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# Contact Lens Health Week — August 19–23, 2019

August 19–23, 2019, marks the sixth annual Contact Lens Health Week. In collaboration with partners from clinical, public health, industry, and regulatory sectors, CDC is promoting healthy contact lens wear and care practices to reduce the risk for eye infections among the approximately 45 million persons in the United States who wear contact lenses. Studies conducted following outbreaks of rare but serious eye infections in the United States have found that these infections occur most frequently in contact lens wearers who do not take proper care of their contact lenses, indicating a need to promote safer wear and care (1).

A report in this issue of MMWR reviews reported provision and receipt of contact lens wear and care recommendations among providers and patients in the United States (2). One third of lens wearers recalled never hearing any lens care recommendations. Most eye care providers reported sharing recommendations always or most of the time. Developing effective health communication messages can help eye care providers communicate with their patients. Practicing proper contact lens hygiene and regularly visiting an eye care provider are important actions for keeping contact lens wearers' eves healthy.

Additional information on Contact Lens Health Week and the proper wear and care of contact lenses is available at https://www.cdc.gov/contactlenses.

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- 2. Konne NM, Collier SA, Spangler J, Cope JR. Healthy contact lens behaviors communicated by eye care providers and recalled by patients-United States, 2018. MMWR Morb Mortal Wkly Rep 2019;68:693-7.

# **Healthy Contact Lens Behaviors Communicated by Eye Care Providers** and Recalled by Patients — United States, 2018

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An estimated 45 million U.S. residents enjoy the benefits of contact lens wear, but many of them might be at increased risk for complications stemming from improper wear and care behaviors (1). One of the most serious complications of contact lens wear is a corneal infection known as microbial keratitis, which can sometimes result in reduced vision or blindness (2). In 2014, 50% of contact lens wearers reported ever sleeping in contact lenses, and 55% reported topping off\* their contact lens solutions (3), which put them at greater risk for a contact lens-related eye infection (2,4). Data on communication between eye care providers and contact lens

\*Adding new solution to existing solution in the contact lens case instead of emptying and cleaning the case before adding new solution.

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wearers on contact lens wear and care recommendations are limited. Two surveys were conducted to better understand and assess contact lens education about nine recommendations: the first assessed contact lens wearer experiences regarding recommendations received from eye care providers during their most recent appointment; the second evaluated providerreported practices for communicating contact lens wear and care recommendations to their patients. One third (32.9%) of contact lens wearers aged  $\geq 18$  years recalled never hearing any lens wear and care recommendations. Fewer than half (47.9%)recalled hearing their provider recommend not sleeping in lenses at their last visit, and 19.8% recalled being told to avoid topping off their contact lens solution. A majority of providers reported sharing recommendations always or most of the time at initial visits, regular checkups, and complication-related visits. Providers reported sharing nearly all recommendations more frequently at initial and complication-related visits than at regular checkups. Of the nine recommendations for safe contact lens wear and care, eye care providers at regular checkups most often recommend complying with the recommended lens replacement schedules (85% of regular visits), not sleeping in lenses (79.0% of regular visits), and not topping off solutions (64.4% of regular visits). Eye care providers play an important role in the health of their contact lens-wearing patients and can share health communication messages with their patients to help educate them about healthy wear and

care habits. These findings can assist in the creation of health communication messages to help encourage eye care providers to communicate more effectively with their patients.

The Porter Novelli 2018 summer HealthStyles survey, an online survey, was used to estimate the number of contact lens wearers who reported receiving contact lens wear and care recommendations from their eye care provider during their most recent visit. The following nine recommendations were evaluated: 1) avoid sleeping overnight or napping in lenses, 2) wash and dry hands before inserting or removing lenses, 3) replace lenses as often as recommended, 4) replace lens case at least once every 3 months, 5) avoid storing lenses in water, 6) avoid rinsing lenses in water, 7) avoid topping off solution, 8) avoid swimming in lenses, and 9) avoid showering in lenses. The Internet survey included 4,088 participants<sup>†</sup> who are part of market research firm GfK's Knowledge Panel. Panel members are recruited using address-based probability sampling methods and provided with Internet access and a computer if needed. Statistical weighting was employed to make the panel representative of the U.S. population by race, ethnicity, sex, age, household income, household size, education level, census region, metropolitan status, and Internet access before joining the panel. Respondents received 5,000 cash-equivalent reward points worth approximately \$5.

<sup>†</sup>Porter Novelli Public Services. Summer HealthStyles 2018 methodology; Washington, DC.

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To describe provider health communication practices, 1,100 randomly selected (based on geographic region of current practice) licensed, practicing eye care providers were surveyed. The survey was piloted by members of the American Optometric Association's Contact Lens and Corneal section, and changes were made based on feedback from members. Invitations to participate in the survey were e-mailed by the American Optometric Association, primarily to optometrists working in private practice settings for  $\geq 5$  years. Four reminder e-mails were sent, one every other week, and the survey was officially closed after 2 months. Of the 1,100 providers who were sent the survey, 365 (33%) responded. Survey questions assessed how often providers mentioned the same nine contact lens wear and care recommendations to their patients at initial contact lens fittings, during regular checkups and annual visits, and at visits when patients are seen for contact lens-related complications.

Frequencies for both surveys were calculated using SAS (version 9.4; SAS Institute) with complex sample survey procedures when appropriate. To protect participant confidentiality, no individual identifiers were included in the data set received by investigators. As a result, analyses of data from the 2018 HealthStyles Fall survey were declared exempt by CDC's institutional review board. Because no interaction or intervention with human subjects occurred by U.S. Department of Health and Human Services researchers for the provider survey and no personally identifiable information was used, collected, or transmitted during the course of this analysis of previously collected data, this analysis was not considered human subjects research<sup>§</sup> requiring review by CDC's institutional review board.

The majority of contact lens-wearing patients surveyed reported wearing soft contact lenses, were non-Hispanic (85.8%), white (77.7%), and female (59.2%) (Table 1). One third (32.9%) of contact lens wearers recalled never hearing any lens wear and care recommendations (Table 2). Fewer than half of patients recalled hearing each of the nine recommendations. During their most recent visit, patients most frequently recalled hearing their provider recommend not sleeping in lenses (47.9%), washing and drying hands before inserting or removing lenses (46.9%), and complying with lens replacement schedules (41.6%), and least frequently recalled being told to avoid swimming (12.4%) and showering in their lenses (8.3%). A majority (54.7%–97.4%) of providers reported sharing all nine messages always or most of the time at initial visits, regular checkups, and complication-related visits (Table 2). Providers reported sharing messages more frequently at initial visits and

TABLE 1. Characteristics	of contact lens-wearing patients, (N = 733) —
Porter Novelli HealthSty	/les Internet survey, United States, 2018

Characteristic	Weighted no. (%*)		
Type of contacts worn			
Soft	629 (85.8)		
Rigid/Gas permeable	55 (7.5)		
Orthokeratology	5 (0.7)		
Other <sup>†</sup>	50 (6.9)		
Gender			
Female	434 (59.2)		
Male	299 (40.8)		
Age group (yrs)			
18–24	116 (15.8)		
25–34	177 (24.2)		
35–44	174 (23.7)		
45–54	127 (17.4)		
55–64	88 (12.0)		
65–74	42 (5.7)		
≥75	9 (1.3)		
Race			
White	569 (77.7)		
Black/African-American	72 (9.9)		
Asian	68 (9.2)		
American Indian or Alaskan Native	7 (0.9)		
Hawaiian/Pacific Islander	3 (0.4)		
Multiracial	14 (2)		
Hispanic ethnicity			
Hispanic	108 (14.8)		
Non-Hispanic	624 (85.2)		
Education			
Less than high school	34 (4.6)		
High school	188 (25.7)		
Some college	194 (26.4)		
Bachelor's degree or higher	317 (43.3)		

\* Some categories do not sum to 100 because of rounding.

<sup>†</sup> A type of contact lens not included among the survey choices.

complication-related visits than at regular checkups. At regular visits, of the nine recommendations, eye care providers reported most often recommending complying with lens replacement schedules (85% of regular visits), washing and drying hands before inserting or removing lenses (79%), and not sleeping in lenses (79%), and least often recommended not swimming (63%) or showering in lenses (55%).

# Discussion

Eye care providers report mentioning nine contact lens wear and care recommendations to patients frequently, but patients recall hearing these messages less often. This discrepancy in provider-patient communication has been reported previously in many medical specialties, despite the identification of patient communication as an important physician competency, and an important component of medical education curricula for physicians in the United States (5). Effective communication between physicians and patients can have a positive impact on health (6). Studies demonstrate evidence of positive associations between physician communication behaviors and

<sup>§</sup>As defined in 45 CFR part 46. https://www.hhs.gov/ohrp/regulations-andpolicy/regulations/45-cfr-46/index.html.

TABLE 2. Percentage of contact lens-wearing patients (N = 733) who recalled hearing their eye care provider mention the recommendations,<sup>\*</sup> and percentage of eye care providers (N = 365) who reported making contact lens wear and care recommendations to their contact lens-wearing patients always or most of the time<sup>†</sup> — United States, 2018

	Patients % (95% Cl)	Providers % (95% Cl)		
Recommendation	Most recent visit	Initial fittings	Regular checkups	Contact lens-related complication visit
Avoid sleeping overnight or napping in lenses	47.9 (43.6–52.2)	96.8 (94.8–98.8)	79.0 (74.5–83.6)	97.4 (95.6–99.2)
Wash and dry hands before inserting or removing lenses	46.9 (42.6-51.2)	97.1 (95.2–99.0)	79.0 (74.4–83.5)	92.2 (89.1–95.2)
Replace lenses as often as recommended	41.6 (37.4-45.7)	96.1 (94–98.3)	85.1 (81.1–89.1)	97.4 (95.6–99.2)
Replace lens case at least every 3 months	23.8 (20.1-27.5)	83.2 (79.0-87.4)	62.6 (57.2–68.0)	86.0 (82.0-89.9)
Avoid storing lenses in water	21.0 (17.4-24.7)	92.6 (89.6–95.5)	70.4 (65.2–75.5)	86.3 (82.5-90.2)
Avoid rinsing lenses in water	19.8 (16.3-23.4)	90.3 (87.0-93.6)	70.7 (65.6-75.8)	86.9 (83.1-90.7)
Avoid "topping off" solution	19.8 (16.3-23.3)	91.3 (88.1–94.4)	64.4 (59.0-69.8)	89.9 (86.5–93.3)
Avoid swimming in lenses	12.4 (9.4–15.4)	83.9 (79.8-88.0)	63.0 (57.6-68.4)	81.7 (77.3-86.1)
Avoid showering in lenses	8.3 (5.8-10.8)	73.2 (68.3-78.2)	54.7 (49.1-60.3)	77.8 (73.1-82.5)
Heard or stated all of recommendations	3.6 (1.7-5.4)	57.1 (51.9-62.2)	39.6 (34.5-44.7)	61.5 (56.5–66.5)
Heard or stated none of recommendations	32.9 (28.8–36.9)	1.4 (0.20–2.6)	1.4 (0.20–2.6)	0.60 (0.00–1.3)

**Abbreviation:** CI = confidence interval.

\* Based on responses to Porter Novelli HealthStyles survey.

<sup>†</sup> Based on responses to American Optometric Association survey.

positive patient outcomes (5,7). Patients continue to report that many of their informational needs remain unmet during a doctor's visit (6). The gap between what providers say and what patients hear might be a factor in the large proportion of contact lens wearers reporting behaviors that put them at risk for a contact lens-related eye infection (1,3). Addressing this gap might improve contact lens wear and care practices.

These survey results show that eye care providers most often recommend complying with the recommended lens replacement schedules. However, other risk behaviors are more common or pose a greater risk for contact lens-related eye infections. For example, sleeping in contact lenses and topping off lens solution both increase the risk for contact lens-related eye infections approximately sixfold (2,4), and both behaviors have been reported by a majority of lens wearers (3). Storing lenses in water increases the risk for infection up to sixteenfold because microorganisms living in water can be transferred to the eye (8). Even household tap water, although treated to be safe for drinking, is not sterile and contains microorganisms that can contaminate lens cases and contact lenses and cause eye infections. Given the evidence showing that sleeping in lenses, topping off solution, and exposing lenses directly to water are risky behaviors and the limited time allowed for a visit with an eye care provider, providers might consider prioritizing these recommendations over others during all types of interactions with contact lens wearers. To alleviate the time constraints of a typical visit, providers can also provide communication materials, like CDC's tear off pads, for their patients to take home.

The findings in this report are subject to at least three limitations. First, the results are taken from two different surveys;

# Summary

## What is already known about this topic?

Most of the 45 million contact lens wearers in the United States practice at least some behaviors that put them at risk for serious eye infections.

#### What is added by this report?

Surveys of contact lens wearers and eye care providers were conducted in 2018. One third of lens wearers recalled never hearing any lens care recommendations. Most eye care providers reported sharing recommendations always or most of the time.

# What are the implications for public health practice?

Eye care providers play an important role in the health of their contact lens-wearing patients and can share health communication messages with their patients to help educate them about healthy wear and care habits.

therefore, the patients surveyed are likely not the patients of the surveyed eye care providers, and direct connections cannot be established. Second, the provider survey had a response rate of 33%, which, although not necessarily unexpected for a survey of practicing providers, might limit the representativeness of the survey and might introduce bias. Systematic differences between eye care providers who completed the survey and those who did not could not be assessed. Finally, although the results of the two surveys demonstrate an apparent gap in patientprovider communications, they do not identify other variables that might explain the reason for this gap. Respondents to the patient survey were not asked to describe their health literacy, which is an equally important factor and component of adherence to care recommendations. In the United States, 12% of adults have proficient health literacy, which suggests that nearly 90% of U.S. residents might find it challenging to obtain, process, and understand basic health information and services needed to make decisions about their health (9). Therefore, identifying ways to promote healthy contact lens practices among patients with low health literacy is challenging.

Previous studies have identified health behaviors that can reduce the risk for contact lens-associated eye infections (e.g., not sleeping in lenses, not exposing lenses to water, and using fresh disinfecting solution to store lenses) (2,4). Although eye care providers report mentioning these behaviors to their patients frequently, patients report hearing the messages less frequently, suggesting that new communication strategies might be needed. CDC has developed health communication materials<sup>9</sup> that target contact lens wearers and eye care providers. Eye care providers can obtain these materials to share with their patients to help educate them about healthy wear and care habits. Eye care provider communication techniques to inform patients of health risks that are easy to understand, specific, use repetition, minimize jargon, and checked for patient's understanding of the information presented are most likely to be effective (5). Improving communications between providers and patients could help contact lens wearers understand proper eye care (10).

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# Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices

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# Introduction

Vaccination against human papillomavirus (HPV) is recommended to prevent new HPV infections and HPV-associated diseases, including some cancers. The Advisory Committee on Immunization Practices (ACIP)\* routinely recommends HPV vaccination at age 11 or 12 years; vaccination can be given starting at age 9 years. Catch-up vaccination has been recommended since 2006 for females through age 26 years, and since 2011 for males through age 21 years and certain special populations through age 26 years. This report updates ACIP catch-up HPV vaccination recommendations and guidance published in 2014, 2015, and 2016 (1-3). Routine recommendations for vaccination of adolescents have not changed. In June 2019, ACIP recommended catch-up HPV vaccination for all persons through age 26 years. ACIP did not recommend catch-up vaccination for all adults aged 27 through 45 years, but recognized that some persons who are not adequately vaccinated might be at risk for new HPV infection and might benefit from vaccination in this age range; therefore, ACIP recommended shared clinical decision-making regarding potential HPV vaccination for these persons.

# Background

HPV is a common sexually transmitted infection, with HPV acquisition generally occurring soon after first sexual activity (1). Most HPV infections are transient and asymptomatic. Persistent infections with high-risk (oncogenic) HPV types can lead to development of cervical, anal, penile, vaginal, vulvar, and oropharyngeal cancers, usually after several decades (1). Most

new HPV infections occur in adolescents and young adults. Although most sexually active adults have been exposed to HPV (4), new infections can occur with a new sex partner (5).

Three prophylactic HPV vaccines are licensed for use in the United States: 9-valent (9vHPV, Gardasil 9, Merck), quadrivalent (4vHPV, Gardasil, Merck), and bivalent (2vHPV, Cervarix, GlaxoSmithKline) (6–8). As of late 2016, only 9vHPV is distributed in the United States. The majority of HPV-associated cancers are caused by HPV 16 or 18, types targeted by all three vaccines. In addition, 4vHPV and 9vHPV target HPV 6 and 11, types that cause anogenital warts. 9vHPV also protects against five additional high-risk types: HPV 31, 33, 45, 52, and 58.

In October 2018, using results from 4vHPV clinical trials in women aged 24 through 45 years, and bridging immunogenicity and safety data in women and men, the Food and Drug Administration expanded the approved age range for 9vHPV use from 9 through 26 years to 9 through 45 years in women and men (6). In June 2019, after reviewing evidence related to HPV vaccination of adults, ACIP updated recommendations for catch-up vaccination and for vaccination of adults older than the recommended catch-up age.

# **Methods**

During April 2018–June 2019, the ACIP HPV Vaccines Work Group held at least monthly conference calls to review and discuss relevant scientific evidence regarding adult HPV vaccination using the Evidence to Recommendations framework. (https://www.cdc.gov/vaccines/acip/recs/grade/ downloads/ACIP-evidence-rec-frame-508.pdf). The Work Group evaluated the quality of evidence for efficacy, safety, and effectiveness for HPV vaccination for primary prevention of HPV infection and HPV-related disease using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (https://www.cdc.gov/vaccines/acip/recs/ grade/about-grade.html).

Scientific literature published during January 1, 2006– October 18, 2018, was searched to identify clinical trials of any licensed HPV vaccine in adults aged 27 through 45 years. Detailed search methods and results for the GRADE tables are available at https://www.cdc.gov/vaccines/acip/recs/grade/ HPV-adults.html. Benefits were based on per-protocol analyses

<sup>\*</sup> Recommendations for routine use of vaccines in children, adolescents, and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of CDC on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children, adolescents, and adults are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG). Recommendations for routine use of vaccines in adults are harmonized with recommendations of AAFP, ACOG, the American College of Physicians (ACP), and the American College of Nurse-Midwives. ACIP recommendations approved by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report. Additional information is available at https://www.cdc.gov/ vaccines/acip.

of vaccine efficacy; immunogenicity data were also considered. Harms were any vaccine-related serious adverse events. Of 1,388 references identified, 100 were selected for detailed review, and 16 publications were included in GRADE tables presented at the October 2018 ACIP meeting; tables were updated in June 2019 to include new results from a 9vHPV trial. At the June 2019 ACIP meeting, two policy issues were considered: 1) harmonization of catch-up vaccination for all persons through age 26 years, and 2) vaccination of adults aged >26 years. Two Evidence to Recommendations documents were developed (https://www.cdc.gov/vaccines/acip/recs/ grade/HPV-harmonization-etr.html) (https://www.cdc.gov/ vaccines/acip/recs/grade/HPV-adults-etr.html) and presented along with proposed recommendations; after a public comment period, ACIP members voted unanimously to harmonize catch-up vaccination recommendations across genders for all persons through age 26 years. ACIP members also voted 10-4 in favor of shared clinical decision-making for adults aged 27 through 45 years, recognizing that some persons who are not adequately vaccinated might be at risk for new HPV infection and might benefit from vaccination in this age range.

# **Summary of Key Findings**

Vaccine efficacy and safety. Data were considered from 11 clinical trials of 9vHPV, 4vHPV, and/or 2vHPV in adults aged 27 through 45 years, along with supplemental bridging immunogenicity data. In per-protocol analyses from three trials, 4vHPV and 2vHPV demonstrated significant efficacy against a combined endpoint of persistent vaccine-type HPV infections, anogenital warts, and cervical intraepithelial neoplasia (CIN) grade 1 (low-grade lesions) or worse. In nine trials, seroconversion rates to vaccine-type HPV after 3 doses of any HPV vaccine were 93.6%-100% at 7 months after the first dose. Overall evidence on benefits was GRADE evidence level 2, for moderate-quality evidence. In nine trials, few serious adverse events and no vaccine-related deaths were reported. Overall evidence on harms was also GRADE evidence level 2, for moderate-quality evidence. In the efficacy trial that was the basis for 9vHPV licensure for adults through age 45 years, per-protocol efficacy of 4vHPV among women aged 24 through 45 years was 88.7% (95% confidence interval [CI] = 78.1–94.8), and intention-to-treat efficacy was 47.2% (95% CI = 33.5-58.2) against a combined endpoint of persistent infections, extragenital lesions, and CIN 1+ related to HPV types 6, 11, 16, or 18 (9).

HPV burden of disease and impact of the vaccination program in the United States. Approximately 33,700 cancers are caused by HPV in the United States each year, including 12,900 oropharyngeal cancers among men and women, 10,800 cervical cancers among women, and 6,000 anal cancers among men and women; vaginal, vulvar, and penile cancers are less common (10). HPV vaccination for adolescents has been routinely recommended for females since 2006 and for males since 2011 (1). The existing HPV vaccination program for adolescents has the potential to prevent the majority of these cancers. Mean age at acquisition of causal HPV infection for cancers is unknown, but is estimated to be decades before cancer is diagnosed. In 2017, coverage with  $\geq 1$  dose of HPV vaccine was 65.5% among adolescents aged 13 through 17 years (11). Although coverage with the recommended number of doses remains below the Healthy People 2020 target of 80% for adolescents (12), the U.S. HPV vaccination program has resulted in significant declines in prevalences of vaccine-type HPV infections, anogenital warts, and cervical precancers (13). For example, prevalences of 4vHPV vaccinetype infection during 2013–2016, compared with those of the prevaccine era, declined from 11.5% to 1.8% among females aged 14 through 19 years and from 18.5% to 5.3% among females aged 20 through 24 years (14). In addition, declines have been observed among unvaccinated persons, suggesting protective herd effects (15).

Health economic analyses. Five health economic models of HPV vaccination in the United States were reviewed (16). The cost effectiveness ratio for the current HPV vaccination program ranged from cost-saving to approximately \$35,000 per quality-adjusted life year (QALY) gained (16). In the context of the existing vaccination program, the incremental cost per QALY for expanding male vaccination through age 26 years was \$178,000 in a subset of analyses in one of the five models reviewed using more favorable model assumptions for adult vaccination (16). In the context of the existing program, expanding vaccination to adults through age 45 years would produce relatively small additional health benefits and less favorable cost-effectiveness ratios. The incremental cost per QALY for also vaccinating adults through age 30 or 45 years exceeded \$300,000 in four of five models (16). Variation in results across models was likely due to uncertainties about HPV natural history, such as prevalence of immunity after clearance of natural infections, and level of herd protection from the existing program. Under the existing program, in a subset of analyses in one of the five models reviewed using more favorable model assumptions for adult vaccination, the number needed to vaccinate (NNV) to prevent one case of anogenital warts, CIN grade 2 or worse (high-grade lesions), or cancer would be 9, 22, and 202, respectively. For expanding recommendations for males through age 26 years to harmonize catch-up vaccination across genders, these NNV would be 40, 450, and 3,260, respectively. For expanding recommendations to include adults through age 45 years, these NNV would be 120, 800, and 6,500, respectively (16).

# Rationale

Adolescents remain the most important focus of the HPV vaccination program in the United States. Recommendations harmonized across genders will simplify the immunization schedule and be more feasible to implement. HPV vaccination is most effective when given before exposure to any HPV, as in early adolescence (1-3). Clinical trials have indicated that HPV vaccines are safe and effective against infection and disease attributable to HPV vaccine types that recipients are not infected with at the time of vaccination.

Because HPV acquisition generally occurs soon after first sexual activity, vaccine effectiveness will be lower in older age groups because of prior infections. Some previously exposed adults will have developed natural immunity already. Exposure to HPV decreases among older age groups. Evidence suggests that although HPV vaccination is safe for adults aged 27 through 45 years, population benefit would be minimal; nevertheless, some adults who are not adequately vaccinated might be at risk for new HPV infection and might benefit from vaccination in this age range.

# **Recommendations**

**Children and adults aged 9 through 26 years.** HPV vaccination is routinely recommended at age 11 or 12 years; vaccination can be given starting at age 9 years. Catch-up HPV vaccination is recommended for all persons through age 26 years who are not adequately vaccinated.<sup>†</sup>

Adults aged >26 years. Catch-up HPV vaccination is not recommended for all adults aged >26 years. Instead, shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27 through 45 years who are not adequately vaccinated. (Box). HPV vaccines are not licensed for use in adults aged >45 years.

**Administration.** Dosing schedules, intervals, and definitions of persons considered adequately vaccinated have not changed (*3*). No prevaccination testing (e.g., Pap or HPV testing) is recommended to establish the appropriateness of HPV vaccination.

**Cervical cancer screening.** Cervical cancer screening guidelines and recommendations should be followed (*17*).

**Special populations and medical conditions.** These recommendations for children and adults aged 9 through 26 years and for adults aged >26 years apply to all persons,

# BOX. Considerations for shared clinical decision-making regarding human papillomavirus (HPV) vaccination of adults aged 27 through 45

Ideally, HPV vaccination should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. For adults aged 27 through 45 years who are not adequately\* vaccinated, clinicians can consider discussing HPV vaccination with persons who are most likely to benefit. HPV vaccination does not need to be discussed with most adults aged >26 years.

- HPV is a very common sexually transmitted infection. Most HPV infections are transient and asymptomatic and cause no clinical problems.
- Although new HPV infections are most commonly acquired in adolescence and young adulthood, some adults are at risk for acquiring new HPV infections. At any age, having a new sex partner is a risk factor for acquiring a new HPV infection.
- Persons who are in a long-term, mutually monogamous sexual partnership are not likely to acquire a new HPV infection.
- Most sexually active adults have been exposed to some HPV types, although not necessarily all of the HPV types targeted by vaccination.
- No clinical antibody test can determine whether a person is already immune or still susceptible to any given HPV type.
- HPV vaccine efficacy is high among persons who have not been exposed to vaccine-type HPV before vaccination.
- Vaccine effectiveness might be low among persons with risk factors for HPV infection or disease (e.g., adults with multiple lifetime sex partners and likely previous infection with vaccine-type HPV), as well as among persons with certain immunocompromising conditions.
- HPV vaccines are prophylactic (i.e., they prevent new HPV infections). They do not prevent progression of HPV infection to disease, decrease time to clearance of HPV infection, or treat HPV-related disease.

regardless of behavioral or medical risk factors for HPV infection or disease.<sup>§</sup> For persons who are pregnant, HPV

<sup>&</sup>lt;sup>†</sup> For persons initiating vaccination before their 15th birthday, the recommended immunization schedule is 2 doses of HPV vaccine (0, 6–12 month schedule). For persons initiating vaccination on or after their 15th birthday, or for persons with certain immunocompromising conditions, the recommended immunization schedule is 3 doses of HPV vaccine (0, 1–2, 6 month schedule).

<sup>\*</sup> Dosing schedules, intervals, and definitions of persons considered adequately vaccinated have not changed.

<sup>§</sup> Persons with specific behavioral or medical risk factors for HPV infection or disease include men who have sex with men, transgender persons, and persons with immunocompromising conditions.

#### Summary

#### What is already known about this topic?

Vaccination against human papillomavirus (HPV) is routinely recommended at age 11 or 12 years. Catch-up recommendations apply to persons not vaccinated at age 11 or 12 years.

#### What is added by this report?

After reviewing new evidence, CDC updated HPV vaccination recommendations for U.S. adults.

#### What are the implications for public health practice?

Routine recommendations for HPV vaccination of adolescents have not changed. Catch-up HPV vaccination is now recommended for all persons through age 26 years. For adults aged 27 through 45 years, public health benefit of HPV vaccination in this age range is minimal; shared clinical decision-making is recommended because some persons who are not adequately vaccinated might benefit.

vaccination should be delayed until after pregnancy; however, pregnancy testing is not needed before vaccination. Persons who are breastfeeding or lactating can receive HPV vaccine. Recommendations regarding HPV vaccination during pregnancy or lactation have not changed (*1*).

# **Future Research and Monitoring Priorities**

CDC continues to monitor safety of HPV vaccines and impact of the vaccination program on HPV-attributable outcomes, including prevalences of HPV infections, anogenital warts, cervical precancers, and cancers. ACIP reviews relevant data as they become available and updates vaccine policy as needed.

# Acknowledgments

Members of the Advisory Committee on Immunization Practices (member roster for June 2019 is available at https://www.cdc.gov/ vaccines/acip/members/index.html).

# **ACIP HPV Vaccines Work Group**

Chair: Peter Szilagyi, University of California at Los Angeles. ACIP members: Kevin Ault, University of Kansas Medical Center; José Romero, University of Arkansas for Medical Sciences, Arkansas Children's Hospital. Ex Officio Members: Joohee Lee, Jeff Roberts, Food and Drug Administration. Liaison representatives: Shelley Deeks, National Advisory Committee on Immunization; Linda Eckert, American College of Obstetricians and Gynecologists; Sandra Fryhofer, American College of Physicians; Amy Middleman, Society for Adolescent Health and Medicine; Chris Nyquist, American Academy of Pediatrics; Sean O'Leary, Pediatric Infectious Disease Society; Robin O'Meara, American Academy of Family Physicians; Patricia Whitley-Williams, National Medical Association; Jane Zucker, Association of Immunization Managers. Consultants: Joseph Bocchini; Tamera Coyne-Beasley; John Douglas; Allison Kempe; Aimee Kreimer, National Cancer Institute; Debbie Saslow, American Cancer Society; Rodney Willoughby; Rachel Winer. CDC Lead: Lauri Markowitz. CDC contributors: Harrell Chesson; Julianne Gee; Elissa Meites; Lakshmi Panagiotakopoulos; Jeanne Santoli; Mona Saraiya; Shannon Stokley; John Su; Elizabeth Unger; Charnetta Williams.

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# Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease

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Lyme disease is a tickborne zoonosis for which serologic testing is the principal means of laboratory diagnosis. In 1994, the Association of State and Territorial Public Health Laboratory Directors, CDC, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Council of State and Territorial Epidemiologists, and the National Committee for Clinical Laboratory Standards convened the Second National Conference on Serologic Diagnosis of Lyme Disease (1).

The conference proceedings recommended a two-test methodology using a sensitive enzyme immunoassay (EIA) or immunofluorescence assay as a first test, followed by a western immunoblot assay for specimens yielding positive or equivocal results (1,2). Regarding the development of future tests, the report advised that evaluation of new serologic assays include blind testing against a comprehensive challenge panel, and that new assays should only be recommended if their specificity, sensitivity, and precision equaled or surpassed the performance of tests used in the recommended two-test procedure. To assist serologic test developers, CDC has made available, with support from NIH, a comprehensive panel of sera from patients with various stages of Lyme disease and other conditions, as well as healthy persons (3).

On July 29, 2019, FDA cleared several Lyme disease serologic assays with new indications for use based on a modified twotest methodology (4). The modified methodology uses a second EIA in place of a western immunoblot assay. Clearance by FDA of the new Lyme disease assays indicates that test performance has been evaluated and is "substantially equivalent to or better than" a legally marketed predicate test.

# Recommendation

When cleared by FDA for this purpose, serologic assays that utilize EIA rather than western immunoblot assay in a two-test format are acceptable alternatives for the laboratory diagnosis of Lyme disease. Based on the criteria established at the 1994 Second National Conference on Serologic Diagnosis of Lyme Disease, clinicians and laboratories should consider serologic tests cleared by FDA as CDC-recommended procedures for Lyme disease serodiagnosis.

#### Summary

#### What is already known about this topic?

Serologic testing is the principal means of laboratory diagnosis of Lyme disease. Current recommendations include using a sensitive enzyme immunoassay (EIA) or immunofluorescence assay, followed by a western immunoblot assay for specimens yielding positive or equivocal results.

What is added by this report?

On July 29, 2019, the Food and Drug Administration (FDA) cleared several Lyme disease serologic assays with new indications for use, allowing for an EIA rather than western immunoblot assay as the second test in a Lyme disease testing algorithm.

### What are the indications for public health practice?

When cleared by FDA for this purpose, serologic assays that utilize a second EIA in place of western immunoblot assay are acceptable alternatives for the serologic diagnosis of Lyme disease.

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# Rabies Outbreak Investigation — Pedernales, Dominican Republic, 2019

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On July 13, 2018, a child from Pedernales, Dominican Republic, died after developing clinical signs and symptoms consistent with rabies. Because of the child's signs and symptoms, history of having been bitten by a dog 4 months earlier, and not having a received postexposure prophylaxis (PEP) (1), the patient was reported as having a probable case of rabies to the Ministerio de Salud Pública (MSP; i.e., Ministry of Public Health) (1). This case was the first reported from Pedernales Province in >30 years. During November 29–December 20, 2018, two additional probable rabies cases (based on clinical signs and history of dog bites) in children were reported from this province. The second patient did not receive any PEP. The third patient began PEP 10 days after being bitten and received 4 doses of vaccine before symptom onset; no rabies immunoglobulin was available in the province. All three children died from rabies encephalitis.

All three cases were confirmed by detection of rabies-specific antigen and nucleic acid in patients' biologic specimens by direct florescent antibody and real-time reverse transcription-polymerase chain reaction testing at CDC (1). Complete nucleoprotein gene sequencing revealed a canine rabies virus variant. Three reported human rabies cases in 6 months exceeded the national average of zero to one per year (2). Because Pedernales borders Anse-à-Pitre, Haiti, and mixing of canine populations occurs, a binational coordinated response was initiated (3). This report focuses on the Dominican Republic response. At MSP's request, CDC assisted with an outbreak investigation focused on active surveillance for animal bites and canine and human rabies cases, evaluation of canine vaccination coverage, and verification of the potency of human and veterinary rabies vaccines. Because it was an emergency outbreak response, the investigation was determined to be nonresearch.

Hospital animal bite records, animal investigations, and medical records were reviewed, and 224 households were surveyed to 1) identify probable animal rabies cases and animal bites to humans and 2) estimate the number of always-confined and sometimes-confined dogs. During January 2018– January 2019, a total of 29 probable animal rabies cases and 387 animal bites to humans were reported to MSP (Figure). Included in the 387 reported animal bites were 31 of the 39 bites identified by the household survey; patients who received eight (21%) of the 39 bites did not seek medical care and would not have been found by routine surveillance. Untreated bites were assessed to ascertain risk for rabies and whether PEP would have been recommended; five of the patients involved in the eight previously unidentified bites did not require PEP because the animal was alive 10 days after the bite. No evidence of unreported deaths consistent with rabies was found.

Before this investigation began on January 28, 2019, a human-to-dog ratio of six to one was used to calculate dog population size and the number of vaccine doses required to reach 70% coverage; the total provincial dog population was estimated to be 5,678. During August 9–27, 2018, MSP conducted a door-to-door canine vaccination campaign and vaccinated 4,099 dogs (72% of the estimated total dog population) using a locally produced canine vaccine. However, a vaccine from a different manufacturer was used to vaccinate an additional 231 dogs during an emergency campaign that was initiated after the second case of human rabies and was ongoing at the time of the investigation.

Because cases of human rabies occurred after the door-todoor dog vaccination campaign in August 2018, population size categorized by roaming status (always-confined, sometimes-confined, and always-free-roaming) was calculated to evaluate vaccination coverage. The always-free-roaming dog population was estimated using a sight-resight methodology (similar to capture-recapture) and a mobile phone application created by Mission Rabies (http://www.missionrabies.com/). Numbers of always-confined and sometimes-confined dogs were obtained from the household survey.

The numbers of sometimes-confined and always–free-roaming dogs was higher than those in previous estimates, resulting in a human-to-dog ratio of 3.39 to one (95% confidence interval = 3.04–3.82; estimated total province dog population = 8,872–11,207). Because the campaign used door-to-door vaccination, which targets always-confined and sometimes-confined dogs, the population of always–free-roaming dogs likely was not adequately reached during the door-to-door vaccination campaign, resulting in ongoing transmission.

To assess canine rabies vaccine potency, available vaccines were collected; because batches used during the campaign were unavailable, serum from eight vaccinated dogs was collected

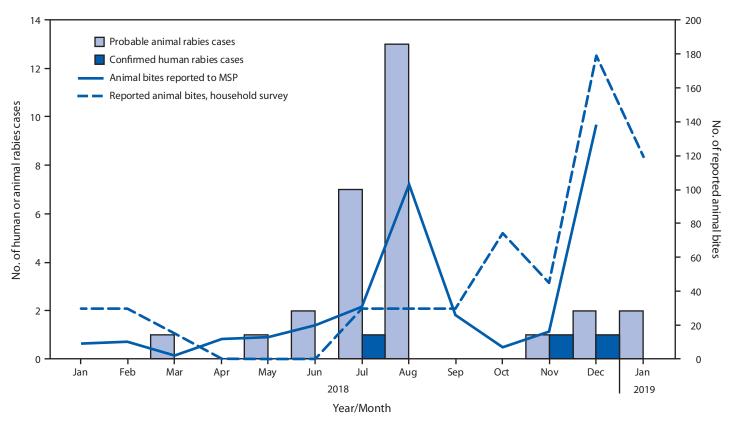


FIGURE. Reported animal bites,\* confirmed human rabies cases, and probable animal rabies cases — Pedernales, Dominican Republic, January 2018–January 2019

Abbreviation: MSP = Ministerio de Salud (Ministry of Health).

\* Animal bites reported to MSP include 31 bites reported in household survey (eight of 39 bites identified in survey were not reported to MSP because patients bitten did not seek treatment).

to measure antibody titers as an indicator of vaccine potency. An antigen-capture electrochemiluminescent assay at CDC was used to evaluate available human and veterinary vaccines (4). Vaccines tested were similar to known potent reference vaccines and predicted to be potent. Eight serum samples from vaccinated dogs were tested for rabies virus–neutralizing antibody titer by rapid fluorescent focus inhibition test; two had a passing titer  $\geq 0.5$  IU/mL, and all displayed complete neutralization at 1:5 at 6 months postvaccination, demonstrating prior vaccination.

CDC recommended to MSP that before future campaigns, the estimated total dog population size and roaming status be evaluated. Vaccination strategies (e.g., door-to-door, capture-vaccinate-release) can be adapted to achieve 70% annual vaccination coverage in all canine population categories (5). Because of the close association between the border towns of Pedernales, Dominican Republic, and Anse-à-Pitre, Haiti, and the mixing of the canine populations, binational coordination for rabies control needs to continue (*3*).

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# A Multipartner Response to Prevent a Binational Rabies Outbreak — Anse-à-Pitre, Haiti, 2019

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Sustained investments in dog rabies vaccination programs and increased access to postexposure prophylaxis have led to a substantial decrease in rabies deaths associated with dogs in the Western Hemisphere (1). Despite recent dog vaccination campaigns in Pedernales, Dominican Republic, three human rabies deaths associated with dogs were reported during July-December 2018 in Pedernales, which shares a border with Anse-à-Pitre, Haiti (2). Canine rabies is endemic in Haiti and the Dominican Republic; over the past decade, Haiti has reported an eighteenfold increase in laboratory-confirmed canine rabies cases after implementation of an active rabies surveillance program, although none were reported from Anse-à-Pitre (3). Haiti conducted a three-phase national dog rabies vaccination campaign during 2017-2018, with the last round occurring during October 16, 2017-May 22, 2018, in the southern third of the country. However, the campaign did not reach the southeastern community of Anse-à-Pitre because of difficult terrain and funding constraints. Although no human or animal rabies cases had been reported from Anse-à-Pitre, health experts from Haiti and Dominican Republic were concerned that dogs from this community could be part of a cross-border enzootic rabies transmission cycle. At the invitation of the Haiti Ministry of Agriculture, a multiagency team deployed to Haiti to vaccinate dogs, conduct human and animal rabies case surveillance, collect retrospective animal and human rabies exposure and case detection data, and evaluate border crossings by dogs. Because it was an emergency outbreak response, CDC determined the activities to be nonresearch.

During January 23–26, 2019, the emergency response team vaccinated 1,331 dogs in the Haitian communities directly adjacent to Pedernales (primarily comprising Anseà-Pitre and a few surrounding communities). Dogs were marked with temporary, nontoxic paint and a paper collar at the time of vaccination. A mobile phone application was used to geospatially record all vaccinations and conduct postvaccination dog-counting surveys to ensure that target coverage (>70% of susceptible dogs) was achieved (4,5). Postvaccination surveys identified vaccination marks on 191 (87%) of 220 free-roaming dogs, and enumeration of survey data resulted in an estimated population of 1,750 total dogs in the community (76% vaccination coverage among the total dog population) (Figure).

To identify unrecognized human and animal rabies deaths, a survey of 92 randomly selected households was conducted, and community leaders were consulted. Thirteen dogs with rabiescompatible signs\* were identified during May 2018 (one), August (one), November (two), December (two), and January 2019 (seven), suggesting that dog rabies activity increased in November and continued during the January emergency vaccination campaign. In Haitian communities that have implemented the national rabies surveillance program, 50% of dogs that are tested after developing these rabies-compatible signs are confirmed rabid (3). Household surveys found no suspected human rabies deaths in the preceding 12 months in Anse-à-Pitre. Household surveys identified 11 persons who had been bitten by dogs in the past year, only two of whom had sought medical evaluation (22%). None reported receiving rabies vaccination, and all were healthy at the time of survey. Four additional persons who had been bitten by dogs were identified during response activities. All 15 exposed persons identified during response efforts who had not initiated the rabies vaccination series were referred to the Anse-à-Pitre government hospital.

Training on medical management and reporting of human rabies cases and dog bite events was conducted at the Anse-à-Pitre government hospital. The response team provided the hospital with 100 doses of human rabies vaccine and 500 rabies prevention information comic books. Human rabies immune globulin, a World Health Organization–recommended component of the rabies postexposure prophylactic treatment regimen, is not routinely available in Haiti and was not available in the Anse-à-Pitre government hospital.

Three surveillance officers were trained to conduct rabies field investigations in Anse-à-Pitre using a custom-built mobile device application to investigate and report rabies exposures and manage suspected rabid animals. This application is used by Haiti's national animal rabies surveillance program, but had not been implemented in Anse-à-Pitre and the surrounding communities until the emergency response. Surveillance

<sup>\*</sup>Acute development of aggression, hypersalivation, or behavioral changes preceding the dog's death. Unpublished data from Haiti's national rabies surveillance program has found that approximately 50% of dogs with these clinical signs, when available for testing, are laboratory-confirmed to be infected with rabies virus.

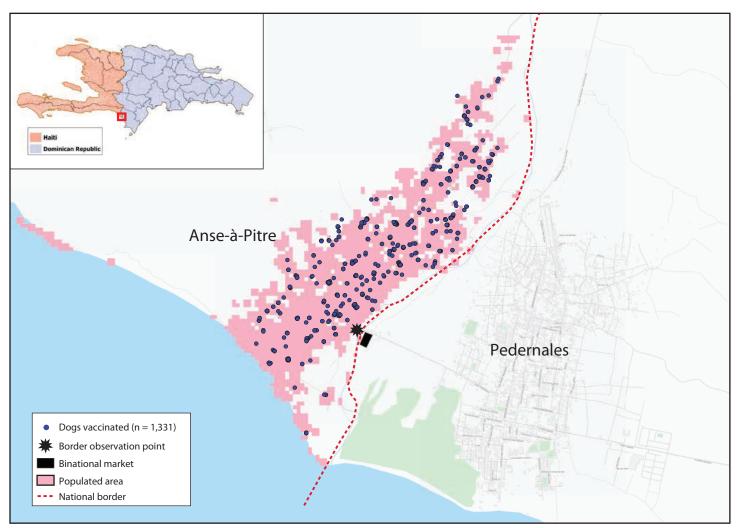


FIGURE. Locations\* of dogs vaccinated with rabies vaccine in the border towns of Anse-à-Pitre, Haiti, and Pedernales, Dominican Republic, the observation point used during the rabies response investigation, and the binational market — Anse-à-Pitre, Haiti, 2019

\* Determined using global position system.

officers collected brain tissue from two dogs with suspected rabies, one of which was found dead by the owner and a second that died a day after being quarantined. Both specimens tested negative for rabies by direct fluorescent antibody testing at the National Veterinary Laboratory, Haiti. From the start of the response until July 30, 2019, surveillance staff members investigated 26 biting dogs in the Anse-à-Pitre community; 17 (65%) of the dogs were known to have been vaccinated during the campaign, and none had signs consistent with rabies virus infection.

Observers recorded six dogs crossing from Pedernales into Anse-à-Pitre with their owners during a 12-hour period. During the same period, a field survey in the Pedernales binational market identified 14 free-roaming dogs, one of which had Haiti's vaccination mark. On January 24, 2019, a binational rabies meeting<sup>†</sup> was held in Anse-à-Pitre. General consensus was obtained on the importance of coordinated binational canine rabies vaccination and surveillance efforts, and participants affirmed their interest in pursuing binational rabies prevention measures.

Dog bites and suspected canine rabies cases are underdetected in Anse-à-Pitre. Intermittent canine rabies cases have likely occurred during the past year; however, a potential rise in cases began in November 2018, 5 months after the first human death in Pedernales. The most cost-effective way to prevent human rabies deaths in Anse-à-Pitre and Pedernales is through

<sup>&</sup>lt;sup>†</sup> Attendees included representatives from the Ministry of Agriculture and Health, Haiti; Ministry of Health, Anse-à-Pitre, Haiti; CDC; Pan American Health Organization, Port-au-Prince, Haiti; and the Pedernales Public Health Department, Dominican Republic.

annual coordinated cross-border dog vaccination campaigns until canine rabies elimination is achieved. The emergency response was successful in achieving vaccination targets and highlighting this important binational public health issue. As both natural and human-associated binational dog movements were confirmed during this investigation, collaborative interventions should be pursued to eliminate canine rabies from border communities. Continued surveillance will be necessary to assess the effectiveness of the interventions.

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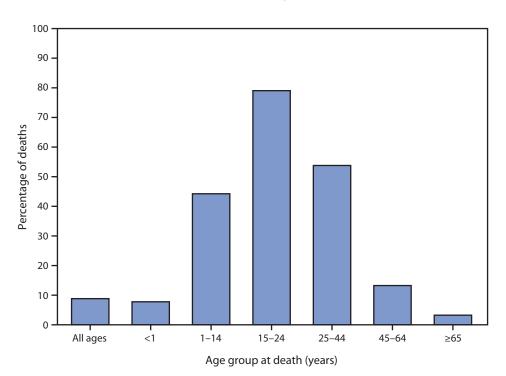
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<sup>&</sup>lt;sup>1</sup>Field Epidemiology Training Program, Department of Epidemiology and Laboratory Resources, Ministry of Sanitation and Public Health, Port-au-Prince, Haiti; <sup>2</sup>Ministry of Agriculture, Rural Development, and Natural Resources, Port-au-Prince, Haiti; <sup>3</sup>Division of High Consequence Pathogens, National Center for Emerging and Zoonotic Infectious Disease, CDC; <sup>4</sup>Mission Rabies, United Kingdom; <sup>5</sup>Pan American Health Organization, Port-au-Prince, Haiti; <sup>6</sup>Christian Veterinary Mission, Port-au-Prince, Haiti; <sup>7</sup>CDC Haiti.

# FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

# Percentage of Deaths from External Causes,\* by Age Group<sup>†</sup> — United States, 2017



\* External causes of death include intentional and unintentional injury, poisoning (including drug overdose), and complication of medical or surgical care and are identified with *International Classification of Diseases*, *Tenth Revision* codes V01–V89 and U01–U03.

<sup>†</sup> Deaths for which an age could not be determined are included in "All ages" but are not included among the age groups given.

In 2017, 9% of all deaths were due to external causes. The percentage of deaths due to external causes was highest for those aged 15–24 years (79%) and lowest for those aged <1 year (8%) and aged >65 years (3%) at death. Among those aged 1–14 years, 44% of deaths were due to external causes, compared with 54% for those aged 25–44 years and 13% for those aged 45–65 years.

Source: National Vital Statistics System. Underlying cause of death data, 2017. https://wonder.cdc.gov/ucd-icd10.html. Reported by: R. Henry Olaisen, PhD, okm7@cdc.gov, 301-458-4438; R.N. Anderson, PhD.

For more information on this topic, CDC recommends the following link: https://www.cdc.gov/injury/.

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