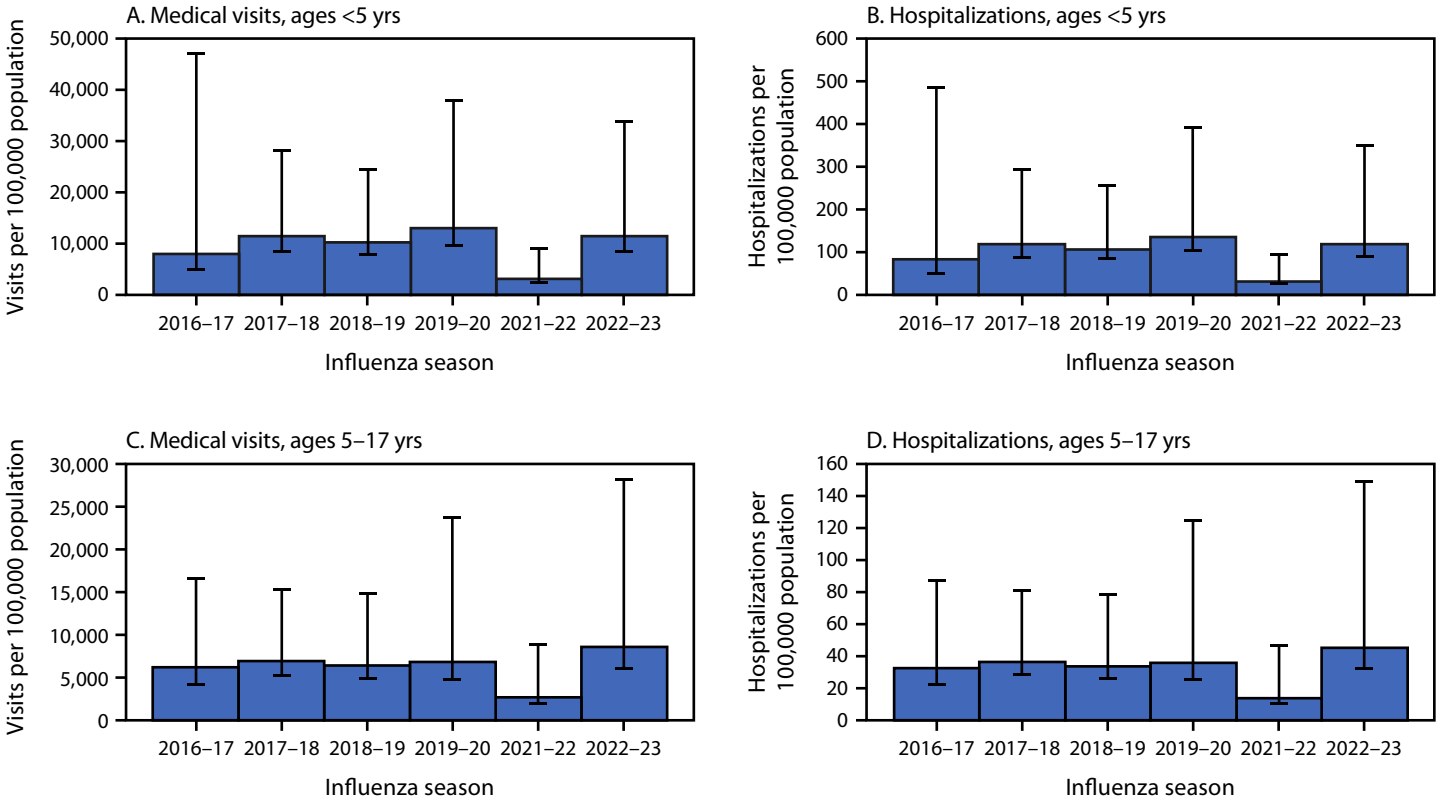
Discussion

The 2022–23 influenza season was classified as high severity among children and adolescents, the fourth season with that classification since the 2009 influenza A(H1N1) pandemic. Further, all three severity indicators not only surpassed intensity levels for high severity, but the peaks also occurred early in the season (late November and early December) (*1*). National estimates of the rates of influenza-associated medical visits and hospitalizations were higher than those during most previous seasons for children aged <5 years and children and adolescents aged 5–17 years. This high incidence strained health care systems, particularly with the co-circulation of SARS-CoV-2 and RSV.[†††]

Among children and adolescents hospitalized with influenza during 2022–23, a substantially lower proportion were vaccinated compared with previous seasons, which could be related to low vaccination coverage in the population, high vaccine effectiveness, or both. The National Immunization Survey[§§§] estimates that when pediatric influenza-associated hospitalization rates peaked during the week ending November 26, 2022, only 41.9% of children and adolescents aged 6 months–17 years nationwide had received their annual influenza vaccination (compared with 55.1% by the end of the season). Influenza vaccination coverage by the end of November was similar in 2022 and in 2021 (45.0%), but lower than in 2019 (51.9%) and 2020 (49.7%). Preliminary assessments have shown that the 2022–23 influenza vaccine provided moderately strong (68%) protection against pediatric hospitalization.[¶¶¶] The combination of low influenza vaccine coverage early in the season and unusually early influenza activity (57.1% of the season's pediatric hospitalizations occurred by the end of November) likely contributed to the high observed

[†††] https://emergency.cdc.gov/han/2022/pdf/CDC_HAN_479.pdf
[§§§] https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-dashboard.html (Accessed September 21, 2023).
[¶¶¶] https://www.cdc.gov/flu/vaccines-work/2022-2023.html

FIGURE 2. Influenza-associated medical visits* (A and C) and influenza-associated hospitalizations* (B and D) among children aged <5 years and children and adolescents aged 5–17 years — United States, 2016–17 through 2022–23 influenza seasons†



* With 95% credible intervals indicated by error bars.
† Excluding 2020–21.

rate of influenza-associated hospitalization, despite the moderately strong protection from the 2022–23 influenza vaccine. In addition, a lower proportion of symptomatic hospitalized patients in 2022–23 received influenza antiviral medication compared with that during pre–COVID-19 pandemic seasons. Taken together, these findings underscore the importance of children and adolescents receiving a seasonal influenza vaccination, ideally by the end of October (*9*), and prompt influenza antiviral treatment for those who are hospitalized.****

Limitations

The findings in this report are subject to at least five limitations. First, within FluSurv-NET, influenza testing was performed at the clinician's discretion or based on facility-level practices, which might affect the observed clinical epidemiology of influenza-associated hospitalizations. Second, severity assessment and incidence estimation adjustments for the frequency of influenza testing and other ratios were based on previous seasons' data and might not reflect current testing practices or health care–seeking behaviors. Third, FluSurv-NET catchment areas cover approximately 9.0% of the U.S. population; characteristics of children and adolescents hospitalized with influenza might not be generalizable to all pediatric hospitalizations in the United States. Fourth,

Summary

What is already known about this topic?

The 2022–23 influenza season began early, coinciding with circulation of other respiratory viruses. High hospitalization rates among children and adolescents were observed.

What is added by this report?

Among children and adolescents aged <18 years, 2022–23 was a high severity influenza season compared with thresholds based on previous seasons' data; influenza-associated medical visits and hospitalizations met or exceeded incidence in previous seasons.

What are the implications for public health practice?

CDC recommends that all persons aged ≥6 months without contraindications should receive the annual seasonal influenza vaccine, ideally by the end of October.

**** https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm#summary

TABLE. Characteristics, treatment, and outcomes among children and adolescents hospitalized with laboratory-confirmed influenza, compared with 2016–17 through 2021–22,* overall and by age group — FluSurv-NET, 2022–23 influenza season

Characteristic	Age group, yrs					
	<18		<5		5–17	
	Weighted %, 2022–23	Range of unweighted %, 2016–17 through 2021–22	Weighted %, 2022–23	Range of unweighted %, 2016–17 through 2021–22	Weighted %, 2022–23	Range of unweighted %, 2016–17 through 2021–22
Sex						
Female	42.6	42.7–45.1	43.8	41.4–45.2	41.5	41.8–47.3
Male	57.4	54.9–57.3	56.2	54.9–58.6	58.5	52.7–58.2
Race and ethnicity						
American Indian or Alaska Native, non-Hispanic	1.3	1.0–1.6	1.4	0.8–1.9	1.1	0.3–1.3
Asian or Pacific Islander, non-Hispanic	5.9	4.1–6.4	6.9	4.5–7.0	5.0	2.7–5.7
Black or African American, non-Hispanic	29.0	24.6–35.0	26.3	24.4–33.2	31.7	24.9–36.8
White, non-Hispanic	31.8	31.1–34.3	28.9	28.4–31.3	34.7	33.9–39.4
Hispanic or Latino	23.8	22.2–27.0	27.1	18.8–29.5	20.4	15.4–23.7
Multiple races, non-Hispanic	1.8	1.2–1.6	1.5	0.4–1.7	2.0	0.7–1.9
Influenza A	95.4	48.9–98.0	95.5	52.4–94.2	94.5	43.9–98.6
Influenza A subtype†						
A(H1N1)pdm09	19.6	0.5–95.5	18.5	1.1–96.7	20.8	0–93.4
A(H3N2)	80.2	4.5–99.5	81.4	3.3–98.9	79.1	6.6–100.0
Received seasonal influenza vaccine§						
Yes	18.3	35.8–41.8	18.1	38.2–45.8	18.4	32.1–40.6
No	67.1	43.7–57.8	67.0	38.7–56.1	67.3	47.0–59.8
Unknown	14.6	5.8–20.5	14.9	5.5–19.8	14.3	6.2–21.0
Underlying medical conditions						
Any underlying medical condition¶	50.5	47.5–58.1	33.9	34.1–39.9	67.1	66.4–76.2
Asthma	27.6	22.9–29.2	14.9	13.5–16.3	39.7	33.6–43.4
Chronic lung disease	4.8	6.4–8.2	2.6	4.5–6.8	6.9	6.6–9.5
Chronic metabolic disease	5.0	4.1–6.2	1.8	2.0–4.5	8.0	6.0–9.5
Diabetes	2.4	1.1–3.5	0.4	0.2–0.8	4.3	2.3–5.7
Cardiovascular disease	6.8	5.0–8.8	6.8	6.1–8.6	6.8	4.0–9.6
Blood disorder	6.5	5.2–10.3	3.3	2.7–7.5	9.6	6.7–13.0
Immunocompromising condition	7.7	6.3–9.9	4.6	3.1–5.6	10.5	8.7–14.9
Liver disease	0.5	0.6–1.5	0	0.4–1.0	1.0	0.9–2.1
Neurologic disorder	15.7	15.6–20.1	13.0	11.4–15.7	18.2	21.4–24.4
Obesity	14.4	13.3–15.5	10.3	8.9–11.3	16.4	15.1–18.2
Renal disease	1.5	1.7–2.3	0.7	0.4–1.6	2.4	2.2–3.9
Treatment and outcomes						
Received influenza antiviral treatment during hospitalization**	64.9	61.5–87.1	64.2	62.3–87.8	65.7	60.7–86.0
Admitted to intensive care unit	18.4	21.2–22.8	17.5	20.2–22.4	19.4	21.9–24.3
Invasive mechanical ventilation	4.7	4.7–5.7	3.7	4.0–5.3	5.6	4.5–6.3
Died in hospital	0.4	0–0.6	0.4	0–0.6	0.5	0–1.1

* Excluding 2020–21.
† Among 49% of Influenza A specimens that were subtyped.
§ Excluding children aged <6 months, who are not eligible to receive influenza vaccine.
¶ At least one of the following conditions: asthma, chronic lung disease, chronic metabolic disease (e.g., diabetes), blood disorder, cardiovascular disease, neurologic disorder, immunocompromising condition, obesity, renal disease, or liver disease.
** Restricted to patients with respiratory symptoms.

historical data used for the severity assessment might be a suboptimal comparison if recent influenza activity differs from that before the COVID-19 pandemic; classifications of being above or between threshold levels are qualitative and do not reflect statistical differences. Finally, comparisons of rates of influenza-associated outpatients visits, hospitalizations, and deaths across seasons based on point estimates are descriptive and intended to highlight trends, not statistical differences.

Implications for Public Health Practice

The 2022–23 influenza season was classified as high severity for children and adolescents based on influenza-associated outpatient visits, hospitalization rates, and deaths. Among hospitalized children and adolescents with influenza, receipt of influenza vaccine was lower than that during previous seasons, which might have been in part related to most influenza hospitalizations occurring earlier. The proportion of pediatric

hospitalizations treated with influenza antiviral medication was lower than in pre–COVID-19 pandemic seasons; prompt antiviral treatment is important for symptomatic patients hospitalized with influenza. All persons aged ≥6 months are recommended by CDC to receive the annual seasonal influenza vaccine, ideally by the end of October.

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Corresponding author: Elizabeth B. White, trj4@cdc.gov.

[1]Influenza Division, National Center for Immunization and Respiratory Diseases, CDC; [2]Epidemic Intelligence Service, CDC; [3]Goldbelt Professional Services, Chesapeake, Virginia; [4]California Emerging Infections Program, Oakland, California; [5]Office of Readiness and Response, CDC; [6]Colorado Department of Public Health & Environment; [7]Connecticut Emerging Infections Program, Yale School of Public Health, New Haven, Connecticut; [8]Georgia Emerging Infections Program, Georgia Department of Public Health, Atlanta, Georgia; [9]Emory University School of Medicine, Atlanta, Georgia; [10]Atlanta Veterans Affairs Medical Center, Decatur, Georgia; [11]Maryland Department of Health; [12]Michigan Department of Health & Human Services; [13]Minnesota Department of Health; [14]New York State Department of Health; [15]University of Rochester School of Medicine and Dentistry, Rochester, New York; [16]New Mexico Department of Health; [17]Ohio Department of Health; [18]Public Health Division, Oregon Health Authority, Portland, Oregon; [19]Vanderbilt University Medical Center, Nashville, Tennessee; [20]Salt Lake County Health Department, Salt Lake City, Utah.

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Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023

Katherine E. Fleming-Dutra, MD[1,*]; Jefferson M. Jones, MD[1,*]; Lauren E. Roper, MPH[1]; Mila M. Prill, MSPH[1]; Ismael R. Ortega-Sanchez, PhD[1]; Danielle L. Moulia, MPH[1]; Megan Wallace, DRPH[1]; Monica Godfrey, MPH[1]; Karen R. Broder, MD[2]; Naomi K. Tepper, MD[3]; Oliver Brooks, MD[4]; Pablo J. Sánchez, MD[5]; Camille N. Kotton, MD[6]; Barbara E. Mahon, MD[1]; Sarah S. Long, MD[7]; Meredith L. McMorrow, MD[1]

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Abstract

Respiratory syncytial virus (RSV) is the leading cause of hospitalization among U.S. infants. Nirsevimab (Bevfortus, Sanofi and AstraZeneca) is recommended to prevent RSV-associated lower respiratory tract infection (LRTI) in infants. In August 2023, the Food and Drug Administration (FDA) approved RSVpreF vaccine (Abrysvo, Pfizer Inc.) for pregnant persons as a single dose during 32–36 completed gestational weeks (i.e., 32 weeks and zero days' through 36 weeks and 6 days' gestation) to prevent RSV-associated lower respiratory tract disease in infants aged <6 months. Since October 2021, CDC's Advisory Committee on Immunization Practices (ACIP) RSV Vaccines Pediatric/Maternal Work Group has reviewed RSV epidemiology and evidence regarding safety, efficacy, and potential economic impact of pediatric and maternal RSV prevention products, including RSVpreF vaccine. On September 22, 2023, ACIP and CDC recommended RSVpreF vaccine using seasonal administration (i.e., during September through end of January in most of the continental United States) for pregnant persons as a one-time dose at 32–36 weeks' gestation for prevention of RSV-associated LRTI in infants aged <6 months. Either maternal RSVpreF vaccination during pregnancy or nirsevimab administration to the infant is recommended to prevent RSV-associated LRTI among infants, but both are not needed for most infants. All infants should be protected against RSV-associated LRTI through use of one of these products.

Introduction

In August 2023, the Food and Drug Administration (FDA) approved RSVpreF vaccine (Abrysvo, Pfizer Inc.) for pregnant persons to prevent RSV-associated lower respiratory tract disease and severe lower respiratory tract disease in infants aged <6 months (*1*,*2*). The Pfizer bivalent RSVpreF vaccine, which is the same formulation and dose approved for use in adults aged ≥60 years, contains stabilized prefusion F glycoproteins from RSV A and RSV B and is approved as a single 0.5 mL intramuscular dose administered during 32 through 36 weeks' gestation.

In clinical trials among pregnant persons at 24–36 weeks' gestation, more preterm births (<37 weeks' gestation) were observed among RSVpreF vaccine recipients than placebo recipients, although the differences were not statistically significant (*1*,*2*). Available data were insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF vaccine. FDA labeled the potential risk for preterm birth as a warning and approved RSVpreF vaccine for use in pregnant persons at 32–36 weeks' gestation to avoid the potential risk for preterm birth at <32 weeks' gestation, which is associated with increased risk for morbidity and mortality (*2*). More hypertensive disorders of pregnancy were observed among RSVpreF vaccine recipients compared with placebo recipients, although the differences were not statistically significant. FDA determined that, when RSVpreF is administered during 32–36 weeks' gestation, the benefit of vaccination in preventing RSV-associated LRTI in infants outweighed risks, including the potential risk for preterm birth and hypertensive disorders of pregnancy (*1*,*2*).

On August 3, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) and CDC recommended nirsevimab (Beyfortus, Sanofi and AstraZeneca), a long-acting monoclonal antibody for prevention of severe RSV disease, for infants aged <8 months who are born during or entering their first RSV season and for children aged 8–19 months at increased risk for severe RSV disease entering their second RSV season (*3*). On September 22, 2023, ACIP and CDC recommended RSVpreF vaccine for pregnant persons as a one-time dose during 32–36 completed weeks' gestation using seasonal administration (September–January in most of the continental United States) to prevent RSV-associated lower respiratory tract infection (LRTI) in infants. Either maternal RSVpreF vaccination during pregnancy or nirsevimab administration to the infant is recommended to prevent RSV-associated LRTI in infants, but both are not needed for most infants. This report describes new recommendations for the use of maternal RSVpreF during pregnancy

*These authors contributed equally to this report.

and updated clinical guidance regarding the use of nirsevimab and maternal RSVpreF vaccine. These recommendations will be updated as new evidence becomes available.

Epidemiology of RSV in U.S. Infants

RSV is a common cause of LRTI in U.S. infants, most of whom are infected with RSV during the first year of life (*4*,*5*). All infants are at risk for experiencing severe RSV disease. RSV is the leading cause of hospitalization among U.S. infants (*6*); 2% to 3% of young infants will be hospitalized for RSV disease (*7*–*9*). Approximately 58,000–80,000 RSV-associated hospitalizations and 100–300 RSV-associated deaths occur annually among U.S. children aged <5 years (*10*–*13*). An estimated 79% of children aged <2 years hospitalized with RSV had no underlying medical conditions (*7*). RSV-associated hospitalization rates are highest in infants aged <6 months, with hospitalization peaking at age 1 month, and then decreasing with increasing age (*7*).

Before the COVID-19 pandemic, RSV circulation consistently peaked during winter months in the continental United States, although the timing varied by geographic region (*14*); however, the COVID-19 pandemic disrupted RSV seasonality, with historically low RSV circulation during 2020–21 and early and prolonged circulation during 2021–22 (*14*). RSV circulation in 2022–23 began later than during the 2021–22 season but earlier than prepandemic seasons (*14*). RSV activity in August and September 2023 suggests that transmission patterns are returning to prepandemic seasonal RSV trends.[†]

Methods

Since October 2021, the ACIP RSV Vaccines Pediatric/Maternal Work Group (the Work Group) has met at least monthly to review evidence regarding RSV epidemiology and safety, efficacy, and potential economic impact of pediatric and maternal RSV prevention products, including RSVpreF vaccine. A systematic literature search was completed to review evidence regarding the efficacy and safety of maternal RSVpreF vaccination during pregnancy. The Work Group determined a priori outcomes that were critical or important to vaccine policy decisions.[§] Evidence of efficacy and safety were derived from multicountry trials that randomized pregnant persons to receive maternal RSVpreF vaccination or placebo during 24–36 weeks' gestation: a phase 2b trial[¶] with 581 pregnant persons (115 of whom received the phase 3 vaccine dose and formulation and 117 of whom received placebo) and a phase 3 trial[**] including 7,392 pregnant persons, randomized 1:1 to vaccine and placebo arms (*15*,*16*). The Work Group used the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach[††] to assess the certainty of evidence for outcomes related to maternal RSVpreF vaccination during pregnancy, rated on a scale of very low to high certainty. The Work Group employed the Evidence to Recommendation (EtR) Framework[§§] to guide its deliberations on recommendations for maternal RSVpreF vaccination during pregnancy and review of data on the public health problem, benefits and harms, value to the target population, acceptability to key stakeholders, feasibility, direct and indirect resource utilization, and equity.

Vaccine Efficacy and Safety

In the Pfizer phase 2b and 3 trials, maternal RSVpreF vaccination was administered during 24–36 weeks' gestation (*15*,*16*). For the GRADE assessment, data were included from phase 2b and 3 trials using the trial dosing interval of 24–36 weeks' gestation. Using all available data from the trial dosing interval provided increased power to detect potential benefits and harms. Additional analyses of efficacy and safety outcomes from participants who received vaccine or placebo during the approved dosing interval of 32–36 weeks' gestation were reviewed and are included as a supplement to the evidence included in GRADE (*2*,*9*). The details of the GRADE evidence profile and supporting evidence for the EtR Framework are available at https://www.cdc.gov/vaccines/acip/recs/grade/pfizer-RSVpreF-pregnant-people.html and https://www.cdc.gov/vaccines/acip/recs/grade/pfizer-RSVpreF-pregnant-people-etr.html.

Vaccine Efficacy

For the GRADE assessment of benefits, data on vaccine efficacy among infants from birth through 180 days of life were evaluated (*9*,*16*). Efficacy against medically attended RSV-associated LRTI was 51.3% among the full trial population (trial dosing interval of 24–36 weeks' gestation) and 57.3% when maternal RSVpreF vaccination was given during the approved dosing interval (32–36 weeks' gestation). Efficacy against hospitalization

[†] https://emergency.cdc.gov/han/2023/han00498.asp; https://www.cdc.gov/surveillance/nrevss/rsv/index.html

[§] Critical outcomes: medically attended RSV-associated LRTI in infants, hospitalization for RSV-associated LRTI in infants, serious adverse events in pregnant persons, serious adverse events in infants, and preterm birth (<37 weeks' gestation). Important outcomes: intensive care unit (ICU) admission from RSV hospitalization in infants, mechanical ventilation from RSV hospitalization in infants, RSV-associated death in infants, all-cause medically attended LRTI in infants, all-cause hospitalization for LRTI in infants, and reactogenicity (grade 3 or higher) in pregnant persons.

[¶] Trial conducted in Argentina, Chile, New Zealand, South Africa, and United States.

[**] Trial conducted in Argentina, Australia, Brazil, Canada, Chile, Denmark, Finland, The Gambia, Japan, Mexico, Netherlands, New Zealand, Philippines, South Africa, South Korea, Spain, Taiwan, and United States.

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

[§§] https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf

for RSV-associated LRTI was 56.8% during the full trial dosing interval and 48.2% during the approved dosing interval (Table 1).

Vaccine Safety

For the GRADE assessment of harms, results from the phase 2b and phase 3 trials were pooled[¶¶] (*9*,*16*). The overall evidence certainty using GRADE criteria was rated as very low, driven by the uncertainty in the critical harm outcome of preterm birth (<37 weeks' gestation).[***] ACIP judged the benefits of maternal RSVpreF vaccination at 32–36 weeks' gestation to outweigh the potential risks for preterm birth and hypertensive disorders of pregnancy.

The most common local and systemic adverse reactions were pain at the injection site, headache, muscle pain, and nausea.[†††] Although not statistically significant, in the full trial population more preterm births and hypertensive disorders of pregnancy (including preeclampsia) were observed in persons administered the vaccine rather than the placebo, and more infants whose mothers received the vaccine had low birthweight ≤5.5 lbs (≤2,500 g) and neonatal jaundice compared with infants whose mothers received the placebo.[§§§] Pregnant persons at increased risk for preterm delivery were excluded from the phase 2b and phase 3 trials. In the full trial population, preeclampsia occurred among 1.8% (95% CI = 1.4%–2.3%)

[¶¶] A serious adverse event is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability or incapacity, or is a congenital anomaly or birth defect. Serious adverse events in pregnant persons were collected ≤6 months after delivery. Serious adverse events in infants were collected ≤12 months after delivery. Reactogenicity events were collected ≤7 days following injection.

[***] The outcome of preterm birth was rated as very low certainty. Very serious concern for imprecision was noted because of the CI range containing estimates for which different policy decisions might be considered as well as not meeting optimum information requirements. In addition, serious concern for indirectness was present as 55% of participants in the phase 3 trial and 62% of participants in the phase 2b trial did not receive vaccine or placebo in the approved dosing interval (32–36 weeks' gestation). In the approved dosing interval, there is less opportunity for serious adverse events, including preterm birth, compared with the trial dosing interval (24–36 weeks' gestation).

[†††] In the phase 3 trial among 3,663 RSVpreF recipients and 3,638 to 3,639 placebo recipients, injection site pain was reported by 40.6% of RSVpreF and 10.1% of placebo recipients; headache by 31.0% of RSVpreF and 27.6% of placebo recipients; muscle pain by 26.5% of RSVpreF and 17.1% placebo recipients; and nausea by 20.0% of RSVpreF and 19.2% of placebo recipients.

[§§§] Low birthweight ≤5.5 lbs (≤2,500 g) and neonatal jaundice are more common among infants born preterm than among infants born at term. https://www.marchofdimes.org/find-support/topics/birth/premature-babies

TABLE 1. Effect estimates for the Pfizer maternal RSVpreF vaccine for the trial dosing interval and the approved dosing interval

Outcome	VE or RR (CI)*	
	Trial dosing interval (24–36 weeks' gestation)[†]	Approved dosing interval (32–36 weeks' gestation)[§]
Benefits (efficacy against outcome), (VE) assessed at age 0–180 days		
Medically attended RSV-associated LRTI in infants	51.3 (29.4 to 66.8)[¶]	57.3 (29.8 to 74.7)
Severe medically attended RSV-associated LRTI in infants**	69.4 (44.3 to 84.1)[¶]	76.5 (41.3 to 92.1)
Hospitalization for RSV-associated LRTI	56.8 (10.1 to 80.7)[††]	48.2 (–22.9 to 79.6)
Intensive care unit admission from RSV hospitalization in infants	42.9 (–124.8 to 87.7)	One event in the vaccine group Two events in the placebo group
Mechanical ventilation from RSV hospitalization in infants	100 (–9.1 to 100)	Zero events in the vaccine group Two events in the placebo group
All-cause medically attended LRTI in infants	2.5 (–17.9 to 19.4)[††]	7.3 (–15.7 to 25.7)
All-cause hospitalization for LRTI in infants	28.9 (–2.0 to 50.8)	34.7 (–18.8 to 64.9)
Harms (RR)[§§]		
Serious adverse events in pregnant persons[¶¶]	1.06 (0.95 to 1.17)	1.02 (0.87 to 1.20)
Reactogenicity (grade 3 or higher systemic reactions) in pregnant persons[***]	0.97 (0.72 to 1.31)	0.98 (0.62 to 1.54)
Serious adverse events in infants[†††]	1.01 (0.91 to 1.11)	1.04 (0.90 to 1.20)
Preterm birth (<37 weeks' gestational age)	1.20 (0.99 to 1.46)	1.15 (0.82 to 1.61)

Abbreviations: GRADE = Grading of Recommendations, Assessments, Development, and Evaluations; LRTI = lower respiratory tract infection; RR = relative risk; RSV = respiratory syncytial virus; VE = vaccine efficacy.

* 95% CI unless otherwise noted. When 95% CI not used, the CI was adjusted using the Bonferroni procedure, accounting for the primary endpoints' results.

† Vaccine efficacy was calculated as (1 – [P / (1 – P)]) x 100%, where P is the number of cases in the RSVpreF group divided by the total number of cases.

§ Vaccine efficacy was calculated as (1 – [hP / (1 – P)]) x 100%, where P is the number of cases in the RSVpreF group divided by the total number of cases and h is the ratio of number of participants at risk in the placebo group to the number of participants at risk in the RSVpreF group.

¶ 97.58% CI.

** Severe medically attended RSV-associated LRTI was a co-primary endpoint of the phase 3 clinical trial. This outcome was not included by CDC's Advisory Committee on Immunization Practices RSV Vaccines Pediatric/Maternal Work Group as an a priori GRADE outcome critical or important to vaccine policy decision making.

†† 99.17% CI.

§§ Pooled RR estimates were independently calculated using counts of events and participants in the phase 3 trial interim analysis and phase 2b trial among those who received the phase 3 vaccine formulation.

¶¶ Serious adverse events in pregnant persons were collected through 6 months after delivery.

*** Up to 7 days after injection. When selecting the a priori harm outcomes, CDC's Advisory Committee on Immunization Practices RSV Vaccines Pediatric/Maternal Work Group defined reactogenicity as both local and systemic reactions. These data only reflect systemic reactions.

††† Serious adverse events in infants were collected through 6 months after delivery.

of vaccine recipients and in 1.4% (95% CI = 1.1%–1.9%) of placebo recipients (*2*). Pregnancy-related serious adverse events overall (which include preeclampsia) occurred in 16.2% (95% CI = 15.1%–17.5%) of participants in the vaccine group and 15.2% (95% CI = 14.0%–16.4%) in the placebo group¶¶¶ (*2*).

The data reviewed by ACIP support that limiting vaccine administration to the approved dosing interval (32–36 weeks' gestation) reduces the potential risk for preterm birth and thereby, the potential for related complications compared with the trial dosing interval of 24–36 weeks' gestation. In the Pfizer phase 3 trial, using the full trial dosing interval, 5.7% of infants born to RSVpreF vaccine recipients were preterm compared with 4.7% of those born to placebo recipients (Table 2). In the full trial population, more than one half of preterm births occurred >30 days after vaccination (121 [60%] of 201 preterm births in the vaccine group and 98 [58%] of 169 preterm births in the placebo group), and most preterm births occurred at or after 33 weeks' gestation (194 [97%] of 201 preterm births in the vaccine group versus 161 [95%] of 169 preterm births in the placebo group). When the prevalence of preterm birth was assessed among phase 3 trial participants who received vaccine during the approved dosing interval (32–36 weeks' gestation), 4.2% of infants were born preterm in the vaccine group versus 3.7% in the placebo group. The majority of preterm births among participants who received vaccination during the approved dosing interval occurred at 36 weeks' gestation (49 [72%] of 68 preterm births in the vaccine group and 35 [59%] of 59 preterm births in the placebo group).

The Pfizer maternal RSVpreF vaccine is the same formulation and dose approved for use in adults aged ≥60 years. In clinical trials in adults aged ≥60 years for RSVpreF vaccine, three inflammatory neurologic events (two cases of Guillain-Barré syndrome, including one case of the Miller-Fisher variant, and one case of undifferentiated motor-sensory polyneuropathy) were reported within 42 days after vaccination among 20,255 investigational vaccine recipients aged ≥60 years, whereas no cases were observed among placebo recipients (*17*). No cases of Guillain-Barré syndrome or other inflammatory neurologic events were reported in the phase 2b or phase 3 trials among pregnant persons (*15*).

Economic Analysis

ACIP considered whether use of RSVpreF vaccine in pregnant persons is a reasonable and efficient allocation of resources. The societal incremental cost effectiveness ratio for RSVpreF vaccine, assuming year-round dosing and cost of $295 per dose, was $400,304 per quality-adjusted life year (QALY) saved. Assuming a pre–COVID-19 typical RSV seasonality in most of the continental United States, the societal incremental cost effectiveness ratio for administering RSVpreF to pregnant persons during September–January would be $167,280/QALY saved (*9*).

Recommendations for Use of RSVpreF Vaccine in Pregnant Persons

On September 22, 2023, ACIP and CDC recommended maternal Pfizer RSVpreF vaccination in pregnant persons as a one-time dose at 32 weeks and zero days'–36 weeks and 6 days' gestation using seasonal administration (meaning September–January in most of the continental United States) for prevention of RSV-associated LRTI in infants aged <6 months.**** These recommendations will be updated as new evidence becomes available.

¶¶¶ Among the full trial population, gestational hypertension occurred in 1.1% (95% CI = 0.8%–1.5%) of vaccine recipients and 1.0% (95% CI = 0.7%–1.4%) of placebo recipients. Hypertension occurred in 0.4% (95% CI = 0.2%–0.6%) of vaccine recipients and 0.2% (95% CI = 0.1%–0.4%) of placebo recipients.

**** On September 22, 2023, ACIP voted 11–1 in favor of the recommendation: maternal RSV vaccine is recommended for pregnant persons during 32–36 weeks' gestation, using seasonal administration, to prevent RSV-associated LRTI in infants.

TABLE 2. Preterm birth (<37 weeks' gestation), low birthweight and neonatal jaundice outcomes in Pfizer RSVpreF vaccine phase 3 trial for the trial dosing interval and the approved dosing interval*

	Group, trial dosing interval (24–36 wks' gestation)†				Group, approved dosing interval (32–36 wks' gestation)§			
	RSVpreF N = 3,568		Placebo N = 3,558		RSVpreF N = 1,628		Placebo N = 1,604	
Outcome	No.	% (95% CI)	No.	% (95% CI)	No.	% (95% CI)	No.	% (95% CI)
Preterm birth¶	202	5.7 (4.9–6.5)	169	4.7 (4.1–5.5)	68	4.2 (3.3–5.3)	59	3.7 (2.8–4.7)
Low birthweight**	181	5.1 (4.4–5.8)	155	4.4 (3.7–5.1)	67	4.1 (3.2–5.2)	54	3.4 (2.5–4.4)
Neonatal jaundice	257	7.2 (6.4–8.1)	240	6.7 (5.9–7.6)	102	6.3 (5.1–7.6)	107	6.7 (5.5–8.0)

* All differences between vaccine group and placebo group were not statistically significant, as determined by nonoverlapping CIs.
† https://www.fda.gov/media/168889/download?attachment
§ Data obtained directly from the sponsor during August, 2023.
¶ Less than 37 weeks' gestation.
** Less than ≤5.5 lbs (2,500 g).

Clinical Guidance

Seasonal Administration of RSVpreF Vaccine. Maternal RSVpreF vaccine should be administered to pregnant persons during September–January in most of the continental United States to target vaccine to pregnant persons whose infants will be in their first months of life, when protection from maternal vaccination would be at its highest, during the RSV season. Administering maternal RSVpreF vaccine starting in September (1–2 months before the anticipated start of the RSV season) and continuing through January (2–3 months before the anticipated end of the RSV season) will maximize cost-effectiveness and benefits. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, providers should follow state, local, or territorial guidance on timing of maternal RSVpreF vaccination.[††††]

Simultaneous Administration with Other Vaccines. In accordance with CDC's General Best Practices Guidelines for Immunization, maternal RSVpreF vaccine can be administered to pregnant persons with other recommended vaccines, such as tetanus, diphtheria, and pertussis (Tdap), influenza, and COVID-19 vaccines, without regard to timing, including simultaneous vaccination at different anatomic sites on the same day (*18*).

Additional Vaccine Doses in Subsequent Pregnancies. Currently, no data are available on either the efficacy of the first lifetime dose to protect infants born after subsequent pregnancies or the safety of additional doses given during subsequent pregnancies. Additional data are needed to determine whether additional seasonal doses during subsequent pregnancies are indicated, and ACIP might update recommendations in the future, as data become available.

Updated Clinical Guidance for Use of Nirsevimab and Maternal RSVpreF Vaccine

Recommendations for nirsevimab, a long-acting monoclonal antibody product, have been previously published (*3*). Either maternal RSVpreF vaccination during pregnancy at 32–36 weeks' gestation or nirsevimab immunization for infants aged <8 months who are born during or are entering their first RSV season is recommended to prevent RSV-associated LRTI in infants, but administration of both products is not needed for most infants. Providers who care for pregnant persons should discuss the relative advantages and disadvantages of both maternal RSVpreF vaccination and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab to the infant (Box) (*19*).

No data are available directly comparing the efficacy of nirsevimab and maternal RSVpreF vaccine in preventing RSV-associated LRTI in infants. Protection conferred through maternal vaccination will likely wane after 3 months, as has been observed in infants born to pregnant persons who have received influenza and COVID-19 vaccines (*16*,*20*,*21*). However, because maternal RSV vaccination at 32–36 weeks' gestation is recommended during only September–January in most of the continental United States, most infants of

BOX. Relative advantages and disadvantages of maternal RSVpreF vaccination and nirsevimab administration to infants to prevent respiratory syncytial virus lower respiratory tract infection in infants — United States, 2023

Maternal RSVpreF vaccination

Advantages

- Provides protection immediately after birth
- Might be more resistant to potential mutations in F protein*

Disadvantages

- Protection potentially reduced if fewer antibodies are produced or are transferred from pregnant person to baby (e.g., pregnant person is immunocompromised or infant born soon after vaccination)
- Potential risk for preterm birth and hypertensive disorders of pregnancy

Infant nirsevimab administration

Advantages

- Studies of antibody levels suggest that protection might wane more slowly than protection from the maternal RSV vaccine
- Assures direct receipt of antibodies rather than relying on transplacental transfer
- No risk for adverse pregnancy outcomes

Disadvantages

- Potentially limited availability during 2023–24 RSV season
- Requires infant injection

Abbreviation: RSV = respiratory syncytial virus.

* Maternal RSV vaccination results in a polyclonal immune response, which is expected to be more resistant to potential mutations in the RSV F protein than a monoclonal antibody product.

[††††] The timing of maternal RSVpreF vaccination might vary in these jurisdictions because the historic timing of RSV circulation differs from the rest of the United States. As maternal RSVpreF vaccination should start 1–2 months before the anticipated start of the RSV season and continue through 2–3 months before the anticipated end of the RSV season, it is not feasible to change maternal RSVpreF vaccination timing based on year-to-year variations in RSV circulation. Thus, in most of the continental United States, maternal RSVpreF vaccination should be given in September–January, regardless of year-to-year variation in RSV circulation.

vaccinated mothers will be born during an RSV season. Mothers of most infants born outside of RSV season (i.e., during April–September) will not have been vaccinated; therefore, nirsevimab is recommended for these infants at the onset of the RSV season if they are aged <8 months.

At least 14 days are likely needed after maternal vaccination for development and transplacental transfer of maternal antibodies to protect the infant (*16*,*22*); therefore, nirsevimab is recommended for infants born <14 days after maternal RSVpreF vaccination. The earliest an infant could be born and be considered protected by maternal receipt of RSVpreF vaccine at 32 weeks' gestation (the earliest recommended time for vaccination) would be at 34 gestational weeks. Therefore, nirsevimab is recommended for all infants born at <34 weeks' gestation.

Nirsevimab is recommended for infants aged <8 months born during or entering their first RSV season whose mother did not receive RSVpreF vaccine, whose mother's receipt of RSVpreF vaccine is unknown, or who were born <14 days after maternal vaccination. Nirsevimab is not needed for most infants aged <8 months whose mother received RSVpreF vaccine ≥14 days before birth. Nirsevimab may be considered for infants born to vaccinated mothers in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted. These situations include, but are not limited to, infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (e.g., persons living with HIV infection) (*23*); infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass (*24*) or extracorporeal membrane oxygenation; and infants with substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, or intensive care admission requiring oxygen at hospital discharge).

Infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season are recommended to receive nirsevimab regardless of maternal RSVpreF vaccination (*3*). Recommendations for timing of nirsevimab administration, coadministration of nirsevimab with routine childhood vaccines, reporting of adverse events, and recommendations for use for infants and children aged 8–19 months who are at increased risk for severe RSV disease and who are entering their second RSV season have been previously published and remain unchanged (*3*).

Summary

What is already known about this topic?

Nirsevimab is recommended in infants to prevent respiratory syncytial virus (RSV)-associated lower respiratory tract infection (LRTI). In August 2023, the Food and Drug Administration approved Pfizer RSV vaccine for pregnant persons at 32–36 weeks' gestation to prevent RSV-associated LRTI in infants aged <6 months.

What is added by this report?

On September 22, 2023, CDC's Advisory Committee on Immunization Practices recommended RSV vaccine for pregnant persons at 32–36 weeks' gestation using seasonal administration (meaning September–January in most of the United States) to prevent RSV-associated LRTI in infants aged <6 months.

What are the implications for public health practice?

CDC recommends protecting all infants against RSV-associated LRTI through use of either the maternal RSV vaccine or infant receipt of nirsevimab.

Precautions and Contraindications

As with all vaccines, RSV vaccination should be delayed for persons experiencing moderate or severe acute illness with or without fever (precaution). RSV vaccines are contraindicated for and should not be administered to persons with a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine.

Reporting of Vaccine Adverse Events

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

Future Research and Monitoring Priorities

CDC will monitor adverse events, including preterm birth, hypertensive disorders of pregnancy, and inflammatory neurologic events after RSVpreF vaccination in pregnant persons through VAERS and the Vaccine Safety Datalink (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html). Reactions and health impacts after RSVpreF vaccination will also be monitored through v-safe. According to FDA post-marketing requirements, the manufacturer will conduct post-marketing studies to assess preterm birth and hypertensive disorders of pregnancy, including preeclampsia (*25*).

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ACIP Pediatric/Maternal RSV Work Group

Chair: Sarah S. Long, Drexel University College of Medicine; ACIP Members: Oliver Brooks, Watts Healthcare Corporation; Camille N. Kotton, Harvard Medical School; Pablo J. Sánchez, The Research Institute at Nationwide Children's Hospital; Consultants: Kevin Ault, Western Michigan University; Carol Baker, McGovern Medical School, University of Texas Health Science Center; Helen Chu, University of Washington; Daniel Feikin, World Health Organization; Natasha Halasa, Vanderbilt University; Denise Jamieson, Emory University School of Public Health; Cody Meissner, Dartmouth Geisel School of Medicine; Liaison Representatives: Nicole Chaisson, American Academy of Family Physicians; Molly Howell, Association of Immunization Managers; Brenna L. Hughes, American College of Obstetricians and Gynecologists; James McAuley, Infectious Diseases Society of America; Sean T. O'Leary, American Academy of Pediatrics; Jennifer Schuster, Pediatric Infectious Diseases Society; Patsy Stinchfield, National Foundation for Infectious Diseases; Ex-officio Members: Judy Beeler, Food and Drug Administration; Yodit Belew, Food and Drug Administration; Matthew Clark, Indian Health Service; Terry Dalle-Tezze, Department of Health and Human Services, Health Resources and Services Administration; Nicholas Geagan, Food and Drug Administration; April Killikelly, Public Health Agency of Canada; Sonnie Kim, National Institute of Allergy and Infectious Diseases; Jessica Lee, Centers for Medicare & Medicaid Services; Lucia Lee, Food and Drug Administration; Valerie Marshall, Office of the Assistant Secretary for Health; Winnie Siu, Public Health Agency of Canada; Prabha Viswanathan, Food and Drug Administration; Robin Wisch, Food and Drug Administration; Rachel Zhang, Food and Drug Administration; CDC Leads: Katherine Fleming-Dutra, Jefferson Jones; CDC Contributors: Amadea Britton, Latifah Boyce, Karen R. Broder, Angela P. Campbell, Doug Campos-Outcalt, Melissa Coughlin, Nicole Dowling, Jarrett Gartin, Monica Godfrey, Kate Grusich, Aron Hall, Anne Hause, Fiona Havers, Demorah Hayes, Andrew Leidner, Ruth Link-Gelles, Elizabeth Greene, Jessica MacNeil, Meredith McMorrow, Michael Melgar, Sarah Meyer; Claire Midgley, Heidi Moline, Rebecca Morgan, Danielle Moulia, Neil Murthy, Christine Olson, Ismael Ortega-Sanchez, Manisha Patel, Pragna Patel, Monica Patton, Amanda Payne, Georgina Peacock, Jamison (Jamie) Pike, Derrell Powers, Mila Prill, Lauren Roper, Hannah Rosenblum, Heather Scobie, Andrea Sharma, David Shay, Tom Shimabukuro, Jordan Singleton, Tami Skoff, Chris Taylor, Naomi Tepper, Natalie Thornburg, Megan Wallace, Denis Wang, Melinda Wharton, Raigan Wheeler, Amber Winn, Patricia (Akpobome) Wodi.

Corresponding author: Katherine E. Fleming-Dutra, media@cdc.gov.

[1]Coronavirus and Other Respiratory Viruses Division, National Center for Immunization and Respiratory Diseases, CDC; [2]Immunization Safety Office, National Center for Emerging and Zoonotic Infectious Diseases, CDC; [3]Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC; [4]Watts Healthcare Corporation, Los Angeles, California; [5]The Research Institute at Nationwide Children's Hospital, The Ohio State University College of Medicine, Columbus, Ohio; [6]Harvard Medical School, Boston, Massachusetts; [7]Drexel University College of Medicine, Philadelphia, Pennsylvania.

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Notes from the Field

Locally Acquired Mosquito-Transmitted (Autochthonous) *Plasmodium falciparum* Malaria — National Capital Region, Maryland, August 2023

Monique Duwell, MD[1]; Timothy DeVita, MD[2]; David Torpey, PhD[3]; Jenny Chen[3]; Robert A. Myers, PhD[3]; Kimberly Mace, PhD[2]; Alison D. Ridpath, MD[2]; Wycliffe Odongo[2]; Brian H. Raphael, PhD[2]; Audrey Lenhart, PhD[2]; Jon Eric Tongren, PhD[2]; Stephen Stanley, MPH[1]; David Blythe, MD[1]

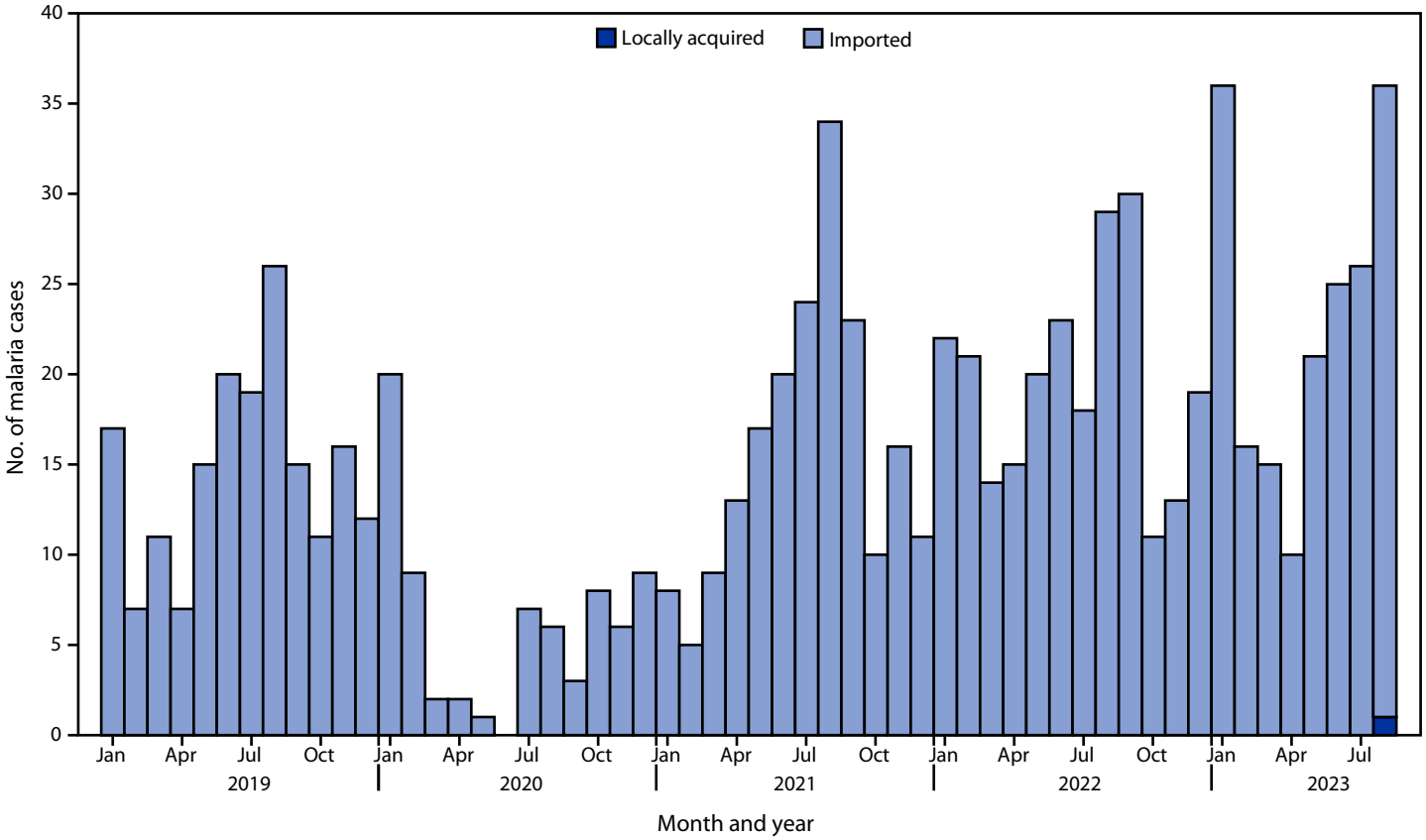
Although malaria was eliminated in the United States in the mid-1950s, approximately 2,000 malaria cases are imported into the United States from regions with endemic disease transmission each year, including approximately 200 in Maryland* (Figure) (*1*). *Anopheles* mosquito species that can transmit malaria exist in many areas in the United States (*2*). Locally acquired mosquito-transmitted (i.e., autochthonous) cases have not been identified since 2003; however, these imported cases represent a potential source of infection. In mid-2023, eight autochthonous malaria cases (*Plasmodium vivax*) were identified in Florida and Texas (*3*); in both states, the autochthonous cases occurred in the vicinity of an imported malaria case.

* https://health.maryland.gov/phpa/OIDEOR/CIDSOR/Pages/disease-conditions-count-rates.aspx

Investigation and Outcomes

On August 6, a previously healthy resident of the Maryland National Capital Region was evaluated for a 7-day history of fever, malaise, and myalgias. In the months preceding symptom onset, the patient reported daily walks near home and an occurrence of a tick attachment but no international travel, blood transfusions, intravenous drug use, or other potential exposures to bloodborne pathogens.

FIGURE. Malaria cases, by month and year* — Maryland, January 1, 2019–August 31, 2023†,§



* Based on symptom onset date or diagnosis date, if onset date is unknown.
† Data from 2023 are preliminary.
§ Cases of imported malaria are influenced by travel, and high numbers of cases occur during July–September and in January. The COVID-19 pandemic affected the numbers of cases imported into the United States.

Initial hospital laboratory testing revealed anemia, thrombocytopenia, hyperbilirubinemia, and intraerythrocytic parasites that raised concern for babesiosis or malaria. The patient was admitted to the hospital and, given the absence of international travel and the reported tick exposure, empiric treatment for presumed babesiosis[†] was initiated. On August 9, a thin blood smear obtained at the time of admission was reported to show *Plasmodium falciparum* malaria with 3.2% parasitemia. Blood smear telediagnosis at CDC could not conclusively differentiate between malaria and babesia parasites from the images provided. In accordance with Maryland law, the smear and whole blood specimen were also submitted to the Maryland Department of Health (MDH) public health laboratory. Because the patient had no reported international travel and did have a history of tick exposure, as well as documented clinical improvement (reduction in parasitemia to 0.2%), the patient was discharged on August 10 with instructions to complete a 7-day babesiosis treatment course.[§]

On August 15, testing at MDH public health laboratory identified *P. falciparum* using smear microscopy, the BinaxNOW Malaria rapid diagnostic test (Abbott), and 18S rRNA polymerase chain reaction (PCR). On August 18, CDC confirmed *P. falciparum* infection by 18S rRNA PCR; the *Babesia spp.* PCR test result was negative. Considering these findings, after completion of the babesiosis treatment, the patient received a course of artemether-lumefantrine.

MDH and the local health department first confirmed that all household members were asymptomatic and that the patient had not traveled internationally recently. Next, a public notice was issued, urging residents to avoid mosquitoes and to seek medical attention for malaria symptoms; Maryland clinicians and public health professionals were alerted to the case and provided recommendations to prioritize timely diagnosis, treatment, and public health reporting. To identify other potential malaria cases in local hospitals, active case finding was implemented. In coordination with the Maryland Department of Agriculture, mosquito surveillance was conducted by trapping *Anopheles* mosquitoes[¶] and applying multiple rounds of larvicide and adulticide. No geographically proximate malaria cases (i.e., within <5 miles [<8 kms] of the patient's residence) during the preceding month were identified, and although *Anopheles* mosquitoes were present near the patient's home, none of the 21 *Anopheles* mosquitoes tested at CDC was positive for *P. falciparum*. The source of the patient's exposure remains unknown. To date, no additional autochthonous malaria cases of any parasite species have been identified in Maryland. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[**]

Preliminary Conclusions and Actions

This case underscores common challenges in malaria diagnosis, including differentiation from babesiosis, and potential for sporadic autochthonous malaria cases in the United States and highlights the need for coordinated efforts among public health officials, clinicians, laboratories, and the public to prevent, detect, and respond to such cases. Proposed interventions include ensuring that travelers to regions where malaria is endemic take appropriate malaria chemoprophylaxis to reduce both personal and community risk. Improving capacity for timely malaria diagnosis through blood smear examination, rapid diagnostic test availability and use, PCR for species confirmation,[††] and early request for CDC support are also recommended.[§§]

[†] Atovaquone (750 mg twice daily), azithromycin (500 mg twice daily), and doxycycline (100 mg twice daily) for 7 days.

[§] Atovoquone is a component of Malarone (atovoquone and proguanil), which is used for *P. falciparum* prophylaxis and treatment, and doxycycline is used for *P. falciparum* prophylaxis.

[¶] *Anopheles quadrimaculatus, A. punctipennis,* and *A. crucians/bradleyi.*

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

[††] The Council of State and Territorial Epidemiologists recommends malaria PCR testing to confirm *Plasmodium* and species.

[§§] CDC provides clinical assistance through the Malaria Hotline at 770-488-7788 or 855-856-4713 (toll-free) Monday–Friday, 9 a.m.–5 p.m. EST. After hours, on weekends, and on federal holidays, health care providers can call 770-488-7100 and ask to speak with the malaria clinician on call and diagnostic laboratory support.

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Corresponding author: Monique Duwell, monique.duwell@maryland.gov.

[1]Infectious Disease and Epidemiology and Outbreak Response Bureau, Maryland Department of Health; [2]Division of Parasitic Diseases and Malaria, Global Health Center, CDC; [3]Maryland Department of Health Laboratories Administration.

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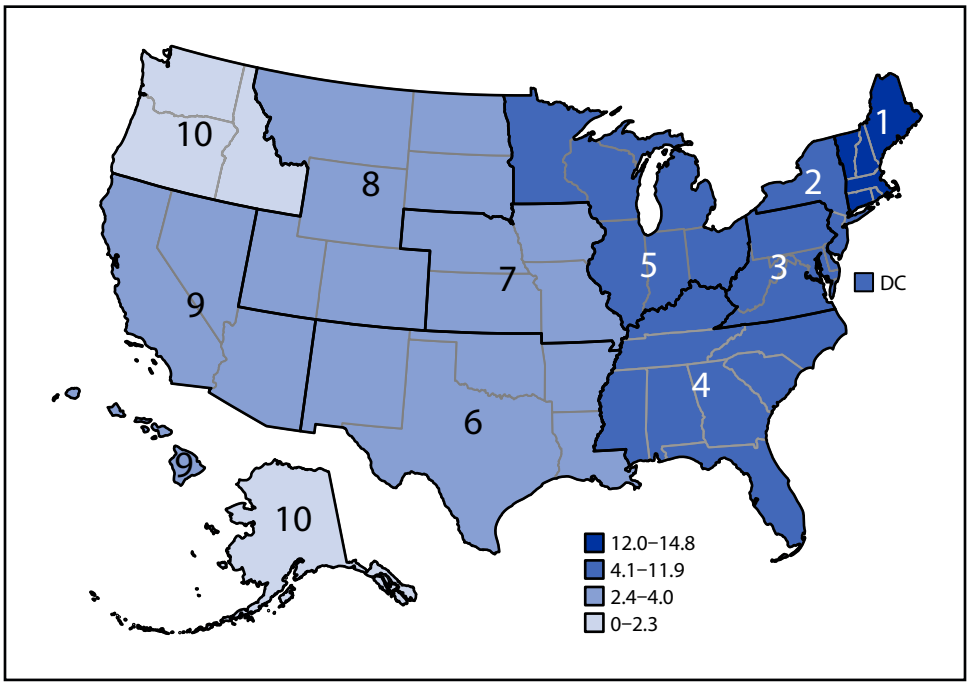
QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Age-Adjusted Drug Overdose Death Rates* Involving Cocaine,† by Region§ — National Vital Statistics System, United States, 2021



Abbreviations: DC = District of Columbia; HHS = U.S. Department of Health and Human Services.

* Deaths per 100,000 standard population. Age-adjusted drug overdose death rates were calculated using the direct method and the 2000 U.S. population. In 2021, the U.S. age-adjusted drug overdose death rate involving cocaine was 7.3 deaths per 100,000 standard population.

† Drug overdose deaths involving cocaine were identified using *International Classification of Diseases, Tenth Revision* underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14 with a multiple cause-of-death code T40.5.

§ HHS regions; rates for regions 2 and 9 do not include the rates for any territories and associated states (Region 2 = New York and New Jersey; Region 9 = Arizona, California, Hawaii, and Nevada). https://www.hhs.gov/about/agencies/iea/regional-offices/index.html

In 2021, the U.S. age-adjusted drug overdose death rate involving cocaine was 7.3 deaths per 100,000 standard population. Rates were higher in HHS regions 1–5 (mostly areas east of the Mississippi River) and were lower in regions 6–10 (areas west of the Mississippi River). The highest rate was in Region 1 (14.8), which includes Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. The lowest rate was in Region 10 (2.3), which includes Alaska, Idaho, Oregon, and Washington.

Source: National Center for Health Statistics, National Vital Statistics System, Mortality Data, 2021. https://www.cdc.gov/nchs/nvss/deaths.htm

Reported by: Matthew F. Garnett, MPH, Mgarnett@cdc.gov; Merianne R. Spencer, MPH.

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